

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/11/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11181013]
2.	Birth Date:	(b) (6)/1957
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: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/11/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/11/2020
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: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPOTHYROIDISM]
	Start Date:	Mar/21/2013
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	Apr/18/2008
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERLIPIDEMIA]
	Start Date:	May/15/2015
	Ongoing:	YES

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/11/2020
2.	Weight:	[79.7]
3.	Unit:	kg
4.	Height:	[161.3]
5.	Unit:	cm
6.	Body Mass Index:	[30.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/11/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/11/2020
2.	Randomization Number:	[225592]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
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	[BP50G5]
5.b	Sample ID	[BP50G6]
5.c	Sample ID	[BP50G7]
5.d	Sample ID	[BPR7K4]
5.e	Sample ID	[BPR7K5]

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
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	[BP50F0]
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/11/2020 14:23
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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/17/2020

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Vital Signs

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

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP50X5]
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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/1/2020 10:35
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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP50Y3]
5.b	Sample ID	[BPR83Z]
5.c	Sample ID	[BPR83L]

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
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	[BPSWPN]
5.b	Sample ID	[BRTCCD]
5.c	Sample ID	[BSHHVG]

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	WORSENING OF HYPERTENSION	Jan/19/2021 18:15	YES	Repeating Pages

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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[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)	[WORSENING OF HYPERTENSION]
4.	Start Date Time:	Jan/19/2021 18:15
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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: [WORSENING OF HYPERTENSION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
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	[2021051419]

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	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: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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Medication Error

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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Concomitant Medications

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[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?	

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	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: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	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: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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:	

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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?	

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/29/2020

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[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
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Aug-11-2020 16:20:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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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-23-2021 11:42:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Feb-05-2021 14:59:44 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Jan-26-2021 16:51:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-21-2021 16:53:30 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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:** 1118**Site Name:** (1118) United Medical Associates**Subject No:** 11181013**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

(b) (6)	N/A	Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Oct-12-2020 12:14:10 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, (b) (6) , verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
(b) (6)	N/A	Sep-29-2020 10:52:30 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Sep-17-2020 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
(b) (6)	N/A	Sep-16-2020 07:03:19 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

(b) (6)	Approved	Sep-14-2020 14:31:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-11-2020 16:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 16:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> STAGE 3 COHORTS	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-11-2020 16:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/11/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Subject ID

Date	Location	User	Value	Reason
Aug-11-2020 16:19:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11181013	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1957	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-11-2020 16:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-11-2020 16:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 16:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-11-2020 16:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/11/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-11-2020 16:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-11-2020 16:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-11-2020 16:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1.a

Date	Location	User	Value	Reason
Aug-11-2020 16:21:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History HYPOTHYROIDISM Term: DISM Start Date: Mar/21/2013 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:21:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 16:21:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPOTHYROIDISM	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:21:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/21/2013	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:21:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

I.b

Date	Location	User	Value	Reason
Aug-11-2020 16:22:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 r: Medical History HYPERTENS Term: ION Start Date: Apr/18/2008 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:22:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 16:22:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERTENSION	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:22:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/18/2008	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:22:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Aug-11-2020 16:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 3 r: Medical History HYPERLIPID Term: EMIA Start Date: May/15/2015 Ongoing: YES	Initial Entry
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 16:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERLIPIDEMIA	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/15/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/11/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 79.7	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 161.3	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.6	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Aug-11-2020 16:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 98.2 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-11-2020 16:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Aug-11-2020 16:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/11/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-11-2020 16:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-11-2020 16:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 225592	Initial Entry

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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Data Origin

Date	Location	User	Value	Reason
Aug-11-2020 16:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-11-2020 16:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-11-2020 16:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-11-2020 16:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 16:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-11-2020 16:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP50G5	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 16:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP50G5	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-11-2020 16:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP50G6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 16:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP50G6	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-11-2020 16:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP50G7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 16:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP50G7	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-11-2020 16:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPR7K4	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.d Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 16:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPR7K4	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-11-2020 16:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPR7K5	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 16:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPR7K5	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Data Origin

Date	Location	User	Value	Reason
Aug-11-2020 16:32:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-11-2020 16:32:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-11-2020 16:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-11-2020 16:32:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 16:32:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-11-2020 16:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP50F0	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 16:32:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP50F0	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020 14:23	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 16:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-11-2020 16:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 15:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Sep-01-2020 16:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last da O y the Subject Diary was com pleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FA TIG	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 06:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Closed	raised in error
Sep-11-2020 06:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Opened	e-Diary: Per eDiary records, FATIGUE is reported on Last day however the last day in Inform is entered as 'No' for the same. Please verify and update. Else, clarify.
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HE AD AC HE	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the Su bject Diary was comp leted?:	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NERD JOI NT PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PA IN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio ns present on the last day t he Subject Diary was com pleted?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 07:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site React PAIN AT I ion:: NJECTION SITE Were injection site YES reactions present o Ongoing? n the last day the S ubject Diary was co NO mpleted?: Stop D ate: Aug/ 17/20 20	Changed Information

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Sep-11-2020 11:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: YES Ongoing ?	Transcription Error
Sep-10-2020 08:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	pain at injection site for vaccination 2.
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: YES Ongoing ?	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 10:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Data Updated
Sep-16-2020 07:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Sep-16-2020 07:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/17/2020	Changed Information
Sep-16-2020 06:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	e-Diary: Form unfreeze, Please update data as per query response.
Sep-15-2020 16:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Pain is not ongoing- cannot enter end date, which was 17Aug2020 following vaccination 1.
Sep-15-2020 09:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	eDiary RQ : Per Diary records PAIN AT INJECTION SITE is not ongoing on 07-Sep-2020

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1118**Site Name:** (1118) United Medical Associates**Subject No:** 11181013**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

				which is seventh day of VAX2. Please reconcile and update stop date for PAIN AT INJECTION SITE reported on last day, 17-Aug-2020 of Vax1. Else, clarify in query response.
Sep-12-2020 03:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-11-2020 11:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-11-2020 11:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? YES	Transcription Error
Sep-11-2020 07:49:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-11-2020 06:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 2: Opened	e-Diary: Per eDiary records, PAIN AT INJECTION SITE is reported on Last day however the last day in Inform is entered as 'No' for the same. Please verify and update. Else, clarify.
Sep-10-2020 08:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	pain at injection site for vaccination 2.
Sep-10-2020 08:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	pain at injection site for vaccination 2.

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Sep-07-2020 13:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Opened	eDiary: Vaccination 2 is given for the subject, however PAIN AT INJECTION SITE associated with Vaccination 1 is still ongoing. Please review and update as appropriate. Else, clarify in query response.
Sep-01-2020 15:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? YES	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 15:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 15:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

2.a Temperature Location:

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Sep-01-2020 15:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 16:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 16:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 16:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 16:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 16:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 16:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP50X5	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 16:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP50X5	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 10:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-05-2020 10:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:29:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EOT page has been completed per query
Oct-01-2020 16:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Visit 3 was completed on 29 Sep 20 and the subject received both doses of vaccine. Per guidelines, the EOT Disposition page is also to be completed at Visit 3. It is currently BLANK. Please review and update EOT Disposition.
Sep-29-2020 10:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FA TIG	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
--	--	--	---	--

2.b Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.c Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WORSE ED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the Su bject Diary was comp leted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENERD MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.h

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 10:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 10:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 10:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-30-2020 07:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-30-2020 04:28:44 (UTC-05:00) Eastern 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-29-2020 10:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 10:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/29/2020	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a

Date	Location	User	Value	Reason
Sep-30-2020 07:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP50Y3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 07:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP50Y3	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 07:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPR83Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 07:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPR83Z	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 07:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPR83L	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 15:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_06
Oct-01-2020 05:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4858124;The Barcode BPR83L is recorded for two subjects 11181004 and 11181013, Please review and update as appropriate.
Sep-30-2020 07:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BPR8 3L	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 11:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/23/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 11:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 11:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 14:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 11:42:43 (UTC-05:00) Eastern 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.
Feb-23-2021 11:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 14:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSWPN	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 14:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPSWPN	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-23-2021 14:18:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRTCCD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 14:18:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRTCCD	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-23-2021 14:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSHHVG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 14:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHHVG	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-02-2020 15:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-02-2020 15:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-02-2020 15:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern 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
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WORSENING OF HYPERTENSI ON	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 18:15	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 11:09

Time (US & Canada)

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

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
Jan-21-2021 04:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE WORSENING OF HYPERTENSION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require o r prolong hospitalization? YES Did this serious event result in persistent or significant disabili ty/incapacity?	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

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			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.

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: WORSENING OF HYPERTENSION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Jan-20-2021 17:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-01-2021 04:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021 12:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	follow up report was submitted
Feb-25-2021 21:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021051419 ,outcome was updated to RECOVERING/RESOLVING on AE CRF while reported as Not Recovered/Not Resolved in Safety database.Please confirm outcome.If safety update is required,please submit a ffup SAE form
Feb-24-2021 15:57:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVI NG	New Information
Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1118) United Medical Associates

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Generated Time (GMT): 29-Mar-2021 11:09

Jan-20-2021 17:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-21-2021 04:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021051419	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-26-2021 16:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-26-2021 16:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1118

Subject No: 11181013

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1118) United Medical Associates

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-26-2021 16:51:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-26-2021 16:51:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Subject Status

Date	Location	User	Value	Reason
Oct-02-2020 15:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-11-2020 16:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-11-2020 16:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-02-2020 15:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/29/2020	Initial Entry
Aug-11-2020 16:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/11/2020	Initial Entry
Aug-11-2020 16:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/11/2020	Initial Entry

090177e196ae40c4\Final\Final On: 01-Apr-2021 05:43 (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: 1118

Site Name: (1118) United Medical Associates

Subject No: 11181013

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-12-2020 07:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry