

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/4/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11161131]
2.	Birth Date:	(b) (6)/1955
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:	

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/4/2020
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: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High Cholesterol]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Heart Palpitations]
	Start Date:	Sep/4/2018
	Ongoing:	YES

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/4/2020
2.	Weight:	[135.1]
3.	Unit:	LB
4.	Height:	[61.0]
5.	Unit:	in
6.	Body Mass Index:	[25.5]

Vital Signs Details

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/4/2020
2.	Randomization Number:	[253146]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN65BH]
5.b	Sample ID	[BN65BJ]
5.c	Sample ID	[BLBFG5]
5.d	Sample ID	[BLBFG6]

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN65NT]
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/4/2020 14:40
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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/23/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/23/2020
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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BP41FN]
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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/23/2020 15:44
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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
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	[BNNRSF]
5.b	Sample ID	[BNNRSG]
5.c	Sample ID	[BP4106]
5.d	Sample ID	[BP4107]

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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:	[]
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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?	
----	--	--

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** DATE OF VISIT
Sep/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** UNPLANNED VISIT
Sep/17/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** CONTACT OUTCOME - UNPLANNED
Sep/17/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Sep/17/2020 Contact Outcome: VISIT ARRANGED
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** VITAL SIGNS - TEMP
Sep/17/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/17/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on **Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT
Sep/17/2020**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[eCRF Audit Trail History](#)**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Sep/17/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

Reaction

4.a	Reaction:	REDNESS
	Reaction Present:	NO
4.b	Reaction:	SWELLING
	Reaction Present:	NO

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	YES
		Symptom Grade: 2 Event related to Study Treatment? YES
5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO
5.c	Symptom:	HEADACHE
	Symptom Present:	NO

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 **Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 15-Sep-2020 21:51 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1116 **Site Name:** (1116) MedPharmics, LLC

Subject No: 11161131 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Symptom Present:	YES Symptom Grade: 2 Event related to Study Treatment? YES
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN
	Symptom Present:	NO
5.h	Symptom:	CHILLS
	Symptom Present:	NO

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/21/2020
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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Disposition - Follow-Up

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

Header Text: c4591001

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

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

Site No: 1116 **Site Name:** (1116) MedPharmics, LLC

Subject No: 11161131 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left Axillary swollen lymph node	Sep/10/2020 00:00	NO End Date Time: Sep/14/2020 00:00	Repeating Pages
2.	ADVERSE EVENT	2	Muscle Pain @ injection site	Sep/10/2020 00:00	NO End Date Time: Sep/14/2020 00:00	Repeating Pages
3.	ADVERSE EVENT	3	Generalized Muscle Pain	Sep/10/2020 UNK:UNK	NO End Date Time: Sep/14/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Muscle Pain @ Chest Wall to Upper Back	Sep/10/2020 UNK:UNK	NO End Date Time: Sep/14/2020 UNK:UNK	Repeating Pages

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Axillary swollen lymph node]
4.	Start Date Time:	Sep/10/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 00:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle Pain @ injection site]
4.	Start Date Time:	Sep/10/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 00:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Generalized Muscle Pain]
4.	Start Date Time:	Sep/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle Pain @ Chest Wall to Upper Back]
4.	Start Date Time:	Sep/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	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: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Medication Error

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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:	//

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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:	

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/21/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Paul Matherne	Approved	Mar-04-2021 15:22:54 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Item	Date	User	Comment
Form	Sep-04-2020 16:33:38 (UTC-06:00) Central 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, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Paul Matherne	Approved	Mar-04-2021 15:22:54 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-23-2021 12:35:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Paul Matherne	Approved	Nov-13-2020 19:54:31 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, PaulMatherne, 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.

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(b) (6)	N/A	Nov-11-2020 15:26:54 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Paul Matherne	Approved	Nov-05-2020 16:46:12 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, PaulMatherne, 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.

