

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/10/2020
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11471239]
2.	Birth Date:	(b) (6) /1964
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/10/2020
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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	Sep/13/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Sep/14/2012
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[menorrhagia]
	Start Date:	Apr/18/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	Dec/3/2012
	Ongoing:	YES

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[IRREGULAR MENSTRUAL CYCLE]
	Start Date:	Apr/18/2019
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[menopause]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
2.	Weight:	[127.0]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[21.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/10/2020
2.	Randomization Number:	[256095]
3.	Randomization Group:	[]

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
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	[BPY3FW]
5.b	Sample ID	[BPY3FX]
5.c	Sample ID	[BPY3FV]
5.d	Sample ID	[BPLF56]
5.e	Sample ID	[BPLF4S]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
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	[BPY3G3]
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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/10/2020 12:46
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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/30/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY3PY]
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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/30/2020 11:57
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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/28/2020
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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMNV0M]
5.b	Sample ID	[BMNV0C]
5.c	Sample ID	[BR7XLB]
5.d	Sample ID	[BR7XLC]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/16/2020
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 Nov/16/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/16/2020
2.	Date of First Symptom Started:	Nov/12/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Nov/16/2020

Symptoms

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

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

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Nov/13/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/13/2020
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:	ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV14381]
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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:	[Site did not collect swab]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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:	YES Number of Visits or Contacts: [1]
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled

Form: VITAL SIGNS - COVID

Visit on Nov/16/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Date Time of Assessment	Arterial Blood Gases PaO ₂	FiO ₂ (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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.	Start Date:	//
6.	Ongoing?	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled

Form: IMAGING

Visit on Nov/16/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/15/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/15/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/15/2020
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	[BSGTWD]
5.b	Sample ID	[BSGTWV]
5.c	Sample ID	[BP8H5Z]
5.d	Sample ID	[BP8H60]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Disposition - Follow-Up

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

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Ovarian Mass	Sep/21/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Increased HDL (95)	Sep/18/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Left Lower Quadrant Pain	Sep/25/2020 UNK:UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	Trace Ketones (Urinalysis)	Sep/24/2020 UNK:UNK	YES	Repeating Pages
5.	ADVERSE EVENT	5	Trace Leukocytes in Urinalysis	Sep/24/2020 UNK:UNK	YES	Repeating Pages
6.	ADVERSE EVENT	6	Decreased Sodium (131)	Sep/24/2020 UNK:UNK	YES	Repeating Pages
7.	ADVERSE EVENT	7	Decreased Chloride (94)	Sep/24/2020 UNK:UNK	YES	Repeating Pages
8. DELETED	ADVERSE EVENT	8	Ovarian Mass	Sep/21/2020 UNK:UNK	YES	Repeating Pages

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Ovarian Mass]
4.	Start Date Time:	Sep/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Ovarian mass of unknown origin]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020403508]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Increased HDL (95)]
4.	Start Date Time:	Sep/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Not related to the study treatment]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Lower Quadrant Pain]
4.	Start Date Time:	Sep/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Not related to the study treatment]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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)	[Trace Ketones (Urinalysis)]
4.	Start Date Time:	Sep/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Not related to study treatment]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Trace Leukocytes in Urinalysis]
4.	Start Date Time:	Sep/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Not related to the study treatment]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Decreased Sodium (131)]
4.	Start Date Time:	Sep/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Not related to the study]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Decreased Chloride (94)]
4.	Start Date Time:	Sep/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: [Not related to study treatment]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1147**Subject No:** 11471239**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

*** THIS REPEATING FORM HAS BEEN DELETED ***

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Ovarian Mass]
4.	Start Date Time:	Sep/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

***** THIS REPEATING FORM HAS BEEN DELETED *****

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: [Not related to the study]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Medication Error

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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?	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471239 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 **Form Status:** Not Started

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471239 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

Lab Urinalysis

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

Lab Result

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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?	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 1

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

Site No: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471239 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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: 1147 **Site Name:** (1147) Ochsner Health System

Subject No: 11471239 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/15/2021
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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/26/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/26/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
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	[BRZXLZ]
5.b	Sample ID	[BRXMC]
5.c	Sample ID	[BR7X6B]
5.d	Sample ID	[BR7X6C]

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
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	[BR7X3L]
-----	-----------	----------

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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/26/2021 11:57
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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Lab Urinalysis

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

Lab Result

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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?	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/28/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-10-2020 13:25:55 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	all inclusion criteria met and no exclusion criteria met
			Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:49
Site No: 1147
Subject No: 11471239
Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1147) Ochsner Health System
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
1	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential <hr/> Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:49
Site No: 1147
Subject No: 11471239
Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1147) Ochsner Health System
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
2	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
3	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
4	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential <hr/> Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:49
Site No: 1147
Subject No: 11471239
Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1147) Ochsner Health System
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
5	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential
			Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:49
Site No: 1147
Subject No: 11471239
Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1147) Ochsner Health System
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential
			Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:49
Site No: 1147
Subject No: 11471239
Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1147) Ochsner Health System
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential
			Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:49
Site No: 1147
Subject No: 11471239
Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1147) Ochsner Health System
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	Neha Upadhyay (b) (4)	patient not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
3	Oct-01-2020 09:14:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	menopause 2009
			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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-28-2021 01:49:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
1	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
2	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
3	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
4	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
5	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
6.a	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
6.a	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
6.a	Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-19-2021 12:25:04 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Julia Garcia-Diaz	Approved	Jan-26-2021 06:23:33 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, JuliaGarcia-Diaz, 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.

Fredrick Okwori	N/A	Dec-15-2020 12:02:35 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Julia Garcia-Diaz	Approved	Nov-17-2020 20:36:21 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Affidavit:

By my dated signature below, I, JuliaGarcia-Diaz, 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.

James McMullen	N/A	Nov-17-2020 19:45:36 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Julia Garcia-Diaz	Approved	Nov-16-2020 15:24:28 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, JuliaGarcia-Diaz, 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.

James McMullen	N/A	Nov-16-2020 10:34:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Julia Garcia-Diaz	Approved	Nov-09-2020 14:52:10 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Affidavit:

By my dated signature below, I, JuliaGarcia-Diaz, 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: COHORT_SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-10-2020 13:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 13:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-10-2020 13:24:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-10-2020 13:23:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11471239	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1964	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-23-2020 05:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB updated. issue resolved
Oct-21-2020 22:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:C andidate	SAE RECON: To check SAE listing if gender will be updated
Oct-21-2020 12:24:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Query 1: Answered	SAE form updated with latest follow up
Oct-20-2020 03:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:O pened	SAE RECON 1: Per latest SAE listing, gender is still reported as MALE. Please confirm if a follow up AEM form was submitted

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				to correct gender in Safety database.
Oct-19-2020 10:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject is female
Oct-19-2020 05:15:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020403508 ,the gender was reported as MALE in Safety database but was recorded as FEMALE in AE CRF. Please confirm gender. If safety update is required, please submit a follow-up form.
Sep-10-2020 13:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-10-2020 13:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 13:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 13:25:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sep/10/2020	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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-10-2020 13:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sep/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-10-2020 13:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-10-2020 13:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Sep-10-2020 13:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Anxiety Start Date: Sep/13/2018 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 13:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 13:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Anxiety	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sep/13/2018	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Sep-10-2020 13:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: YES	Initial Entry
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I.b

Date	Location	User	Value	Reason
Sep-10-2020 13:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History T Hypertensi erm: on Start Date: Sep/14/20 12 Ongoing: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 13:27:58 (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
Sep-10-2020 13:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sep/14/2012	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 13:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-11-2020 12:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Numbr: 3 Medical History Term: mennorrhagia Start Date: Apr/18/2019	Transcription Error

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Ongoing: YES	
Sep-10-2020 13:29:01 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical Hi mennorrhagia story Term with irregular c : ycle Start Date: Apr/18/2019 Ongoing: YES	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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 13:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-12-2020 05:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-11-2020 12:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-11-2020 12:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mennorrhagia	Transcription Error
Sep-11-2020 04:49:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term MENORRHAGIA WITH IRREGULAR CYCLE. Split the term into MENORRHAGIA and IRREGULAR MENSTRUAL CYCLE and submit

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				separately. Thank you.
Sep-10-2020 13:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry : mennorrhagia with irregular cycle	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Apr/18/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 13:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-14-2020 10:55:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Num 4 ber: Medical History Term: seasonal allergies Start Date: Dec/3/2012 Ongoing: YES	Transcription Error

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

<p>Sep-10-2020 13:29:29 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Number: 4 Medical History: Allergy Term: Start Date: Dec/3/2012 Ongoing: YES</p>	<p>Initial Entry</p>
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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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 13:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 10:58:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchemo (b) (4)	Query 1: Closed	Response satisfies query
Sep-14-2020 10:55:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-14-2020 10:55:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: seasonal allergies	Transcription Error
Sep-11-2020 14:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchemo (b) (4)	Query 1: Opened	GPDCLIN: Please consider updating the verbatim term including type of allergy/allergen.
Sep-10-2020 13:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Allergy	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Dec/3/2012	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 13:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-14-2020 10:56:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 5 Number: Medical History T IRREGULAR erm: MENSTRUAL CYCLE Start Date Apr/18/2019 : Ongoing: YES	Changed Information
Sep-11-2020 12:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 5 er: Medical History irregular c Term: ycle Start Date: Apr/18/2019 Ongoing: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 12:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 11:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-14-2020 10:56:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-14-2020 10:56:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IRREGULAR MENSTRUAL CYCLE	Changed Information
Sep-12-2020 05:51:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify IRREGULAR CYCLE as follows... term is unclear. Please edit term to clarify the type of cycle. If reporting IRREGULAR MENSTRUAL

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				CYCLE, edit and submit as such. Otherwise, please edit term. Thank you.
Sep-11-2020 12:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: irregular cycle	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 12:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/18/2019	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 12:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-14-2020 10:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: menopause Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-14-2020 10:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 10:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: menopause	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-14-2020 10:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-14-2020 10:56:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sep/10/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: 127.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: 64.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.8	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Record Identifier: Temperature: 97.8 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: 97.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Sep-10-2020 13:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sponsor-Defined Not Applicable Identifier: icable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-10-2020 13:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-10-2020 13:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sep/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-10-2020 13:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: 256095	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 13:33:12 (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-10-2020 13:33:12 (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-11-2020 09:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 04:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 13:33:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Sep-10-2020 13:33:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-11-2020 09:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY3FW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 09:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPY3FW	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-11-2020 09:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY3FX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 09:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPY3FX	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-11-2020 09:23:17 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (6)	Data Entry: Sample ID: BPY3FV	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)		(b) (4)		
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5.c Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 09:23:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPY3FV	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-11-2020 09:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLF56	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 09:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLF56	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-11-2020 09:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLF4S	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 09:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLF4S	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 13:33:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 13:33:27 (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-11-2020 08:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 04:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 13:33:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Sep-10-2020 13:33:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-11-2020 08:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY3G3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 08:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPY3G3	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 13:33:58 (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-10-2020 13:33:58 (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-10-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: Sep/10/2020 12:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 13:33:58 (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
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Sep-10-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-10-2020 13:34:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Neha Upadhyay (b) (4)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECT ED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-01-2020 09:12:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-01-2020 09:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-01-2020 09:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-01-2020 09:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-01-2020 09:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Oct-01-2020 09:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry
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2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-01-2020 09:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

3. Collection Date:

Date	Location	User	Value	Reason
Oct-01-2020 09:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-01-2020 09:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: Not Done:: NOT DONE	Initial Entry
Oct-01-2020 09:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-01-2020 09:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

6.a Test:

Date	Location	User	Value	Reason
Oct-01-2020 09:14:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX 113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-01-2020 09:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 09:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-01-2020 09:15:07 (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-01-2020 11:01:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 09:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-01-2020 09:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Oct-01-2020 11:01:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY3PY	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 11:01:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPY3PY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-01-2020 09:15:56 (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
Oct-01-2020 09:15:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-01-2020 09:15:56 (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
Oct-01-2020 09:15:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 11:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-01-2020 09:15:56 (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
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Oct-01-2020 09:15:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Oct-01-2020 09:15:56 (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
Oct-01-2020 09:15:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 09:15:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-28-2020 13:14:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Oct/28/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-28-2020 13:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 13:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-28-2020 14:26:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 13:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 13:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES Date of Collection: Oct/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Oct-28-2020 14:26:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNV0M	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 14:26:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNV0M	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-28-2020 14:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNV0C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 14:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNV0C	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-28-2020 14:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7XLB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 14:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7XLB	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d

Date	Location	User	Value	Reason
Oct-28-2020 14:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7XLC	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 14:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7XLC	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-16-2020 10:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-16-2020 10:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-16-2020 10:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-16-2020 10:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Nov/16/2020	Initial Entry

3. COVID-19 Illness Visit:

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Nov-16-2020 10:34:25 (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 Nov/16/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 10:36:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Nov/16/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Nov/12/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO Date of Last Symptom Resolved: Nov/16/2020	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.a

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Symptom NEW OR INCR s: EASED COUG H Symptom NO Present:	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Sympt NEW OR INCRE oms: ASSED SHORTNE SS OF BREATH Sympt NO om Pre sent:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.d

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms: CHILL S Symptom Present NO :	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	James McMullen (b) (4)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms: NEW OR INCRE ASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> Sympto NEW LOSS OF ms: TASTE OR SME LL Sympto NO m Prese nt:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.g

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms: VOMITIN G Symptom Prese NO nt:	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 10:35:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

5.a

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Nov-16-2020 10:36:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms - Othe Headach r: e	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Headache	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-16-2020 10:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Symptoms - Other Fatigu : e	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Fatigue	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Nov/13/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC T EST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: ABBOTT MOLECULAR R EALTIME SARS-COV-2 A SSAY	Initial Entry
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7. Test Result:

Date	Location	User	Value	Reason
Nov-16-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NEGATIVE	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-16-2020 10:35:38 (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-16-2020 10:35:38 (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
Nov-17-2020 19:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-17-2020 07:20:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-16-2020 10:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				appropriate.
Nov-16-2020 10:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: YES Date of Collection: Nov/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-17-2020 19:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Sample ID: CV14381	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 19:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: CV14381	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-16-2020 10:35:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-16-2020 10:35:50 (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
Nov-16-2020 10:35:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	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
Nov-16-2020 10:35:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Site did not collect swab	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Type of Prac PRIMARY itioner: CARE PHY SICIAN Occurrence NO of Visits or C ontacts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: PRIMARY CARE PHYSICI AN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.d

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.e

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Occurrence NO of Visits or C ontacts:	
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I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: TELEPHONE CONSULTAT ION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Type of Practitioner OTH : ER Occurrence of Visits NO or Contacts:	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 10:36:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Nov/16/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLN ESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-16-2020 10:36:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-16-2020 10:36:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: 1	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/15/2020

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-15-2020 12:02:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Dec/15/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-15-2020 12:02:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: COVID_A1	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-15-2020 12:02:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-15-2020 12:02:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-16-2020 11:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-16-2020 05:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-15-2020 12:02:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-15-2020 12:02:49 (UTC-06:00) Central	ACV0PFEINFP6000	Fredrick Okwori	Data Entry: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/15/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)	(b) (4)	Date of Collection:	Dec/15/2020
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5.a

Date	Location	User	Value	Reason
Dec-16-2020 11:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sample ID: BSGTWD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 11:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: BSGTWD	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-16-2020 11:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sample ID: BSGTWW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 11:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: BSGTWW	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-16-2020 11:55:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sample ID: BP8H5Z	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 11:55:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: BP8H5Z	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-16-2020 11:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sample ID: BP8H60	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 11:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: BP8H60	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-28-2020 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Oct/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-28-2020 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-28-2020 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Form Created	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Form Created	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Form Created	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Form Created	

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-21-2020 12:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Form Deleted	Duplicate AE
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (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-16-2020 13:04:47 (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
Oct-21-2020 22:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 12:25:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-21-2020 12:25:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Ovarian Mass	Changed Information
Oct-21-2020 05:05:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020403508,the term was updated to 'surgical removal of OVARIAN MASSin Safety database while recorded as 'Ivis Mass' in AE CRF.

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1147**Subject No:** 11471239**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

				Please confirm correct term.If safety update is required, please submit a follow-up form.
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: Pelvis Mass	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-21-2020 12:26:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: Sep/21/2020 UNK:UNK	Changed Information
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: Sep/28/2020 08:16	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	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**

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-19-2020 05:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pelvis Mass: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: YES Is this serious event associa ted with congenital anomal y or birth defect? NO Did this serious event result in death? NO Did this serious event requi re or prolong hospitalizatio n? YES Did this serious event result in persistent or significant d isability/incapacity? NO Is this serious event life thr eatening?	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			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-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-21-2020 12:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Ovarian mass of unknown origin	Changed Information
Oct-16-2020 13:12:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Transcription Error

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

			pelvic mass of unknown origin	
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 13:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Corinne Abraham (b) (4)	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
Oct-16-2020 13:04:47 (UTC-06:00) Central	ACV0PFEINFP6000	Corinne Abraham	Data Entry: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)

(b) (4)

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-19-2020 05:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020403508	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (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-16-2020 15:27:52 (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
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Increased HDL (95)	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sep/18/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	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.

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Not related to the study treatment	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 15:28:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (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-16-2020 15:33:44 (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
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Left Lower Quadrant Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sep/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	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.

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Not related to the study treatment	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (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-16-2020 15:37:14 (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
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Trace Ketones (Urinalysis)	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sep/24/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	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.

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Not related to study treatment	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 15:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (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-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Trace Leukocytes in Urinalysis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sep/24/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	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.

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Not related to the study treatment	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 15:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (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-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Decreased Sodium (131)	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sep/24/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	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.

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Not related to the study	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 15:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (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-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Decreased Chloride (94)	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sep/24/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	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.

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Not related to study treatment	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 15:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (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-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-22-2020 07:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closing as log line deleted
Oct-20-2020 09:18:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-20-2020 09:18:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Ovarian Mass	Changed Information
Oct-20-2020 08:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Pelvic Mass is present in more than one AE logs however Toxicity grades are different. Please confirm if an End date needs to be

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Deleted

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

*** THIS REPEATING FORM HAS BEEN DELETED ***

				updated for the AE on logline 1, Thank you.
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Pelvic Mass	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 09:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Sep/21/2020 UNK:UNK	Changed Information
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: Oct/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NOT RELATED If Not Related to study treat ment(s), this event is due to: OTHER <i>If Other, specify:</i> Not related to the study	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40	ACV0PFEINFP6000	Fredrick	<u>Data Entry:</u>	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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, Deleted

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

*** THIS REPEATING FORM HAS BEEN DELETED ***

(UTC-06:00) Central Time (US & Canada)		Okwori (b) (4)	NO	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Fredrick Okwori (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-19-2021 12:25:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/29/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-19-2021 12:25:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-19-2021 12:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Feb/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-19-2021 12:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Feb-28-2021 01:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION -
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Feb-28-2021 01:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtai ned Feb/26/2021	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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-28-2021 01:50:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-28-2021 01:50:11 (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
Feb-28-2021 01:50:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (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
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (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	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 01:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (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:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 07:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 07:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 07:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 07:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 07:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Mar-01-2021 07:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRZXLZ	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 07:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRZXLZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-01-2021 08:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRZXMC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 08:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRZXMC	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-01-2021 08:40:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7X6B	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 08:40:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7X6B	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

5.d

Date	Location	User	Value	Reason
Mar-01-2021 08:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7X6C	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 08:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7X6C	Initial Entry

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471239**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 07:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 07:13:05 (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
Mar-01-2021 07:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 07:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 07:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Mar-01-2021 07:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7X3L	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 07:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7X3L	Initial Entry

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-28-2021 01:52:37 (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-28-2021 01:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-28-2021 01:52:37 (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-28-2021 01:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/26/2021 11:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-28-2021 01:52:37 (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
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090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471239

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Feb-28-2021 01:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Feb-28-2021 01:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-28-2021 01:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-28-2021 01:52:37 (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-28-2021 01:52:37 (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-28-2021 01:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-28-2020 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-10-2020 13:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-10-2020 13:26:14 (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-28-2020 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/28/2020	Initial Entry
Sep-10-2020 13:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry
Sep-10-2020 13:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry

090177e196ae3d77\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471239

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-09-2020 14:15:12 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	James McMullen (b) (4)	Data Entry: Click Here to Enable	Initial Entry