

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/8/2020
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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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11701217]
2.	Birth Date:	(b) (6) /1963
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/8/2020
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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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:	[Hypertension]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Deep Vein Thrombosis (DVT)]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type II Diabetes]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/1963
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tobacco Use]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Alcoholism]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Idiopathic Thrombocytopenic Purpura]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obstructive Sleep Apnea]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2020
	Ongoing:	YES

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/8/2020
2.	Weight:	[164.2]
3.	Unit:	kg
4.	Height:	[182.88]
5.	Unit:	cm
6.	Body Mass Index:	[49.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/8/2020
2.	Randomization Number:	[254081]
3.	Randomization Group:	[]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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: Sep/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9BKV]
5.b	Sample ID	[BNW6JG]
5.c	Sample ID	[BNW6JZ]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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?	YES Date of Collection: Sep/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9BK0]
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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:	Sep/8/2020 11:05
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

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/29/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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?	YES Date of Collection: Sep/29/2020
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	[BGJKTY]
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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:	Sep/29/2020 10:06
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

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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: Oct/27/2020
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	[BS51ZV]
5.b	Sample ID	[BS51ZW]
5.c	Sample ID	[BR7RWJ]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/18/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/18/2020
2.	Date of First Symptom Started:	Oct/17/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/21/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
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?	NO

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[Fatigue]
5.b	Symptoms - Other Text:	[Malaise]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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.	Oct/19/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:54

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/19/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

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_SELF
3.	Sample Collected?	YES Date of Collection: Oct/18/2020
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	[CV20549]
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject instructed to self swab.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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:	YES Number of Visits or Contacts: [1]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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
----	--	----

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:53

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:52

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

#	Category f or Lab Test	Vendor Name	Collecti on Date:	Specim en Type	Lab Result			Form Instan ce
1.	Not Applica ble	Not App licable	Not App licable	Not App licable	Sponsor-Defi ned Identifie r	Test:	Result:	Repeating Pages
					Not Applicabl e	Not Ap plicable	Not Ap plicable	
					Not Applicabl e	Not Ap plicable	Not Ap plicable	
					Not Applicabl e	Not Ap plicable	Not Ap plicable	
					Not Applicabl e	Not Ap plicable	Not Ap plicable	
					Not Applicabl e	Not Ap plicable	Not Ap plicable	
					Not Applicabl e	Not Ap plicable	Not Ap plicable	
					Not Applicabl e	Not Ap plicable	Not Ap plicable	

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING
CHEMISTRY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.e

Sponsor ID:	Not Applicable _____ []	Comments
Test:	Bilirubin_PX21	
Result:	Not Applicable _____ []	Comments
Not Done:	Not Applicable _____ _____	Comments
LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date :	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

#	Category f or Lab Te st	Vendor Nam e (DERIVE D)	Collecti on Date :	Specim en Typ e	Lab Result			Form Insta nce
					Sponsor-Def ined Identifi er	Test:	Result:	
					Not Applica ble	Not Ap plicable	Not Ap plicable	
					Not Applica ble	Not Ap plicable	Not Ap plicable	

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 21-Aug-2020 02:51**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING
Hematology**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.c

Sponsor ID:	Not Applicable _____ []	Comments
Test:	Erythrocytes_PX3	
Result:	Not Applicable _____ []	Comments
Not Done:	Not Applicable _____ _____	Comments
LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.d

Sponsor ID:	Not Applicable _____ []	Comments
Test:	Platelets_PX5	
Result:	Not Applicable _____ []	Comments
Not Done:	Not Applicable _____ _____	Comments
LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____ _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____ _____	Comments
4.	Assessment:	Not Applicable _____ _____	Comments

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/19/2020

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/19/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

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: 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	[BRTW81]
5.b	Sample ID	[BRTW80]
5.c	Sample ID	[BR7S80]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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 - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/27/2020
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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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:	
----	-----------------------	--

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
New Unscheduled Visit SWAB

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

Site No: 1170 **Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217 **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	[]
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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	Cellulitis of left lower leg	Oct/1/2020 U NK:UNK	NO End Date Time: Nov/1/2020 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	Neutropenia	Oct/1/2020 U NK:UNK	NO End Date Time: Nov/1/2020 UNK: UNK	Repeating Pages
3.	ADVERSE EVENT	3	Thrombocytopenia	Oct/1/2020 U NK:UNK	NO End Date Time: Nov/1/2020 UNK: UNK	Repeating Pages
4.	ADVERSE EVENT	4	Wound of left lower leg	Sep/12/2020 U NK:UNK	NO End Date Time: Sep/30/2020 UNK: UNK	Repeating Pages

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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Adverse Event Report

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

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

7.	<p>Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [underline comorbidities pt with a hx of Type II Diabetes and morbid obesity]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020389615]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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Adverse Event Report

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

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

7.	<p>Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [underline comorbidities pt with a hx of Type II Diabetes and morbid obesity]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020389615]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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Adverse Event Report

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

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

7.	<p>Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Cellulitis]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020389615]

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Wound of left lower leg]
4.	Start Date Time:	Sep/12/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/30/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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Medication Error

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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.	1	VACCINATIONS	NO	Pneumonia Vaccine	Sep/UNK/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[Pneumonia Vaccine]
5.	Date:	Sep/UNK/2020

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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?	

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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?	

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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?	

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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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

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

Site No: 1170 **Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217 **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	Jan/19/2021
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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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 local/national recommendations 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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/19/2021
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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/20/2021
----	--------------	--

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/20/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSGDBF]
5.b	Sample ID	[BSGDBG]
5.c	Sample ID	[BPSBXR]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPSBXN]
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/20/2021 08:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/10/2021 08:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/10/2021
3.	Comments:	[]

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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 :	Mar/10/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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	Oct/27/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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
Mezgebe Berhe	Approved	Mar-12-2021 15:36:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-08-2020 11:56:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:53

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:53

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:53

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

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Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - Comments

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Item	Date	User	Comment
5	Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
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Subject No: 11701217

Subject Initials: ---

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Item	Date	User	Comment
6	Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 17-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ILLNESS DETAILS - SEVERE - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
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Subject Initials: ---

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Form	Oct-30-2020 10:47:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
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Generated By: (b) (4)

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Item	Date	User	Comment
1	Oct-30-2020 10:47:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Version: 17-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ILLNESS DETAILS - SEVERE - Comments

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Site Name: (1170) North Texas Infectious Diseases
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2	Oct-30-2020 10:47:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
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5.a	Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

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5.b	Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Site Name: (1170) North Texas Infectious Diseases
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Site No: 1170

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Item	Date	User	Comment
5.c	Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Site No: 1170

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Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING
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Site Name: (1170) North Texas Infectious Diseases
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5.d	Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Site No: 1170

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Subject No: 11701217

Generated By: (b) (4)

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5.g	Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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Item	Date	User	Comment
5.h	Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

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Generated By: (b) (4)

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Hematology - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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5.h	Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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

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Site No: 1170

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Item	Date	User	Comment
5.j	Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:50

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - COVID - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
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Item	Date	User	Comment
1	Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:50

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - COVID - Comments

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Item	Date	User	Comment
2.a	Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR -
Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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Item	Date	User	Comment
Form	Oct-30-2020 10:52:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

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Form: VITAL SIGNS - PULSE OX ROOM AIR -
Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
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Item	Date	User	Comment
1	Oct-30-2020 10:52:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Version: 21-Aug-2020 02:51

Site No: 1170

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Form: VITAL SIGNS - PULSE OX ROOM AIR -
Comments

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Site Name: (1170) North Texas Infectious Diseases
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Item	Date	User	Comment
2.a	Oct-30-2020 10:52:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:52

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Oct-30-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:52

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
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Item	Date	User	Comment
1	Oct-30-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

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Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS - Comments

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Header Text: c4591001

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Header Text: c4591001

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Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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Form	Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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Item	Date	User	Comment
4	Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Subject No: 11701217

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Header Text: c4591001

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Subject No: 11701217

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
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Subject No: 11701217

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Generated By: (b) (4)

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Item	Date	User	Comment
Form	Oct-30-2020 10:54:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Status: Data Complete, Frozen, Verified

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Status: Data Complete, Frozen, Verified

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Generated By: (b) (4)

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Item	Date	User	Comment
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Item	Date	User	Comment
4	Oct-30-2020 10:54:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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Form	Jan-20-2021 14:58:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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
Mezgebe Berhe	Approved	Mar-12-2021 15:36:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, MezgebeBerhe, 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-10-2021 11:02:03 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mezgebe Berhe	Approved	Jan-21-2021 15:47:54 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (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:** 1170**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**Affidavit:**

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

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

(b) (6)	N/A	Dec-21-2020 10:01:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mezgebe Berhe	Approved	Nov-25-2020 10:39:59 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MezgebeBerhe, 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 09:58:12 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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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:** 1170**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**Affidavit:**

N/A

Mezgebe Berhe	Approved	Nov-13-2020 19:13:37 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MezgebeBerhe, 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) [REDACTED]	N/A	Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mezgebe Berhe	Approved	Nov-11-2020 16:47:49 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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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:** 1170**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**Affidavit:**

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

(b) (6)	N/A	Nov-09-2020 08:31:53 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mezgebe Berhe	Approved	Nov-07-2020 18:34:35 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MezgebeBerhe, 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-06-2020 12:48:58 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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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:** 1170**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**Affidavit:**

N/A

Mezgebe Berhe	Approved	Nov-06-2020 12:10:07 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MezgebeBerhe, 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) [REDACTED]	N/A	Nov-05-2020 08:14:18 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mezgebe Berhe	Approved	Nov-04-2020 18:28:57 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-08-2020 11:54:51 (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
Sep-08-2020 11:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-08-2020 11:55:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/8/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-08-2020 11:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11701217	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-08-2020 11:54:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1963	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-08-2020 11:55:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-08-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

11:55:19 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NOT HISPANIC OR LA TINO(A) OR OF SPAN ISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-08-2020 11:55:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-08-2020 11:56:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-08-2020 11:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-08-2020 11:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-08-2020 11:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Jan-06-2021 10:36:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 1 Number: Medical Hi Hyperte story Term nsion : Start Date: UNK/U NK/199 8 Ongoing: YES	Transcription Error
Oct-23-2020 14:56:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 1 Number: Medical Hi Hyperte story Term nsion : Start Date: UNK/U NK/198 0 Ongoing: YES	Transcription Error
Oct-23-2020 10:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 1 Number: Medical Hi Hyperte story Term nsion :	Transcription Error

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1170
Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.
Subject No: 11701217
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 12:23

			Start Date: UNK/U NK/199 8 Ongoing: YES	
Sep-08-2020 11:57:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Hypertension : Start Date: UNK/U NK/198 0 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 11:57:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 11:57:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Hypertension	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

1.a Start Date:

Date	Location	User	Value	Reason
Jan-06-2021 10:36:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Transcription Error
Oct-23-2020 14:56:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Transcription Error
Oct-23-2020 10:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Transcription Error
Sep-08-2020 11:57:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 11:57:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

1.b

Date	Location	User	Value	Reason
Jan-06-2021 10:36:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 2 H Num ber: Medica Chronic De l Histor ep Vein Thr y Term: ombosis (D VT) Start D UNK/UNK/ ate: 1980 Ongoin YES g:	Transcription Error
Oct-23-2020 14:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 2 H Num ber: Medica Chronic De l Histor ep Vein Thr y Term: ombosis (D VT) Start D UNK/UNK/ ate: 1998 Ongoin YES g:	Transcription Error
Oct-23-2020 10:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 2 H Num ber:	Transcription Error

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

			Medical History Term: Chronic Deep Vein Thrombosis (DVT) Start Date: UNK/UNK/1980 Ongoing: YES	
Oct-20-2020 07:31:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 Medical History Term: Chronic Deep Vein Thrombosis (DVT) Start Date: UNK/UNK/1998 Ongoing: YES	New Information
Sep-08-2020 11:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Blood Clots Start Date: UNK/UNK/1998 Ongoing: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 11:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 20:56:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Jan-06-2021 10:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Data entered.
Jan-05-2021 09:38:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Reissued:O pened	GPDClin: Thank you! I think MHx module is currently open/unfrozen and you should be able to enter data.
Jan-04-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Monitor has

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

18:50:10 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		been contacted to unlock medical history form. If you are able to on your end, please unlock to update data.
Dec-30-2020 13:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	GPDClin: 1. There are quite a few MHx reported in SAE report are missing here, please add in. 2. Per previous queries, the onset year for HTN is 1980, DVT is 1998 (correct here), but are incorrect in SAE report, please submit SAE FU report for them.
Oct-20-2020 08:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-20-2020 07:31:18	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1170**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)				
Oct-20-2020 07:31:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Chronic Deep Vein Thrombosis (DVT)	New Information
Oct-20-2020 00:47:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED] [REDACTED]	Query 1: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Oct-19-2020 17:08:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Candidate	GPDClin: Please unfreeze MHx module, so the site can make change.
Oct-19-2020 14:11:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Yes, please unfreeze form in med hx to update. Thank you.
Oct-08-2020 14:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: In the SAE report, the MHx was reported as chronic deep vein thrombosis. If chronic DVT is more

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Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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				appropriate term, please make the change here.
Sep-08-2020 11:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Clots	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jan-06-2021 10:36:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Transcription Error
Oct-23-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-23-2020 14:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 14:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Transcription Error

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Header Text: c4591001

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Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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& Canada)				
Oct-23-2020 14:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Op ened	GPDClin: It is unlikely that DVT started 18 years earlier than HTN and diabetes. I would think the data previously in InForm was correct, i.e., HTN 1980, diabetes and DVT 1998, and likely there was error in SAE report for HTN and DVT dates. Please check.
Oct-23-2020 10:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 10:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Transcription Error
Oct-08-2020 15:11:06 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Noticed a mismatch vs. SAE report in

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Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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& Canada)				which DVT started 1980 and HTN started 1998. If the information in SAE report is incorrect, please submit a FU SAE report to correct it.
Sep-08-2020 11:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 11:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-28-2020 08:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N 3 umber: Medical His Type II tory Term: Diabetes	New Information

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			Start Date: UNK/U NK/1998	
			Ongoing: YES	
Sep-08-2020 11:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His Diabetes tory Term: Start Date: UNK/U NK/1998 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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Generated By: (b) (4)

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1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 09:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-28-2020 08:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-28-2020 08:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type II Diabetes	New Information
Oct-28-2020 04:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please specify type of diabetes (TYPE I or II, for example)

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				and update medical history term as applicable.
Oct-27-2020 16:45:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Please specify type of diabetes (TYPE I or II, for example) and update medical history term as applicable.
Sep-08-2020 11:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Initial Entry

Header Text: c4591001

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1.c Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-28-2020 14:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N 4 umber: Medical Hi Seasonal story Term Allergies : Start Date: UNK/U NK/1963 Ongoing: YES	Transcription Error
Sep-08-2020 11:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 4 umber: Medical Hi Allergies story Term /Hayfeve : r Start Date: UNK/U NK/1963 Ongoing: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

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Subject Initials: ---

Generated By: (b) (4)

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:19 (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
Oct-30-2020 19:07:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-28-2020 14:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-28-2020 14:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Seasonal Allergies	Transcription Error
Oct-28-2020 11:23:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm type of allergies? Seasonal per source?

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Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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Subject Initials: ---

Generated By: (b) (4)

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Sep-08-2020 11:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergies/Hayfever	Initial Entry
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1.d Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1963	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-06-2021 10:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 5 mber: Medical Hist Tobacco ory Term: Use	Initial Entry

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Subject No: 11701217

Generated By: (b) (4)

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			Start Date: UNK/UNK/1995	
			Ongoing: YES	

Header Text: c4591001

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Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Jan-06-2021 10:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 10:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tobacco Use	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Jan-06-2021 10:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Jan-06-2021 10:28:50 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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If

Date	Location	User	Value	Reason
Jan-06-2021 10:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Alcoholism Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

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Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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1.f Line/MH Number:

Date	Location	User	Value	Reason
Jan-06-2021 10:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 10:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alcoholism	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Jan-06-2021 10:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Jan-06-2021 10:29:31 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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I.g

Date	Location	User	Value	Reason
Jan-06-2021 10:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 7 H Num ber: Medical Idiopathic History Thrombocy Term: topenic Pur pura Start D UNK/UNK/ ate: 2006 Ongoin YES g:	Transcription Error
Jan-06-2021 10:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 7 Number: Medical Thromboc History ytopenic P Term: urpura Start Dat UNK/UN e: K/2006 Ongoing: YES	Initial Entry

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Header Text: c4591001

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1.g Line/MH Number:

Date	Location	User	Value	Reason
Jan-06-2021 10:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 10:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-08-2021 08:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Yes, correct as is
Jan-07-2021 20:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Just want to confirm this comorbidity as the subject is also using warfarin for chronic deep vein thrombosis.
Jan-06-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription

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10:31:02 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Idiopathic Thrombocytopenic Purpura	Error
Jan-06-2021 10:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Thrombocytopenic Purpura	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Jan-06-2021 10:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Jan-06-2021 10:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Jan-06-2021 10:32:33	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

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

**Line/MH N 8
umber:**

Medical Hi Obstructive
story Term Sleep Apne
:
a

Start Date: UNK/UNK/
2010

Ongoing: YES

Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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Subject Initials: ---

Generated By: (b) (4)

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1.h Line/MH Number:

Date	Location	User	Value	Reason
Jan-06-2021 10:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 10:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obstructive Sleep Apn ea	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Jan-06-2021 10:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Jan-06-2021 10:32:33 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Date	Location	User	Value	Reason
Jan-06-2021 10:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Obesity Start Date: UNK/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

1.i Line/MH Number:

Date	Location	User	Value	Reason
Jan-06-2021 10:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 10:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obesity	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Jan-07-2021 03:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-06-2021 10:35:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Date/Year unknown. Data recorded is going based off when subject reported.

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Jan-06-2021 10:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 08/Sep /2020. Please review and update as appropriate.
Jan-06-2021 10:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2020	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Jan-06-2021 10:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-11-2020 23:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per site confirmation.
Sep-11-2020 14:41:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not clinically significant
Sep-10-2020 06:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thanks for response. Please verify and confirm if recorded data is clinically significant or not. If yes,

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

				please update medical history. Thank you.
Sep-09-2020 08:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-09-2020 02:25:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please verify and confirm if recorded data is clinically significant or not. If yes, please update medical history. Thank you.
Sep-08-2020 14:28:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-08-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 164.2 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Sep-08-2020 11:58:50 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 164.2	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)

3. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 182.88	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:50 (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
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Sep-08-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 49.1	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-08-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 97.0 Temperature F Unit: Temperature FOREH Location:: EAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:50 (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
Sep-08-2020 11:58:50 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.0	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)

7.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 11:58:50 (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
Sep-08-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-08-2020 11:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-08-2020 11:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 254081	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (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: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Sep-08-2020 11:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-08-2020 11:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-08-2020 15:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 11:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (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: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Sep-08-2020 11:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 15:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP9BK : V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 15:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP9BKV	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-08-2020 16:06:20	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (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: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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)	Sample ID BNW6J : G	
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 16:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNW6JG	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-08-2020 16:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNW6J : Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 16:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNW6JZ	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (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: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Sep-08-2020 11:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-08-2020 11:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-08-2020 15:20:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 11:59:21 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (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: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Sep-08-2020 11:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 15:20:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP9BK0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 15:20:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP9BK0	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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
Sep-08-2020 11:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-08-2020 11:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-08-2020 11:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-08-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

11:59:38 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Sep/8/2020 11:05	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-08-2020 11:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-08-2020 11:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-08-2020 11:59:38 (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
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

Sep-08-2020 11:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-08-2020 11:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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
Sep-08-2020 11:59:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICI TY E-DIARY NOT CO LLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-29-2020 11:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-29-2020 11:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 11:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 97.3 Temperature F Unit: Temperature FOREH Location:: EAD	Initial Entry
Sep-29-2020 11:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Temperature Location::	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

Sep-29-2020 11:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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2.a Temperature:

Date	Location	User	Value	Reason
Sep-29-2020 11:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-29-2020 11:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-29-2020 11:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Sep-29-2020 11:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 11:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 12:36:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 11:19:22 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Sep-29-2020 11:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 12:36:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BGJKT : Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 12:36:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BGJKTY	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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
Sep-29-2020 11:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-29-2020 11:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-29-2020 11:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-29-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

11:19:48 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Sep/29/2020 10:06	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-29-2020 11:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 11:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-29-2020 11:19:48 (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
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Sep-29-2020 11:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-29-2020 11:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-02-2020 05:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Oct-30-2020 14:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Barcode has been entered
Oct-30-2020 07:43:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	HOLDS: Nasal self swab barcode CV20549 was received by the lab for COVID_A. Please review and update or submit an updated SCF.
Oct-27-2020 11:48:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Oct/27/2020	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Oct-27-2020 14:12:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-27-2020 14:12:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-27-2020 14:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 14:12:27 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Oct-27-2020 14:12:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 14:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS51ZV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 14:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS51ZV	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 14:12:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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)

Sample ID: BS51ZW

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 14:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS51ZW	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 14:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7RWJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 14:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7RWJ	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-03-2020 13:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 3: Closed	Response satisfies query
Nov-03-2020 10:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Query answered.
Nov-03-2020 07:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:O pened	DM1: Thank you for your response. However, please keep the query open until updates are made. Else clarify.
Nov-02-2020 08:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Will need to talk to subject to get information on COVID test and illness Potential.

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Nov-02-2020 02:55:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update missing COVID TEST, ILL POTEN forms or else clarify. Thank you.
Oct-30-2020 14:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-30-2020 10:36:57 (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.
Oct-30-2020 10:36:57 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
 Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit
 Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
 Consultants, P.A.

Subject Initials: ---

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

& Canada)				both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-30-2020 10:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-30-2020 10:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Oct/21/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

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: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Present: YES	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (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
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR IN CREASED C OUGH	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

			Symptom Present:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (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
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

			Symp tom P resent :	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pre sent: NO	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (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
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TAST E OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED S ORE THROA T Sympt NO om Pr esent:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom P NO resent:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (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
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMIT ING Symptom P NO resent:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 10:45:56 (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
Oct-30-2020 10:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 10:54:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Ot Fatig her: ue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 10:54:57 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 16:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Central Time (US
& Canada)

5.b

Date	Location	User	Value	Reason
Oct-30-2020 10:55:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - O Malai ther: se	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 10:55:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Malaise	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:54

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-03-2020 13:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Closed	Response satisfies query
Nov-03-2020 10:49:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Nov-03-2020 10:49:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry
Nov-03-2020 00:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: The response for "Actual Date of Collection" is missing. Kindly review and update.
Nov-02-2020 08:51:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
 Unscheduled Visit on Oct/18/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail
 History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
 Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Nov-02-2020 08:51:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Actual Date of Collection is more than 14 days before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIA L	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:54

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-02-2020 08:51:04 (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
Nov-03-2020 10:49:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONA VIRUS 2	Initial Entry
Nov-02-2020 08:51:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONA VIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-03-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 06-Jul-2020 21:54**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail
History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

10:49:17 (UTC-06:00) Central Time (US & Canada)		(autocalc)	SARS-COV-2 DIAGNO STIC TEST	
Nov-02-2020 08:51:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNO STIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEGATIVE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:54

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-02-2020 08:51:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NALT Unknown	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 14:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 14:24:43 (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
Oct-30-2020 14:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 14:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

& Canada)				entered. Please review and correct as appropriate.
Oct-30-2020 14:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 14:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV20549	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 14:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV20549	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-30-2020 10:46:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 10:46:25 (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
Oct-30-2020 10:46:25 (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
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Oct-30-2020 10:46:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject instructed to sel f swab.	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
 Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 15:59

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
 History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
 Consultants, P.A.

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pra EMERG ctitioner: ENCY R OOM Occurrence NO of Visits or Contacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (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
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr PRIMAR	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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)	actitioner: Y CARE PHYSICI AN Occurrence of Visits or Contact s:	
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PH YSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Oct-30-2020 10:47:00 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT CA RE	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)			Occurrence of NO f Visits or Co ntacts:	
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pract URGE itioner: NT CA RE Occurrence of f Visits or Co ntacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (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
Oct-30-2020 10:47:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry
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I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Number of Visits or Contacts: 1	Initial Entry

I.f

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts: NO	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 10:46:50 (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
Oct-30-2020 10:46:50 (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
Oct-30-2020 10:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 10-Oct-2020 15:59

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

& Canada)

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 06-Jul-2020 21:53**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail
History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 06-Jul-2020 21:52**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-03-2020 10:49:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-1 9 ILLNESS	Initial Entry
Nov-02-2020 08:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	New Information
Nov-02-2020 08:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-1 9 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-03-2020 13:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Nov-03-2020 10:49:29	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1170**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)				
Nov-03-2020 10:49:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
Nov-03-2020 00:07:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: Kindly review the form and update.
Nov-02-2020 08:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	New Information
Nov-02-2020 08:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Negative for COV ID. Was tested bec ause of admission into hospital due t o leg infection. Date of Diagnosis: Oct/1/2020	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:52

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 10:49:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
Nov-02-2020 08:51:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-02-2020 08:51:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Nov-02-2020 08:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Nov-02-2020 08:49:34	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:52

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)				
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020**Form Version:** 17-Jul-2020 21:55**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail
History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-30-2020 10:47:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-30-2020 10:47:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-30-2020 10:47:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 17-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Oct-30-2020 10:47:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

5.a Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Central Time (US
& Canada)

5.b LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Central Time (US
& Canada)

5.c LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Central Time (US
& Canada)

5.d LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

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Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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Generated By: (b) (4)

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

Central Time (US & Canada)				
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5.e LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Subject No: 11701217

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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Subject Initials: ---

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

Central Time (US
& Canada)

5.f LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Form Version: 21-Aug-2020 02:49

Site No: 1170

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Consultants, P.A.

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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5.g Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Consultants, P.A.

Subject Initials: ---

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Central Time (US & Canada)				
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5.g LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

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Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

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Site No: 1170

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Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

& Canada)

5.a Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Header Text: c4591001

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Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Central Time (US
& Canada)

5.b LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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5.c Result:

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5.c Not Done:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.d

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

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Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

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5.f

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US
& Canada)

5.f LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Central Time (US
& Canada)

5.g LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US
& Canada)

5.h LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-30-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

10:52:23 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.i LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Central Time (US & Canada)				
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5.j LNMT

Date	Location	User	Value	Reason
Oct-30-2020 10:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Systolic: Not Applicable Diastolic: Not Applicable Respiratory Rate in respirations/minute: Not Applicable Heart Rate in beats/minute: Not Applicable	Initial Entry

2.a Record Identifier:

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:50

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:50

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 21-Aug-2020 02:51

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-30-2020 10:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-30-2020 10:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

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Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Oct-30-2020 10:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:52

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-30-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-30-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-30-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form Version: 06-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Version: 06-Jul-2020 21:55

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 10:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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
Oct-30-2020 10:54:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-30-2020 10:54:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-30-2020 10:54:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/18/2020

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Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: IMAGING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Oct-30-2020 10:54:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/19/2020

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-19-2020 09:58:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/19/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-19-2020 09:58:12 (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 Nov/19/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-19-2020 10:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-19-2020 10:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-19-2020 10:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-19-2020 10:52:57 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/19/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1170**Subject No:** 11701217**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1170) North Texas Infectious Diseases
Consultants, P.A.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

& Canada)				entered. Please review and correct as appropriate.
Nov-19-2020 10:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-19-2020 10:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRTW8 : 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRTW81	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-19-2020 10:53:23	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/19/2020

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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

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

Sample ID BRTW8
:
0

5.b Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:53:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRTW80	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-19-2020 10:53:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7S80	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:53:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7S80	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Oct-27-2020 11:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 11:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 11:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-02-2020 11:28:01 (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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-29-2020 10:32:39 (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: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Oct-02-2020 11:28:01 (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
Oct-02-2020 11:28:01 (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
Nov-05-2020 08:14:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cellulitis of left lower leg	New Information
Oct-09-2020 16:20:20 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cellulitis of Left Lower extremity	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Oct-02-2020 11:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cellulitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-28-2020 14:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 10: Closed	Response satisfies query
Dec-23-2020 11:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 10: Answered	Correct as is as this is date of diagnosis.
Dec-22-2020 00:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 10: Opened	GPDClin: From the SAE report, looks like the subject had been taken penicillin V potassium for cellulitis of leg before 1/Oct/2020. Please clarify the onset date of cellulitis.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Nov-10-2020 01:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 9: Closed	onset date updated to 01Oct2020, matched with SDB
Nov-09-2020 17:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 8: Closed	Response satisfies query
Nov-09-2020 15:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 8: Answered	Event started after vaccination. Not related to vaccination though
Nov-09-2020 14:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 8: Reissued: Opened	A response was not provided ' As start date of AE is same as Vaccination date please confirm if event started prior to Vaccination or after Vaccination? Thank You!
Nov-09-2020 08:31:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Answered	Transcription Error
Nov-09-2020 08:31:53	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Answered	Answer Auto Query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1170**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)				
Nov-09-2020 08:31:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/1/2020 UNK:U NK	Transcription Error
Nov-07-2020 09:14:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 9: Opened	SAE RECON: AER#2020389615
Nov-06-2020 16:02:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 7: Closed	Response satisfies query
Nov-06-2020 15:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 8: Reissued: Opened	DM: Thank you for the response. As start date of AE is same as Vaccination date please confirm if event occur prior to Vaccination or post vaccination.
Nov-06-2020 12:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 8: Answered	Changed data per query

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Nov-06-2020 12:48:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Opened	For AE Cellulitis of left lower leg: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Nov-06-2020 12:48:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Answered	Transcription Error
Nov-06-2020 12:48:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020 UNK: UNK	Transcription Error
Nov-05-2020 22:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Reissued: Opened	onset date updated to 01oCT2020
Nov-05-2020 08:14:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020 UNK:U NK	New Information
Nov-05-2020 08:14:47 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	Original value is correct

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)				
Nov-05-2020 04:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Opened	c
Oct-29-2020 11:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	resolved
Oct-28-2020 14:37:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Date is correct.
Oct-28-2020 11:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	Please confirm the source entered for the start date of 12-Sep-2020, Visit 2 has a date of 29-Sep-2020.
Oct-20-2020 03:21:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Oct-19-2020 13:04:52 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Central Time (US & Canada)				
Oct-19-2020 13:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020 UNK: UNK	Transcription Error
Oct-16-2020 04:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	SAE RECON: AER#2020389615
Oct-16-2020 04:46:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	onset date updated in SDB but mismatch. new query issued
Oct-12-2020 04:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	SAE RECON 1:Onset date updated to 29Sep2020 in Inform but still missing in Safety database. Please confirm if a follow up AEM form was submitted to update the correct onset date.
Oct-11-2020 04:46:27	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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)		
Oct-09-2020 16:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Time unknown.
Oct-09-2020 16:20:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Cellulitis of Left Lower extremity: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Oct-09-2020 16:20:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-09-2020 16:20:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-09-2020 16:20:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020 UNK: UNK	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Oct-09-2020 16:20:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For Cellulitis of Left Lower extremity: Start date 01/Sep/2020 is before VID1VX1L visit date 08/Sep/2020. Please review and update as appropriate.
Oct-09-2020 16:20:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Start date is before Consent Date 08/Sep/2020.
Oct-09-2020 16:20:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-09-2020 16:20:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 UNK:U NK	New Information
Oct-08-2020 05:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020389615

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Oct-02-2020 11:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020 UNK:U NK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-21-2020 10:01:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/1/2020 UNK: UNK	New Information
Dec-17-2020 10:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-16-2020 07:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Will contact subject to see if AE is ongoing or has ended.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-15-2020 11:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	ClinQuery: Please verify if Cellulitis of Left Lower Leg is ongoing, then update the END DATE and OUTCOME as appropriate.
Oct-11-2020 20:11:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Oct-09-2020 16:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Awaiting medical records to update SAE form.
Oct-08-2020 15:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	The subject was hospitalized for 36 hours; information from discharge summary would be

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				helpful since the origin of neutropenia and nature of infection is not specified. Please consider an update or fu SAE form. Thank you.
Oct-02-2020 11:28:01 (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
Oct-02-2020 11:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	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).

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Date	Location	User	Value	Reason
Oct-09-2020 16:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-09-2020 16:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	New Information

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			NO	
			Is this serious event life threatening ?	
			NO	
			Other medically important serious event	
			NO	
Oct-08-2020 05:15:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Cellulitis of left lower extremity recorded in SDB
Oct-03-2020 07:29:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	SAE RECON: Cellulitis(Onset date:01Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF

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<p>Oct-02-2020 11:30:35 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Other medically important serious event NO</p>	<p>Transcription Error</p>
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Oct-02-2020 11:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-02-2020 11:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Cellulitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-02-2020 11:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 04:56:00 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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(US & Canada)				
Oct-21-2020 08:55:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated.
Oct-12-2020 00:53:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM1: Thank you for the response. However, The response for item #9,10,11,12,13, and 14 are missing? kindly review and update.
Oct-09-2020 16:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-09-2020 16:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-05-2020 02:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for item#8,9,10,11,12,13, and 14 are missing? kindly review and update.

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Oct-21-2020 22:35:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-21-2020 08:54:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Oct-21-2020 08:54:41 (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 <i>If Other, specify:</i> underline comorbidityes pt with a hx of Type II Diabetes and morbid obesity	Initial Entry

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			y	
Oct-14-2020 06:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Opened	SAE RECON:AER#2020389615 ,causality was recorded as UNRELATED in Safety database but was missing in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Oct-11-2020 20:10:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Oct-09-2020 16:21:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Awaiting medical records to update SAE form.
Oct-08-2020 09:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	The subject was hospitalized for 36 hours; information from discharge summary would be helpful since the origin of neutropenia and nature of infection is not specified in case narrative. Please consider an update or fu SAE form. Thank you.

10. Latest Action Taken with Study Treatment:

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Date	Location	User	Value	Reason
Oct-21-2020 22:35:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 08:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-21-2020 08:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
Oct-14-2020 06:18:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020389615 ,action taken was recorded as NOT APPLICABLE in Safety database but was missing in AE CRF. Please confirm correct action taken. If safety update is required, please submit a follow-up form.

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-21-2020 08:50:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-21-2020 08:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-02-2021 02:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	outcome updated in SDB. Issue resolved
Dec-31-2020 02:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reis sued:C andida te	PSSR review
Dec-23-2020 11:34:44 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	Updated report sent to Safety.

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(US & Canada)				
Dec-22-2020 05:50:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020389615 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome.If safety update is required,pls submit a ffup form
Dec-21-2020 10:03:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-21-2020 10:03:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECOVERED/RESOLVED	New Information
Dec-21-2020 10:01:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Cellulitis of left lower leg: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-20-2020 03:23:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	sed	
Oct-19-2020 11:09:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information
Oct-19-2020 11:09:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECO VERI NG/R ESOL VING	Changed Information
Oct-14-2020 06:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ope ned	SAE RECON:AER#2020389615,outcome was reported as Recovering/Resolving to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-09-2020 16:22:51 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NOT	Initial Entry

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(US & Canada)			RECOVERED
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-09-2020 16:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-08-2020 05:16:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020389615	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-02-2020 11:32:22 (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
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 14:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Clo sed	Appreciate it. Thank you.
Nov-16-2020 13:54:56 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: An swered	Yes. I have it written down to do so when final diagnosis is available.

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(US & Canada)				
Nov-16-2020 13:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Reissued:Opened	Would you kindly submit a FU report when this information is available?
Nov-16-2020 12:53:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Final Diagnosis not available.
Nov-16-2020 09:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Opened	The subject had two remarkable lab abnormalities during hospitalization (neutropenia and thrombocytopenia), please provide a final diagnosis related to this events if available. Thank you.
Oct-30-2020 05:57:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-29-2020 10:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Entered.
Oct-28-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued	SAE RECON

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23:09:25 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	ssued:Opened	1:Thrombocytopenia is still missing in AR CRF. Please confirm if this is a valid SAE and should be added in AE log or event should be downgraded in Safety database
Oct-28-2020 15:21:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Thank you!
Oct-28-2020 11:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Was not initially reported by patient when doing initial SAE form. No information regarding this. But will be updated on AE log.
Oct-28-2020 11:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Faxed yesterday 27Oct2020.
Oct-28-2020 04:47:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020389615 thrombocytopenia(onset date:01Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.

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Oct-21-2020 10:34:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Op ened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed during hospitalization (yes/no) and if yes, the results. Thank you.
Oct-16-2020 04:49:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	updated to O2OCT2020 in SDB
Oct-11-2020 07:16:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	SAE RECON: AER#2020389615 ,onset date was missing in Safety database however, recorded as 1/Oct/2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-11-2020 07:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-09-2020 16:23:14 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swered	New Information

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1170**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Central Time (US & Canada)				
Oct-09-2020 16:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutropenia	New Information
Oct-08-2020 05:31:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	SAE RECON:AER#2020389615 Neutropenia(blank onset date)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Thrombocyt oenia of left leg	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-28-2020 23:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

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Oct-28-2020 08:11:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Oct-28-2020 08:11:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020 UNK:U NK	New Information
Oct-28-2020 03:37:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020389615 ,onset date was updated to 01Oct2020 in Safety database however, recorded as 02Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-20-2020 03:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-19-2020 11:10:10	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)				
Oct-19-2020 11:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020 UNK:U NK	Transcription Error
Oct-16-2020 04:50:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020389615 ,onset date was reported as 02Oct2020 in Safety database however, recorded as 1/Oct/2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-08-2020 05:27:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query text intended for AE 1
Oct-08-2020 05:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020389615

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Subject Initials: ---

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& Canada)				
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-21-2020 10:02:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/1/2020 UNK :UNK	New Information
Dec-17-2020 10:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-16-2020 07:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Will contact subject to see if AE is ongoing or has ended.
Dec-15-2020 11:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Neutropenia is ongoing, then update the END DATE and

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				OUTCOME as appropriate.
Nov-11-2020 07:58:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Transcription Error
Oct-29-2020 10:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date Time: Oct/2/2020 UNK: UNK	New Information
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 3	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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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
Oct-11-2020 07:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 16:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-09-2020 16:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	New Information

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			<p>n?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
<p>Oct-09-2020 16:23:14 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 1: Candidate</p>	<p>For AE Neutropenia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.</p>
<p>Oct-03-2020 07:30:26 (UTC-06:00)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	<p>Query 1: Opened</p>	<p>SAE RECON: Thrombocytopenia of left leg(Onset</p>

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1170**Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.**Subject No:** 11701217**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Central Time (US & Canada)				date:01Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-02-2020 11:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Thrombocytopenia of left leg : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-02-2020 11:32:22	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Subject Initials: ---

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

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

Is this serious event associated with congenital anomaly or birth defect?

NO

Did this serious event result in death?

NO

Did this serious event require or prolong hospitalization?

YES

Did this serious event result in persistent or significant disability/incapacity?

NO

Other medically important serious event

NO

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

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-22-2020 04:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Generated By: (b) (4)

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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
Oct-21-2020 09:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated.
Oct-12-2020 00:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for the response. However, The response for item#9,10,11,12, are missing? kindly review and update.
Oct-09-2020 16:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-09-2020 16:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-05-2020 02:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for item#8,9,10,11,12,13,and 14 are missing? kindly review and update.

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Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-05-2021 10:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Dec-22-2020 07:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject reported and his medical history that the cause of his neutropenia is his obesity and type 2 diabetes
Dec-22-2020 00:25:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	GPDClin: Please clarify the cause of neutropenia which is rarely caused by type 2 diabetes or obesity.
Oct-21-2020 22:37:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:18:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-21-2020 09:18:21 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

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Central Time (US & Canada)			If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> underline comorbidityes pt with a hx of Type II Diabetes and morbid obesity	
Oct-14-2020 06:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	SAE RECON:AER#2020389615 ,causality was recorded as UNRELATED in Safety database but was missing in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.

10. Latest Action Taken with Study Treatment:

[Empty box for latest action taken with study treatment]

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Date	Location	User	Value	Reason
Oct-21-2020 22:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:18:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-21-2020 09:18:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
Oct-14-2020 06:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020389615 ,action taken was recorded as NOT APPLICABLE in Safety database but was missing in AE CRF. Please confirm correct action taken. If safety update is required, please submit a follow-up form.

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-21-2020 09:18:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-23-2020 13:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Dec-23-2020 11:29:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-23-2020 11:29:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Dec-22-2020 00:30:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify what non-drug treatment was given to treat neutropenia.
Oct-21-2020 09:18:21 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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& Canada)

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

Date	Location	User	Value	Reason
Jan-02-2021 02:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 10: Closed	outcome updated in SDB. Issue resolved
Dec-31-2020 02:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 10: Reissued: Candidate	PSSR review
Dec-23-2020 11:26:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 10: Answered	Yes, recovered. Updated submission sent to Safety.
Dec-22-2020 05:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 10: Opened	SAE RECON:AER#2020389615 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome.If safety update is required, please submit a follow-up form.

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Dec-21-2020 10:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Clo sed	Close Auto Query
Dec-21-2020 10:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : REC OVE RED/ RESO LVE D	New Information
Dec-21-2020 10:02:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Op ened	For AE Neutropenia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-12-2020 06:04:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 7: Clo sed	Response satisfies query
Nov-11-2020 07:58:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Clo sed	Close Auto Query

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Nov-11-2020 07:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Op ened	For AE Neutropenia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-11-2020 07:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: An swere d	Transcription Error
Nov-11-2020 07:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : REC OVE RING /RES OLVI NG	Transcription Error
Nov-10-2020 23:57:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 7: Op ened	SAE RECON:AER#2020389615,outcome was recorded as RECOVERING/RESOLVING to Safety DB however, updated as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-09-2020 14:20:31	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 5: Clo	Response satisfies query

Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)			sed	
Nov-09-2020 08:32:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: An swere d	Answer Auto Query
Nov-09-2020 08:32:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : REC OVE RED/ RESO LVE D	Transcription Error
Nov-07-2020 09:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 6: Clo sed	SDB data updated to recovering/resolving
Nov-06-2020 16:05:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 5: Rei ssued: Open ed	DM: Thank you for your response. However, 'recovering/resolving' is not expected if AE is not ongoing. Please refer to CRF Completion Requirements and update response as appropriate.

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Nov-06-2020 13:04:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 5: An swere d	Changed data per query
Nov-06-2020 13:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 6: An swere d	Changed data per query
Nov-06-2020 04:57:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 6: Op ened	SAE RECON:AER#2020389615,outcome was reported as RECOVERED/RESOLVED to Safety DB however, updated as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-05-2020 14:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Op ened	For AE Neutropenia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-05-2020 14:33:54 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : REC OVE	New Information

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Header Text: c4591001

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Canada)			RING /RES OLVI NG	
Oct-29-2020 10:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Clo sed	Close Auto Query
Oct-29-2020 10:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : REC OVE RED/ RESO LVE D	New Information
Oct-29-2020 10:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Op ened	For AE Neutropenia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-29-2020 04:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query

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Generated By: (b) (4)

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Subject Initials: ---

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Oct-28-2020 11:19:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swere d	New Information
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Header Text: c4591001

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Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-28-2020 11:19:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECO VERI NG/R ESOL VING	New Information
Oct-28-2020 04:02:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Ope ned	For AE Neutropenia: Response to "What was the outcome of this adverse event?" is 'RECOVERED/RESOLVED' but End Date/Time is missing.
Oct-28-2020 04:01:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Clo sed	invalid query
Oct-21-2020 22:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-21-2020	ACV0PFEINFP6000	auto query	Query	For AE Neutropenia: Response to

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Site No: 1170

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Subject No: 11701217

Subject Initials: ---

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09:18:44 (UTC-06:00) Central Time (US & Canada)		(autoquery)	2: Opened	"What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-21-2020 09:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-21-2020 09:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECOVERED/RESOLVED	New Information
Oct-20-2020 03:32:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	SAE RECON 1: Per latest SAE listing outcome is still 'RECOVERED/RESOLVED' however, RECOVERING/RESOLVING in AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-19-2020 11:10:30 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

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(US & Canada)				
Oct-19-2020 11:10:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECOVERING	Changed Information
Oct-14-2020 06:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020389615,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-09-2020 16:24:01 (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?

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-09-2020 16:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-11-2020 07:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020389615	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:39 (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
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-23-2020 13:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Dec-23-2020 11:32:19 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Yes, all part of medical history however please unlock MH form

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& Canada)				to add.
Dec-22-2020 00:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if the subject has MHx of idiopathic thrombocytopenic purpura, tobacco use, alcoholism, and obstructive sleep apnea, which were included in the SAE report.
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Thrombocytopenia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-21-2020 10:04:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	New Information

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	End Date Time: Nov/1/2020 UN K:UNK	
Dec-17-2020 10:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-16-2020 07:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Will contact subject to see if AE is ongoing or has ended.
Dec-15-2020 11:32:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Thrombocytopenia is ongoing, then update the END DATE and OUTCOME as appropriate.
Oct-30-2020 10:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/2/2020 UNK	Initial Entry

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			:UNK	
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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
Oct-30-2020 05:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Thrombocytopenia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event

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				Number" is blank.
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

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			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-29-2020 10:32:39 (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
Oct-31-2020 09:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-30-2020 11:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 09:26:56	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry

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Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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Subject Initials: ---

Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)				
Oct-30-2020 09:26:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 09:26:56 (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 <i>If Other, specify:</i> Cellulitis	Initial Entry
Oct-30-2020 06:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020389615 ,causality was recorded as UNRELATED in Safety database but was MISSING in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 00:24:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete this item. Thank you.
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:39 (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
Oct-29-2020 10:32:39 (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
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site No: 1170

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Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-02-2021 02:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	outcome updated in SDB. Issue resolved
Dec-31-2020 02:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Candidate	PSSR review
Dec-23-2020 11:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Updated report sent to Safety.
Dec-22-2020 05:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020389615 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome.If safety update is required, please submit a follow-up form.
Dec-21-2020 10:04:33 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query

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Central Time (US & Canada)				
Dec-21-2020 10:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-21-2020 10:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Thrombocytopenia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-31-2020 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	outcome updated to recovering/resolving in AE CRF
Oct-30-2020 10:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-30-2020 10:56:42 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED	New information provided AE still ongoing.

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(US & Canada)			NG/RESOLVING	
Oct-30-2020 10:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Thrombocytopenia: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-30-2020 09:30:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Recovered.
Oct-30-2020 06:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020363610,outcome was reported as Recovering/Resolving to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Oct-29-2020 10:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-30-2020 05:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020389615	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-28-2020 14:37:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Dec-23-2020 11:34:11 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Yes.

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Dec-22-2020 00:46:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if the cellulitis was resulted from the injury/wound of left lower leg.
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Wound of left lower l eg	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-13-2020 07:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/30/2020 UN K:UNK	Transcription Error

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/29/2020 UN K:UNK	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	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
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (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 <i>If Other, specify:</i> injury to leg.	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (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
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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Generated By: (b) (4)

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

Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 14:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-12-2020 14:51:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/ RESOLVED	Transcription Error
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Wound of left lower leg: Response to "What was the outcome of this adverse event?" is

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

				'Recovering/Resolving' but AE End Date/Time is present.
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING /RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 14:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-20-2021 14:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-20-2021 14:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-20-2021 14:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-20-2021 14:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-20-2021 14:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pneumonia Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-20-2021 14:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

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

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

Site No: 1170 **Site Name:** (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217 **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
Jan-20-2021 14:56:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION -
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-20-2021 14:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 14:56:30 (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.
Jan-20-2021 14:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Participant is willing t o return for Vaccinatio n 3 Participant is: eligible per local/na tional recommendat ions and confirmed to have received onl y placebo at Vaccin ation 1/2	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-20-2021 14:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-20-2021 14:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL V ACCINATION	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 14:57:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-20-2021 14:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Jan/20/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Jan-20-2021 14:58:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-20-2021 14:58:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-20-2021 14:58:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Jan-20-2021 15:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 15:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 15:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 15:03:07 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

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Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Jan-20-2021 15:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 15:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BSGDB : F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 15:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGDBF	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 15:03:38	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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)	Sample ID BSGDB : G	
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5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 15:03:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGDBG	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 15:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPSBX : R	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 15:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSBXR	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Jan-20-2021 15:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 15:02:50 (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
Jan-20-2021 15:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 15:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Jan-20-2021 15:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 15:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPSBX : N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 15:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSBXN	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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
Jan-20-2021 14:59:12 (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
Jan-20-2021 14:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-20-2021 14:59:12 (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
Jan-20-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

14:59:12 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Jan/20/2021 08:30	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-20-2021 14:59:12 (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
Jan-20-2021 14:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-20-2021 14:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Jan-20-2021 14:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
Jan-20-2021 14:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-20-2021 14:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 14:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 11:02:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

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
Feb-10-2021 11:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 11:02:14 (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
Feb-10-2021 11:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 11:02:14 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Feb-10-2021 11:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 11:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSBDJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 11:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSBDJ	Initial Entry

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Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

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
Feb-10-2021 11:02:59 (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
Feb-10-2021 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-10-2021 11:02:59 (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
Feb-10-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

11:02:59 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Feb/10/2021 08:30	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-10-2021 11:02:59 (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
Feb-10-2021 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-10-2021 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject No: 11701217

Subject Initials: ---

Generated By: (b) (4)

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

Feb-10-2021 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
Feb-10-2021 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-10-2021 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 13:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-10-2021 13:45:38 (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-10-2021 13:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/10/2021	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail
History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1170

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject No: 11701217

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
Mar-10-2021 13:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-10-2021 13:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATM ENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-10-2021 13:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1170) North Texas Infectious Diseases Consultants, P.A.

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-27-2020 11:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-08-2020 11:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMI ZED	Initial Entry
Sep-08-2020 11:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-27-2020 11:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Sep-08-2020 11:59:04 (UTC-06:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/8/2020	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

Central Time (US & Canada)				
Sep-08-2020 11:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/8/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1170

Subject No: 11701217

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1170) North Texas Infectious Diseases
Consultants, P.A.

Subject Initials: ---

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-04-2020 15:32:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3f91\Final\Final On: 01-Apr-2021 05:19 (GMT)