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-04-2020 16:32:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:32:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-04-2020 16:32:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/4/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Subject ID

Date	Location	User	Value	Reason
Sep-04-2020 16:32:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11161131	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-04-2020 16:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-04-2020 16:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-04-2020 16:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LA TINO(A) OR OF SPANI SH ORIGIN	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Sep-04-2020 16:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-04-2020 16:33:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-04-2020 16:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-04-2020 16:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-04-2020 16:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I.a

Date	Location	User	Value	Reason
Sep-04-2020 16:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Initial Entry Hypertension on UNK/UNK/2018 YES

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 16:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Sep-04-2020 16:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry
--	-----------------	---------------------	------------------------------------	---------------

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 16:34:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-04-2020 16:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical History Term: High Chol esterol Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 16:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: High Cholesterol	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 16:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 16:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Sep-04-2020 16:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Heart Palpitations Start Date: Sep/4/2018 Ongoing: YES	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 16:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Heart Palpitations	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 16:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 16:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 135.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 61.0	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Canada)

5. Unit:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Ident 1 ifier:: Temperature 97.8 : Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

7.a Record Identifier:

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

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

17:00:32 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	1	
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7.a Temperature:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-De 113 fined Identi fier: Test:: Choriogonado tropin Beta_P X113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Bet a_PX113	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Central Time (US & Canada)				
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6.a Not Done:

Date	Location	User	Value	Reason
Sep-04-2020 17:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-04-2020 17:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-04-2020 17:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 253146	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Sep-04-2020 17:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-04-2020 17:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-04-2020 17:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-04-2020 17:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Sep-04-2020 17:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/4/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-04-2020 17:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: Sample ID: BN65BH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 17:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: BN65BH	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-04-2020 17:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: Sample ID: BN65BJ	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 17:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: BN65BJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-04-2020 17:59:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: Sample ID: BLBFG5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 17:59:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: BLBFG5	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-04-2020 17:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: Sample ID: BLBFG6	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 17:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: BLBFG6	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Sep-04-2020 17:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-04-2020 17:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-04-2020 17:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-04-2020 17:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Sep-04-2020 17:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/4/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-04-2020 17:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: Sample ID: BN65NT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 17:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Heather Lambert (b) (4)	Data Entry: BN65NT	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020 14:40	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Sep-04-2020 17:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-04-2020 17:03:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICI TY E-DIARY NOT CO LLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 05:49:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Per site confirmation Not COVID ILLNESS
Oct-13-2020 09:53:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject was brought in for an unplanned visit, but it did not meet criteria for Covid illness visit
Oct-01-2020 15:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 17SEP2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-30-2020 06:18:35	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)				
Sep-29-2020 13:13:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-29-2020 13:13:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry
Sep-29-2020 08:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Sep-29-2020 13:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 13:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Ident 1 ifier:: Temperature 97.3 : Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 13:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Sep-29-2020 13:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.3	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Sep-29-2020 13:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-29-2020 13:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-De 113 fined Identi fier: Test:: Choriogonado tropin Beta_P X113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta _PX113	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Time (US & Canada)				
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6.a Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 13:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-01-2020 10:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-30-2020 03:28:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Sep-29-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 13:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 10:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP41FN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP41FN	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 15:44	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Sep-29-2020 13:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: 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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-27-2020 06:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 13:23:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EOT does match V3 Date. Please clarify if further action is required
Oct-24-2020 10:25:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Hence, please complete treatment disposition CRF and update date of EOT to match the date the Visit 3.
Oct-22-2020 08:47:18 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Central Time (US & Canada)				
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 08:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-24-2020 09:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Closed	Query raised in hidden items
Oct-24-2020 04:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Hence, please complete treatment disposition CRF and update date of EOT to match the date the Visit 3.

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Oct-22-2020 08:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry
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3. Sample Collected?

Date	Location	User	Value	Reason
Oct-22-2020 10:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 08:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 08:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 10:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNNRSF	Initial Entry

5.a Sample ID

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-22-2020 10:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNNRSF	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 10:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNNRSG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 10:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNNRSG	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 10:46:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP4106	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 10:46:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP4106	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-22-2020 10:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP4107	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 10:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP4107	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** DATE OF VISIT - eCRF Audit Trail History
Sep/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 12:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/17/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** UNPLANNED VISIT - eCRF Audit Trail History
Sep/17/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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I. Assessments

Date	Location	User	Value	Reason
Sep-30-2020 12:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 12:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-30-2020 12:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOM E	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit
Sep/17/2020 Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Contact Type:

Date	Location	User	Value	Reason
Sep-30-2020 12:31:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-30-2020 12:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-30-2020 12:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Sep/17/2020 Contact Outcome: VISIT ARRANGE D	Transcription Error
Sep-30-2020 12:31:55	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Contact Outcome' is selected as

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 **Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)				'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Sep-30-2020 12:31:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Sep-30-2020 12:31:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Contact Outcome: VISIT ARRANGE D	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History
Sep/17/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date:

Date	Location	User	Value	Reason
Sep-30-2020 12:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-30-2020 12:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature 98.7 : Temperature Unit: Temperature Location: ORAL C AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-30-2020 12:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History
Sep/17/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Sep-30-2020 12:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-30-2020 12:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-30-2020 12:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History
Sep/17/2020

Form Version: 15-Sep-2020 21:51 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1116 **Site Name:** (1116) MedPharmics, LLC

Subject No: 11161131 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

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1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/17/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

4.a

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNE SS	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 **Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1116 **Site Name:** (1116) MedPharmics, LLC

Subject No: 11161131 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Canada)			Reaction Present: NO	
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4.a Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction: SWELLING Reaction Present: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116 Site Name: (1116) MedPharmics, LLC

Subject No: 11161131 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

4.b Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympto PAIN AT INJE m:: CTION SITE Sympto YES m Prese Symptom Gr nt:: ade: 2 Event related to Study Trea ment? YES	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116 Site Name: (1116) MedPharmics, LLC

Subject No: 11161131 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

5.a Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 2 Event related to Study Treatment? YES	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom FATIGUE/T :: IREDNESS Symptom NO Present::	Initial Entry
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom FATIGUE/T :: IREDNESS	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116 Site Name: (1116) MedPharmics, LLC

Subject No: 11161131 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

			Symptom Present::	
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5.b Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE Symptom Present:: NO	Initial Entry
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE Symptom Present::	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116 Site Name: (1116) MedPharmics, LLC

Subject No: 11161131 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

5.c Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITI NG Symptom Pr esent:: NO	Initial Entry
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITI NG Symptom Pr esent::	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 **Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1116 **Site Name:** (1116) MedPharmics, LLC

Subject No: 11161131 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

5.d Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARR HEA Symptom Present:: NO	Initial Entry
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARR HEA Symptom Present::	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116 Site Name: (1116) MedPharmics, LLC

Subject No: 11161131 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

5.e Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSE SENED MUSCLE PAIN Symptom Present: YES Symptom Grade: 2 Event related to Study Treatment? YES	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116 Site Name: (1116) MedPharmics, LLC

Subject No: 11161131 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

5.f Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCLE PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 2 Event related to Study Treatment? YES	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSENER JOINT PAIN Symptom Present: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116 Site Name: (1116) MedPharmics, LLC

Subject No: 11161131 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

5.g Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CHIL LS Symptom Pres ent:: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/17/2020 **Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1116 **Site Name:** (1116) MedPharmics, LLC

Subject No: 11161131 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

5.h Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Sep-30-2020 12:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-26-2020 13:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-26-2020 13:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-26-2020 13:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category:

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left Axillary swollen lymph node	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 00:00	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 16:57:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-12-2020 16:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/14/2020 00:00	New Information
Oct-12-2020 14:35:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please determine if this Adverse Event is still ONGOING. Please update or clarify.
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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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
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-15-2020 05:12:22 (UTC-06:00)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	closed per site response

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Central Time (US & Canada)				
Oct-14-2020 18:23:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI, timing and proximity to injection site suggest a causal relationship to administered vaccine. Assessed as likely a local reaction.
Oct-01-2020 15:02:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Per protocol investigator's causality assessment is the determination of whether there is a reasonable possibility that IP caused or contributed to AE. Please kindly provide the evidence/arguments to suggest a causal relationship?
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

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Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 16:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-12-2020 16:06:50	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RE	New Information

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	SOLVED	
Oct-12-2020 16:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Left Axillary swollen lymph node: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/R ESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 12:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-02-2020 16:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-02-2020 15:26:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-02-2020 15:26:04 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle Pain @ injecti on site	Changed Information

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Central Time (US & Canada)				
Oct-23-2020 14:07:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: This AE needs to be split into two Adverse Event Records to match the Unplanned Assessment of Local Reactions. Please update to include both PAIN AT INJECTION SITE and NEW OR WORSENERED MUSCLE PAIN. Thank you.
Oct-23-2020 11:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: This AE needs to be split into two Adverse Event Records to match the Unplanned Assessment of Local Reactions. Please update to include both PAIN AT INJECTION SITE and NEW OR WORSENERED MUSCLE PAIN. Thank you.

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Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle pain extending from injection site to chest wall and upper back	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-12-2020 16:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/14/2020 00:00	New Information
Oct-12-2020 14:36:04	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please determine

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Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)				if this Adverse Event is still ONGOING. Please update or clarify.
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

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Generated By: (b) (4)

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If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 16:07:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-12-2020 16:07:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Oct-12-2020 16:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Muscle pain extending from injection site to chest wall and upper back: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-30-2020 13:05:20 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Not Complete

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

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Central Time (US & Canada)

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

Date	Location	User	Value	Reason
Sep-30-2020 13:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-12-2020 19:11:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-12-2020 15:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Locked, Frozen**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Nov-12-2020 11:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: An swere d	Transcription Error
Nov-12-2020 11:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swere d	Transcription Error
Nov-12-2020 11:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Gener alized Muscl e Pain	Transcription Error
Nov-12-2020 05:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Clo sed	Response satisfies query
Nov-12-2020 04:27:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	DM: A trailing or leading space is identified. To avoid processing errors, please remove the identified character by

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				deleting the entry and re-entering the data (without using copy and paste).
Nov-12-2020 04:27:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	New query raised
Nov-12-2020 04:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: A trailing or trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Nov-12-2020 01:13:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Spacing: Verbatim Term contains leading, trailing or

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				more than one consecutive space.
Nov-11-2020 15:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 15:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Generalized Muscle Pain	Transcription Error
Nov-07-2020 15:34:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Reissued: Opened	GPD Clin: page unlocked, please update AE term accordingly. Thanks
Nov-06-2020 13:31:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please Unlock to change answer
Nov-06-2020 08:34:40 (UTC-06:00) Central Time	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Reissued: Open	GPD Clin: if participant experienced generalized

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(US & Canada)			ed	muscle pain, please update AE term to "generalized muscle pain". If it was local, please update AE term to specify anatomic location (example: neck muscle pain, low back muscle pain). Thanks
Nov-05-2020 16:30:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please provide option to update and answer to clarify query
Nov-05-2020 06:26:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: can you please confirm this is or is not generalized muscle pain? If yes - please update verbatim,

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Header Text: c4591001

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Generated By: (b) (4)

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				otherwise clarify in query response. Thank you
Nov-04-2020 14:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Candidate	GPD Clin: can you please confirm this is or is not generalized muscle pain? If yes - please update verbatim, otherwise clarify in query response. Thank you
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Muscle Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 UNK:UNK	Initial Entry

Header Text: c4591001

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/14/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1116

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Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category:

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle Pain @ Chest Wall to Upper Back	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 UNK:UNK	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time: Sep/14/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 12:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Feb-25-2021 11:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 11:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-25-2021 11:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to r eturn for Vaccination 3 Participant is: eligible and NOT con firmed to have receiv ed only placebo at Va ccination 1/2	Transcription Error
Feb-23-2021 12:35:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willi ng to return for Vaccinat ion 3 OR otherwise not eligible	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-25-2021 11:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-25-2021 11:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY F OR ADDITIONAL VAC CINATION	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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1. Subject Status

Date	Location	User	Value	Reason
Oct-26-2020 13:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-04-2020 17:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZ ED	Initial Entry
Sep-04-2020 16:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-26-2020 13:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/21/2020	Initial Entry
Sep-04-2020 17:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/4/2020	Initial Entry
Sep-04-2020 16:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/4/2020	Initial Entry

090177e196ae3f2b\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161131

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail
History

Form Status: Data Complete, Signed, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-05-2020 16:28:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry