

**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:** 11161059

**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

**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:** 11161059

**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 Aug/31/2020
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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:** 11161059                         **Subject Initials:** ---  
**Generated By:** (b) (4)                           **Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Demography		
1.	Subject ID	[11161059]
2.	Birth Date:	(b) (6)/1999
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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	Aug/31/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1116

**Subject No:** 11161059

**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:** DISPOSITION - SCREENING

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL 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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Abdominal Pain undiagonised origin]
	Start Date:	Aug/UNK/2019
	Ongoing:	NO End Date: Sep/19/2020
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

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**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/31/2020
2.	Weight:	[201.8]
3.	Unit:	LB
4.	Height:	[59.5]
5.	Unit:	in
6.	Body Mass Index:	[40.1]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_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:** 11161059

**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:	Aug/31/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** RANDOMIZATION

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[75043]
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:** 11161059

**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: Aug/31/2020
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	[BN65X6]
5.b	Sample ID	[BN65X7]
5.c	Sample ID	[BN65X8]
5.d	Sample ID	[BL9RBF]
5.e	Sample ID	[BL9RBG]
5.f	Sample ID	[BL9RBH]
5.g	Sample ID	[BL9RBJ]

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**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:** 11161059

**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: Aug/31/2020
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	[BN65LJ]
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1116

**Subject No:** 11161059

**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:	Aug/31/2020 11:54
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1116

**Subject No:** 11161059

**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:** 11161059

**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/22/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/22/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.8]
	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:** 11161059

**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/22/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3f2c\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:** 11161059

**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/22/2020
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	[BP41DK]
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090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_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:** 11161059

**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/22/2020 14:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3f2c\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:** 11161059

**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/20/2020
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	<b>Form:</b> ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
<b>Visit:</b> V3_MONTH1_POSTVAX2_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1116) MedPharmics, LLC
<b>Site No:</b> 1116	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11161059	<b>Generated Time (GMT):</b> 29-Mar-2021 10:58
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
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	[BNNRR2]
5.b	Sample ID	[BNNRR3]
5.c	Sample ID	[BP40Z1]
5.d	Sample ID	[BP40Z0]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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:** 11161059

**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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090177e196ae3f2c\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:** 11161059

**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:** 11161059

**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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090177e196ae3f2c\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:** 11161059

**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:** 11161059

**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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090177e196ae3f2c\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:** 11161059

**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\_ILL - New  
Unscheduled Visit

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

**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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090177e196ae3f2c\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:** 11161059

**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	[ ]
----	-----------	-----

090177e196ae3f2c\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:** 11161059

**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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090177e196ae3f2c\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:** 11161059

**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?	
----	--	--

090177e196ae3f2c\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:** 11161059

**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:** 11161059

**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:** 11161059

**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	[ ]
----	-----------	-----

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Not Started

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**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 - New Unscheduled Visit **Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/20/2020
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:** 11161059

**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 -  
New Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**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:** 11161059

**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	[ ]
----	-----------	-----

090177e196ae3f2c\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: 11161059

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	Gall Stone Pancreatitis	Sep/13/2020 UNK:UNK	NO End Date Time:  Sep/18/2020 U NK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Cholelithiasis	Sep/13/2020 19:00	NO End Date Time:  Sep/19/2020 01: 01	<a href="#">Repeating Pages</a>
3. DELETED						<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	unprotected, heterosexual intercourse	Nov/23/2020 UNK:UNK	NO End Date Time:  Nov/23/2020 22: 00	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	maternal exposure before pregnancy	Nov/9/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Gall Stone Pancreatitis]
4.	Start Date Time:	Sep/13/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Undiagnosed preexisting condition]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	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	[2020363544]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cholecholithiasis]
4.	Start Date Time:	Sep/13/2020 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/19/2020 01:01
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Patient had underlying, undiagnosed condition]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	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	[2020363544]

090177e196ae3f2c\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:** 11161059

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Incomplete, Data Complete, Deleted

**Site Name:** (1116) MedPharmics, LLC

**Subject Initials:** ---

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

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

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**Adverse Event Report**

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Incomplete, Data Complete, Deleted

**Site Name:** (1116) MedPharmics, LLC

**Subject Initials:** ---

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

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

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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
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:** 11161059

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, 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)	[unprotected, heterosexual intercourse]
4.	Start Date Time:	Nov/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/23/2020 22:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unprotected, heterosexual intercourse]
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 WITH SEQUELAE
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:** 11161059

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data 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:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[maternal exposure before pregnancy]
4.	Start Date Time:	Nov/9/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unprotected heterosexual intercourse]
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?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3f2c\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:** 11161059

**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.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1116

**Subject No:** 11161059

**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:** 11161059

**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.						<a href="#">Repeating Pages</a>

**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:** 11161059

**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:	//

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**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:** 11161059

**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.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1116

**Subject No:** 11161059

**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.	<p>Medication:</p> <p>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).</p>	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

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**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:** 11161059

**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.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae3f2c\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:** 11161059

**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

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**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:** 11161059

**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:** 11161059

**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:	

090177e196ae3f2c\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:** 11161059

**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?	

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**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:** 11161059

**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:** 11161059

**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:** 11161059

**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:** 11161059

**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	[ ]
----	-----------	-----

090177e196ae3f2c\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:** 11161059

**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	[ ]
----	-----------	-----

090177e196ae3f2c\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:** 11161059

**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	Feb/23/2021
2.	Erroneous Visit	

090177e196ae3f2c\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:** 11161059

**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/23/2021
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:** 11161059

**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:** 11161059

**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:** 11161059

**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/20/2020

**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:** 11161059

**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:** 11161059

**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 14:18:36 (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.

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1116

**Subject No:** 11161059

**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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 19:04:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1116) MedPharmics, LLC

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-01-2020 09:59:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Aug-31-2020 19:04:45 (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:** 11161059

**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 14:18:36 (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-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

**Affidavit:**

N/A

Paul Matherne	Approved	Oct-27-2020 13:36:21 (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.

090177e196ae3f2c\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:** 11161059

**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
Aug-31-2020 19:03:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 19:03:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Consent Was:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-31-2020 19:03:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent O btained  Aug/31/2020	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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-31-2020 19:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11161059	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-31-2020 19:02:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1999	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-31-2020 19:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-31-2020 19:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LA TINO(A) OR OF SPANI SH ORIGIN	Initial Entry

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

090177e196ae3f2c\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:** 11161059

**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

Date	Location	User	Value	Reason
Aug-31-2020 19:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRICAN AMERICAN	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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
Aug-31-2020 19:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	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:** 11161059

**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
Aug-31-2020 19:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-31-2020 19:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-31-2020 19:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f2c\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:** 11161059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Oct-01-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical</b> Abdominal Pain <b>History T</b> undiagonised ori <b>erm:</b> gin <b>Start Dat</b> Aug/UNK/2019 <b>e:</b> <b>Ongoing:</b> NO End Date: Sep/19/2020	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-01-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Abdominal Pain undiagno nised origin	Initial Entry

*I.a Start Date:*

**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Oct-01-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/UNK/2019	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Oct-01-2020 10:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Sep/19/2020	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Oct-01-2020 10:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 2</b> <b>ber:</b> <b>Medical Histor</b> Obesity <b>y Term:</b> <b>Start Date:</b> UNK/UN K/2019 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Oct-01-2020 10:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 10:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Obesity	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Oct-01-2020 10:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Oct-01-2020 10:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - 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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 201.8	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 59.5	Initial Entry

090177e196ae3f2c\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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 40.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature 97.2</b> <b>:</b> <b>Temperature F</b> <b>Unit:</b> <b>Temperature ORAL C</b> <b>Location:: AVITY</b>	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Canada)				
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**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f2c\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:** 11161059

**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
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

090177e196ae3f2c\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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-De</b> 113 <b>fined Identi</b> <b>fier:</b> <b>Test::</b> Choriogonado tropin Beta_P X113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta _PX113	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**6.a Result:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-31-2020 19:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** RANDOMIZATION - 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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-31-2020 19:06:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-31-2020 19:06:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 75043	Initial Entry

090177e196ae3f2c\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:** 11161059

**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
Aug-31-2020 19:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 19:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 19:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

19:06:36 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	YES Date of Collection:  Aug/31/2020	
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**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN65X6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN65X6	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN65X7	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN65X7	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN65X8	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN65X8	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-31-2020 19:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9RBF	Initial Entry

090177e196ae3f2c\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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 19:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9RBF	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-31-2020 19:53:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9RBG	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 19:53:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9RBG	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-31-2020 19:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9RBH	Initial Entry

090177e196ae3f2c\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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 19:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9RBH	Initial Entry

5.g

Date	Location	User	Value	Reason
Aug-31-2020 19:54:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9RBJ	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 19:54:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9RBJ	Initial Entry

090177e196ae3f2c\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:** 11161059

**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
Aug-31-2020 19:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 19:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 19:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 19:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f2c\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:** 11161059 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

19:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	YES Date of Collection:  Aug/31/2020
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**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 19:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN65LJ	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 19:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN65LJ	Initial Entry

090177e196ae3f2c\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: 11161059

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020 11:54	Initial Entry

**5. Anatomical Location:**

090177e196ae3f2c\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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 19:07:21	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f2c\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:** 11161059

**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

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

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - 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. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-31-2020 19:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICIT Y E-DIARY NOT COLL ECTED FOR THIS SUB JECT	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: 11161059

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
Oct-22-2020 02:36:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation- not indicative of possible COVID 19
Oct-21-2020 16:24:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Participant was contacted, investigator consulted, clinical picture not indicative of possible COVID 19.
Oct-14-2020 10:49:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness ed diary: 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 06OCT2020. But corresponding COVID Illness visit not reported. Please clarify.
Sep-22-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**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

18:42:15  
(UTC-06:00)  
Central Time (US &  
Canada)

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

Sep/22/2020



**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:** 11161059

**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-22-2020 18:42:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature</b> 97.8 : <b>Temperature</b> F <b>Unit:</b> <b>Temperature</b> ORAL C <b>Location::</b> AVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
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090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - 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-22-2020 18:42:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.8	Initial Entry
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**2.a Unit:**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f2c\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:** 11161059

**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-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-23-2020 18:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 18:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Transcription Error
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date 21/Sep/2020 is not the same as the Date of Visit 22/Sep/2020. Please correct or

090177e196ae3f2c\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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

				confirm.
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonado tropin Beta_P X113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

**6.a Sponsor ID:**

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta _PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f2c\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:** 11161059

**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-22-2020 18:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-22-2020 18:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-23-2020 18:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 05:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 18:42:53 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no

090177e196ae3f2c\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:** 11161059 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Central Time (US & Canada)				barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 18:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-23-2020 18:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP41DK	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-23-2020 18:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP41DK	Initial Entry

090177e196ae3f2c\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: 11161059

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-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020 14:40	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
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090177e196ae3f2c\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: 11161059

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-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**6. Body Side:**

Date	Location	User	Value	Reason
Sep-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 18:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-27-2020 06:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Oct-26-2020 12:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-24-2020 10:28:36 (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-20-2020 16:35:08 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Central Time (US & Canada)				
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090177e196ae3f2c\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:** 11161059

**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-20-2020 16:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-24-2020 09:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Closed	Query raised in hidden items
Oct-24-2020 04:22:09 (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-20-2020 16:35:19	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

(UTC-06:00) Central Time (US & Canada)				
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**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 12:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-21-2020 05:22:55 (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.
Oct-20-2020 16:35:19 (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-20-2020 16:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Oct-21-2020 12:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNNRR2	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 12:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNNRR2	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-21-2020 12:18:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNNRR3	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 12:18:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNNRR3	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-21-2020 12:19:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP40Z1	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 12:19:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP40Z1	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Oct-21-2020 12:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP40Z0	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 12:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP40Z0	Initial Entry

090177e196ae3f2c\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:** 11161059

**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 12:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-26-2020 12:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-26-2020 12:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Date	Location	User	Value	Reason
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

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Date	Location	User	Value	Reason
Feb-24-2021 14:58:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f2c\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:** 11161059

**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
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (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

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161059

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-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-02-2020 13:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-01-2020 10:01:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Oct-01-2020 08:31:47 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Open	ClinQuery - based on this event of cholelithiasis in a young woman, please review and consider recording obesity (BMI 40.1) in the past medical history

090177e196ae3f2c\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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)			ed	
Sep-30-2020 04:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Sep-30-2020 04:53:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	event recorded in AE CRF
Sep-29-2020 14:42:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Sep-29-2020 14:42:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Sep-29-2020 14:42:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Gall Stone Pancreatitis	New Information
Sep-29-2020 14:42:01	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: An	SAE update was submitted on 29SEP2020

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**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)	swere d	
Sep-25-2020 06:04:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Op ened	SAE RECON:AER#2020363544 Cholelithiasis(onset date:13Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-25-2020 06:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	SAE RECON: AER#2020363544,the term was updated to 'Gall stone Pancreatitis' in Safety database while retained as 'Gall Stones' in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form.
Sep-25-2020 05:57:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Event terms updated in SDB, Pancreatitis no longer listed. New query issued for new event issues.
Sep-25-2020 05:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Event terms updated in SDB, Hepatitis no longer listed. New query issued for new event issues.
Sep-22-2020 14:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Op ened	ClinQuery - based on this event of cholelithiasis in a young woman, please review and consider recording obesity (BMI 40.1) in the past medical history

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

Sep-21-2020 04:54:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020363544 PANCREATITIS(onset date:14Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-21-2020 04:54:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020363544Hepatitis(onset date:14Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Gall Stones	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 04:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-29-2020 14:42:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-29-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	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**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

14:42:46 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Sep/13/2020 UNK:UNK	
Sep-25-2020 06:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020363544
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-05-2020 11:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 10:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The pancreatitis was resolved by the first procedure in the hospital. The Overall event was not resolved until a second procedure was completed.
Sep-30-2020 15:34:10	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL The SAE end date

**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:** 11161059**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)		for gall stone pancreatitis is Sep 15 at 00:00; however the AE end date is Sep 18. Please review and update as required.
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/18/2020 UNK:U NK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Sep-21-2020 04:39:25 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event entered in SDB

**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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Central Time (US & Canada)				
Sep-20-2020 09:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:Gall Stones(Onset date:14Sep2020) is not reported on SAE Report Form but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Gall Stones: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1116) MedPharmics, LLC

**Subject Initials:** ---

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

			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

**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-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
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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: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Undiagnosed preexisting condition	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-18-2020 17:58:15 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Sep-25-2020 05:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	outcome updated in SDB. issue resolved
Sep-21-2020 04:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#11161059,outcome was reported as RECOVERING/RESOLVING to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 17:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f2c\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:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Sep-21-2020 04:39:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020363544	Initial Entry



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-02-2020 13:58:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 13:57:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-01-2020 10:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query

090177e196ae3f2c\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:** 11161059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Oct-01-2020 10:05:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Sep-30-2020 15:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE information reports a past medical History of Abdominal Pain since Aug 2019; as relevant history to this SAE consider addition of this condition to Past Med History CRF
Sep-30-2020 15:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL On review of the SAE report, an event of sinus arrhythmia was noted, yet does not appear in the CRF. Please review for safety and update AE log CRF accordingly.
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cholelithiasis	Initial Entry

**4. Start Date Time:**

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Form Status: Data Complete, Locked, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/13/2020 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/19/2020 01:01	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-30-2020 04:51:05	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen  
**Site No:** 1116 **Site Name:** (1116) MedPharmics, LLC  
**Subject No:** 11161059 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)				
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Cholelithiasis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with cong enital anomaly or bir th defect?  NO  Did this serious eve nt result in death?  NO  Did this serious eve nt require or prolong hospitalization?  YES  Did this serious eve nt result in persisten t or significant disab ility/incapacity?  NO	Initial Entry

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			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

**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-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Patient had underlying, undiagnosed condition	Initial Entry

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**Site No:** 1116

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**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLV ED	Initial Entry

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**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

Date	Location	User	Value	Reason
Sep-29-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Sep-30-2020 04:51:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020363544	Initial Entry

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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:** Incomplete, Data Complete, Deleted**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-24-2021 14:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-24-2021 14:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-24-2021 14:58:16 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information



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Site Name: (1116) MedPharmics, LLC

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Canada)				
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sinus Arythima	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 14:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 14:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-26-2020 13:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Oct-26-2020 12:06:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Yes the event is ongoing
Oct-26-2020 10:29:54 (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 confirm.
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-24-2021 14:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

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**Subject No:** 11161059

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**Generated By:** (b) (4)

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

*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
Feb-24-2021 14:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Oct-01-2020 10:04:45 (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
Feb-24-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

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Date	Location	User	Value	Reason
Feb-24-2021 14:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  This was likely the re before and just undiagnosed	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-24-2021 14:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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**Subject Initials:** ---

**Generated By:** (b) (4)

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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-24-2021 14:57:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-24-2021 14:57:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 14:57:52 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information

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Central Time (US & Canada)				
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/N OT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 14:58:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-01-2020 10:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-13-2021 07:52:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Feb-12-2021 14:14:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	closed based on site's response
Feb-10-2021 14:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Ae of maternal exposure before pregnancy will be added as an AE.

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**Generated By:** (b) (4)

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Feb-10-2021 07:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	CLINICAL_ Per safety report (AER# 2021113072), the additional SAE of Exposure during pregnancy has been reported to safety. Pls revise and update AElog accordingly. Thanks
Feb-05-2021 16:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SEXUAL RELATIONSHIP WITH HIV POSITIVE MALE IS UNKNOWN WILL CONTACT PATIENT TO OBTAIN THIS INFORMATION.
Feb-05-2021 06:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Can you please confirm if this is or isn't risky sexual relationship (unprotected) with an HIV positive male? Thanks
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> unprotected, heterosexual intercourse	Initial Entry

**4. Start Date Time:**

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Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/23/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-25-2021 08:43:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 14:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-24-2021 14:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/23/2020 22:00	Changed Information
Feb-16-2021 07:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please confirm this AE should have an END Date the same as the START Date and update the data. Otherwise, provide clarification.

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**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-04-2021 15:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Feb-10-2021 14:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-10-2021 14:16:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 14:16:57 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed info per crf guidelines

090177e196ae3f2c\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, Frozen

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Central Time (US & Canada)				
Feb-09-2021 02:45:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-08-2021 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Feb-08-2021 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Feb-08-2021 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious event require or prolong hospitalization?  NO	Transcription Error

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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1116  
**Subject No:** 11161059  
**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1116) MedPharmics, LLC  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Feb-05-2021 12:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: unprotected, heterosexual intercourse is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Feb-05-2021 01:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Only the seriousness criteria "Other medically

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**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Canada)				important serious event" is answered, all other serious criteria's are left blank. Please answer all seriousness criteria questions with "Yes" or "No" response. Thank you.
Feb-04-2021 15:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	it is a medically important serious event; pregnancy
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE unprotected, heterosexual intercourse: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is

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Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1116

Site Name: (1116) MedPharmics, LLC

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Generated By: (b) (4)

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				blank.
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Other medically important serious event  YES	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-04-2021 15:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unprotected, heterosexual intercourse	New Information
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

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Generated By: (b) (4)

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			e to:	
			OTHER	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 14:44:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Feb-24-2021 14:44:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED WITH SEQUELAE	Changed Information
Feb-24-2021 14:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE unprotected, heterosexual intercourse: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-04-2021 22:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 15:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject is currently 12 weeks pregnant, outcome is unknown
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE unprotected, heterosexual intercourse: Response to "What was the

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**Visit:** Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen  
**Site No:** 1116 **Site Name:** (1116) MedPharmics, LLC  
**Subject No:** 11161059 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

				outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 15:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

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**Generated By:** (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> maternal exposure before pregnancy	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-04-2021 14:51:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Mar-01-2021 11:40:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020 UNK:UNK	Changed Information

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

(UTC-06:00) Central Time (US & Canada)				
Mar-01-2021 11:39:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Onset date updated on SAE form and faxed in
Feb-25-2021 17:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Open ed	If the date of 09Nov2020 is accurate, the start date of this SAE should be updated based on the CRF CG 8.50.2.5.
Feb-24-2021 14:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per subject this date is correct
Feb-16-2021 18:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Open ed	Per report, "First day of last menstrual period was on 09Nov2020," Pls clarify
Feb-13-2021 14:09:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	date of onset was determined by date of last menstrual period per subject
Feb-10-2021 15:41:28 (UTC-06:00)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	As per V12 CRF CG 8.50.2.5, Date of onset is

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Central Time (US & Canada)				determined by ultrasound results or date of last menstrual period. Please revise/update accordingly. Thank you
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/23/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unprotected heteros exual intercourse	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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**Visit:** Logs - Unscheduled

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**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

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**Generated By:** (b) (4)

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

(UTC-06:00) Central Time (US & Canada)				
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-14-2021 23:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-13-2021 14:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Adverse event is ongoing as subject is pregnant
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE maternal exposure before pregnancy: Response to

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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

**Site No:** 1116

**Site Name:** (1116) MedPharmics, LLC

**Subject No:** 11161059

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Canada)				"What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 14:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**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:** 11161059

**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 13:24:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/23/2021	Initial Entry



**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form:** FURTHER VACCINATION CONFIRMATION - eCRF  
Audit Trail History**Form Version:** 10-Dec-2020 02:25**Form Status:** Data Complete, Frozen**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-24-2021 17:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 17:30:04 (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-24-2021 17:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT co nfirmed to have recei ved only placebo at V accination 1/2	Transcription Error
Feb-23-2021 13:24:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Participant is NOT willi ng to return for Vaccinat ion 3 OR otherwise not eligible	Initial Entry

**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:** 11161059

**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-24-2021 17:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/23/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-24-2021 17:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY F OR ADDITIONAL VACC INATION	Initial Entry

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**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:** 11161059

**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 12:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-31-2020 19:06:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZE D	Initial Entry
Aug-31-2020 19:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Feb-08-2021 00:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-05-2021 16:29:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Participant was contacted by CRC and consulted about symptoms, clinical picture not indicative of possible COVID 19, therefore illness visit not initiated.

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1116) MedPharmics, LLC

**Subject Initials:** ---

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

Dec-22-2020 03:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Response states ' clinical picture not indicative of possible COVID 19'. Please confirm if Illness ed diary entry of 10DEC2020 was deemed erroneous and subject had no symptoms on that day.
Dec-21-2020 16:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Participant was contacted, investigator consulted, clinical picture not indicative of possible COVID 19.
Dec-15-2020 10:44:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness ed diary: 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 10DEC2020. But corresponding COVID Illness visit not reported. Please clarify.

090177e196ae3f2c\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1116

**Subject No:** 11161059

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1116) MedPharmics, LLC

**Subject Initials:** ---

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

Oct-26-2020 12:02:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Initial Entry
Aug-31-2020 19:06:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry
Aug-31-2020 19:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

090177e196ae3f2c\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:** 11161059

**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

[Back to Form](#)

*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-27-2020 13:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry