

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[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	08 SEP 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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/14/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10871557]
2.	Birth Date:	(b) (6) 1986
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Form Comments

Inclusion Criteria Not Met

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

2.	Description of Exclusion Criterion Met	Not Applicable
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Oct/14/2020
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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to under cooked shrimp]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vitamin D Deficiency]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[POLYCYSTIC OVARIAN SYNDROME]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/14/2020
2.	Weight:	[55.92]
3.	Unit:	kg
4.	Height:	[154.94]
5.	Unit:	cm
6.	Body Mass Index:	[23.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/14/2020
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:	

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/14/2020
2.	Randomization Number:	[107612]
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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
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	[BSJ8JZ]
5.b	Sample ID	[BSJ21L]
5.c	Sample ID	[BR2DSG]

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
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	[BR2DRB]
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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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:	Oct/14/2020 13:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/5/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BR8Y7F]
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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	Not Done _____	Comments
2.	Treatment Name	Not Done _____ []	Comments
3.	Formulation:	Not Done _____	Comments
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:	Not Done _____	Comments
6.	Body Side:	Not Done _____	Comments
7.	Route:	Not Done _____	Comments
8.	Actual Dose:	Not Done _____ []	Comments
9.	Unit:	Not Done _____	Comments
10.	Timeframe Subject Was Observed	Not Done _____	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	Comments

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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 Version: 20-Feb-2021 02:17

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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:	[]
----	------------------------	-----

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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?	
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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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 Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Site No: 1087 **Site Name:** (1087) PMG Research of Wilmington, LLC

Subject No: 10871557 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:22

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	EXPOSURE DURING PREGNANCY	Oct/24/2020 UNK:UNK	YES	Repeating Pages

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[EXPOSURE DURING PREGNANCY]	
4.	Start Date Time:	Oct/24/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments
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	

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: [Sexual Intercourse]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
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	[]

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Medication Error

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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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:	//

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Concomitant Medications

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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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?	

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Vital Signs

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

Vital Signs Details

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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:	

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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?	

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	PREGNANCY
4.	Specify Status:	[]

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible
----	---	---

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/5/2020

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Kevin Cannon	Approved	Mar-05-2021 15:33:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, KevinCannon, 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.

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
Form	Oct-19-2020 10:43:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
Form	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
1	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Nov-06-2020 09:10:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	IP PERMANENTLY WITHDRAWN DUE TO PREGNANCY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
2	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
3	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
4	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
5	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
6	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
7	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
8	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
9	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
10	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
11	Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
6	Nov-09-2020 15:40:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Kevin Cannon	Approved	Mar-05-2021 15:33:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, KevinCannon, 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.

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-19-2020 10:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 10:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-19-2020 10:42:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Ob tained Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Subject ID

Date	Location	User	Value	Reason
Oct-19-2020 10:41:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10871557	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-19-2020 10:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1986	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-19-2020 10:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Nov-09-2020 17:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-09-2020 16:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-09-2020 16:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATI NO(A) OR OF SPANI SH ORIGIN	Transcription Error
Nov-09-2020 08:52:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Ethnicity is reported as NOT Hispanic; however, SAE report has ethnicity reported as Hispanic. Please review, harmonize ethnicity status and update in the required location.
Nov-09-2020 07:43:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINICAL - Ethnicity is reported as NOT Hispanic; however, SAE report has ethnicity reported as Hispanic. Please review, harmonize

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				ethnicity status and update in the required location.
Nov-09-2020 07:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	reissue as Candidate
Nov-06-2020 14:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze so that I may update
Nov-06-2020 09:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Ethnicity is reported as NOT Hispanic; however, SAE report has ethnicity reported as Hispanic. Please review, harmonize ethnicity status and update in the required location.
Oct-19-2020 10:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

Date	Location	User	Value	Reason
Oct-19-2020 10:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASIAN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 10:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871557**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Oct-19-2020 10:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 1 Number: Medical History Term: Allergy to under cooked shrimp Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry
Oct-19-2020 10:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical History Term: Allergy to under cooked shrimp Start Date: UNK/UNK/2005 Ongoing:	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Oct-19-2020 10:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergy to under cooked s hrimp	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 10:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 10:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-19-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His Vitamin D tory Term: Deficiency Start Date: UNK/UNK /2018 Ongoing: YES	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 23:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-10-2020 17:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	MED HX HAS BEEN UPDATED
Nov-09-2020 08:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - per PREGNANCY report, subject has a history of polycystic ovary disease. Please review for clinical relevance to the pregnancy event, and add to Medical History if appropriate
Nov-09-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINICAL - per

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087 Site Name: (1087) PMG Research of Wilmington, LLC Subject No: 10871557 Subject Initials: --- Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:22				
07:41:08 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		PREGNANCY report, subject has a history of polycystic ovary disease. Please review for clinical relevance to the pregnancy event, and add to Medical History if appropriate
Nov-09-2020 07:40:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	move to candidate form
Nov-06-2020 14:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze so that we may update
Nov-06-2020 09:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - per PREGNANCY report, subject has a history of polycystic ovary disease. Please review for clinical relevance to the pregnancy event, and add to Medical History if appropriate
Oct-19-2020 10:50:07	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vitamin D Deficiency	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-05:00)
Eastern Time (US
& Canada)

1.b Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-10-2020 17:03:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical History POLYCYSTIC OVARIAN SY Term: NDROME Start Date: UNK/UNK/20 05 Ongoing YES :	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

1.c Line/MH Number:

Date	Location	User	Value	Reason
Nov-10-2020 17:03:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 17:03:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POLYCYSTIC OVARIAN SYNDROME	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Nov-10-2020 17:03:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Nov-10-2020 17:03:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-19-2020 10:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 55.92	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 154.94	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 36.6 Temperature C Unit: Temperature ORAL C Location:: AVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)

7.a Temperature:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-19-2020 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 113 efined Iden tifier: Test:: Choriogonad otropin Beta_ PX113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-05:00) Eastern
Time (US & Canada)

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

PX113

6.a Result:

Date	Location	User	Value	Reason
Oct-19-2020 10:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-19-2020 10:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-19-2020 10:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 107612	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 10:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 10:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 17:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 10:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Oct-19-2020 10:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-19-2020 17:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ8JZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 17:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJ8JZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 18:01:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BSJ21 : L	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:01:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJ21L	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 18:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR2DS D: G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR2DSG	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 10:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 10:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 17:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 10:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Oct-19-2020 10:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-19-2020 17:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR2DR D: B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 17:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR2DRB	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020 13:08	Initial Entry

5. Anatomical Location:

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-19-2020 10:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECI FIED OBSERVATION PE RIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

10:47:13

(UTC-05:00) Eastern
Time (US & Canada)

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

YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-19-2020 10:47:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICIT Y E-DIARY NOT COLLE CTED FOR THIS SUBJE CT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-06-2020 08:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-06-2020 09:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 36.7 Temperature Unit: Temperature Location:: AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Nov-06-2020 09:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 113 efined Identifier: Test:: Choriogonad otropin Beta _PX113 Result:: POSITIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-06-2020 09:07:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Bet	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-05:00)
Eastern Time (US
& Canada)

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

a_PX113

6.a Result:

Date	Location	User	Value	Reason
Nov-07-2020 03:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 09:12:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PREGNANCY DISCOVERED AT VISIT 2. SUBJECT HAD NEGATIVE PREGNANCY TEST AT V1 AND NO REASON TO BELIEVE SHE WAS PREGNANT. VAX 2 NOT GIVEN AT V2
Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Lab result is "Positive", but subject has been vaccinated. Please review and update as appropriate. Else explain.

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-06-2020 09:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Data Origin

Date	Location	User	Value	Reason
Nov-06-2020 09:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-06-2020 09:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-06-2020 09:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-06-2020 09:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-06-2020 09:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Nov-06-2020 09:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR8Y7 : F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 09:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR8Y7F	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-12-2020 02:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 09:51:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not Done added to form level comment
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Nov-11-2020 04:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Patient is discontinued, if correct please update this form as Not done by selecting form level comment or else clarify. Thank you.

2. Treatment Name

Date	Location	User	Value	Reason
Nov-11-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

09:50:35
(UTC-05:00) Eastern
Time (US & Canada)

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

Not Done

3. Formulation:

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

7. Route:

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Nov-11-2020 09:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern 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, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Category:

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 11:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	follow-up was received and already updated in safety database
Nov-16-2020 11:08:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	SAE RECON 1:Per PSSR confirmation, no follow up form was received indicating update in term.Please submit a follow up AEM form to update term in Safety database.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-14-2020 10:23:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Candidate	Pending SDB update
Nov-13-2020 16:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	updated report just sent to safety with term "exposure during pregnancy"
Nov-13-2020 05:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020433197, the term in Safety database was recorded as pregnancy. Per 3 Nov EDP guidance (study communication), the term should be reported as 'EXPOSURE DURING PREGNANCY'. Please submit a follow up AEM form to update SDB term.
Nov-10-2020 08:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	update submitted (as drug exposed pregnancy)
Nov-08-2020 09:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - please submit updated event term 'Exposure during Pregnancy' as a SAE safety update.
Nov-08-2020 09:18:52 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087 Site Name: (1087) PMG Research of Wilmington, LLC Subject No: 10871557 Subject Initials: --- Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:22				
Eastern Time (US & Canada)				
Nov-08-2020 09:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-07-2020 12:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020433197, the term in Safety database was recorded as pregnancy. Based on the latest EDP guidance, the term should be reported as 'EXPOSURE DURING PREGNANCY'. Please submit a follow up AEM form to update SDB term.
Nov-06-2020 14:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Event is termed exposure during pregnancy
Nov-06-2020 09:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Healthy Pregnancy is not an AE, required to be on the CRF. Please update event to Exposure during Pregnancy.
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EXPOSURE DURING PREGNANCY	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, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-17-2020 05:17:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	onset date updated in SDB. issue resolved
Nov-17-2020 00:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Candidate	Pending SDB update
Nov-16-2020 15:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	An SAE Follow up report was sent to safety on Friday 13NOV2020 with an undated start date of 24OCT2020
Nov-14-2020 11:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020433197,onset date reported as 24Oct2020 in AE CRF while recorded as 14Oct2020 in Safety database.Per LMP, subject was pregnant before Vax1. The correct onset date is the date of vaccination1 = 14Oct2020. Please confirm and update.
Nov-12-2020 13:32:54 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query closed; will follow for SAE update with onset date

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871557**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22

Eastern Time (US & Canada)				
Nov-12-2020 13:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	October 24th is the correct date. Updated SAE reported being sent to safety confirming this information.
Nov-12-2020 13:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/24/20 20 UNK: UNK	October 24th is the correct date. Updated SAE reported being sent to safety confirming this information.
Nov-11-2020 16:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	CLINICAL - Event start date is 24Oct20; however, SAE event start date is 14Oct20. Please review to harmonize, and update in the appropriate location.
Nov-10-2020 08:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Closed	wrong pt
Nov-10-2020 08:17:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	CLINICAL Estimated date of Conception was 24Sep20 rather than 24Oct20; please review and update if appropriate

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-08-2020 09:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 14:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Nov-06-2020 14:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Oct/24/20 20 12:28	updated
Nov-06-2020 09:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Pregnancy onset occurred before the date of + pregnancy test at Visit 2; please update AE & PG report (#2020433197) to either the estimated date of conception (24Oct20) or date by any ultrasound (considered more accurate)
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Nov/5/202 0 12:28	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-09-2020 17:03:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-09-2020 15:40:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-09-2020 15:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-09-2020 15:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Nov-09-2020	ACV0PFEINFP6000	Hayley Wyper	Query 1: Opened	CLINQUERY:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

11:08:59 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)		For exposure during pregnancy events, toxicity grade can be entered as Not Applicable. Please update
Nov-06-2020 09:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-13-2020 12:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-12-2020 12:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	updated per query.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-12-2020 12:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Deleted	updated per query.
Nov-12-2020 12:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	updated per query.
Nov-11-2020 16:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	CLINICAL - The event reported here is study Drug Exposure during the regular pregnancy itself, which is NOT considered to be a SAE. Should a complication of pregnancy occur in the future, that event will also be reported, with it's own severity.
Nov-11-2020 02:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Reissued: Candidate	For Clinical review
Nov-10-2020 17:02:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Answered	subject is currently pregnant so it is unknown if outcome will be abnormal. What is the appropriate choice here?
Nov-07-2020 12:01:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	SAE RECON: AER#2020433197,'EXPOSURE DURING PREGNANCY' event was appropriately reported to safety; however, seriousness

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Header Text: c4591001 Visit: Logs - Unscheduled Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Version: 22-Apr-2020 21:02 Form Status: Data Complete, Frozen Site No: 1087 Site Name: (1087) PMG Research of Wilmington, LLC Subject No: 10871557 Subject Initials: --- Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:22				
				criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Nov-07-2020 12:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE EXPOSURE DURING PREGNANCY: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Did this serious event require or prolong hospitalization? NO	
			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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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-17-2020 19:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-17-2020 16:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Closed	Response satisfies query
Nov-17-2020 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-17-2020 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Changed Information

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

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			<i>If Ot her , s pe cif y: S e x u a l I n te r c o u r s e</i>	
Nov-17-2020 16:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Sexual Intercourse
Nov-17-2020 05:23:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Open ed	SAE RECON:AER#2020433197,causality was recorded as RELATED in AE CRF.Per narrative of the case The investigator considered there was NOT a reasonable possibility that the event was related to any clinical trial

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

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				procedure.Please update as appropriate.
Nov-16-2020 18:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Reiss ued:Op ened	GPD CLIN: Study relation is in reference to event of pregnancy. Please review and update causality as soon as possible. Thank you.
Nov-16-2020 14:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Related
Nov-15-2020 12:59:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reiss ued:Op ened	CLINICAL - drug exposure during pregnancy is NOT reported as related to itself (so NOT RELATED). Any later issue with the pregnancy or baby would be reported as a separate event, and relationship assessed for that.
Nov-13-2020 15:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	The PI is unsure how to assess this as the pregnancy at this point is normal and the outcome is unknown. Should it be assessed as related to IP?
Nov-13-2020 13:10:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reiss ued:Op ened	CLINICAL - Thank you. As both Pregnancy and study Drug Exposure are in the term, the causality is not related to those 2 events themselves; ie PG would not be related to PG. Please review, and update as appropriate.

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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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-11-2020 15:59:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Ans wered	The PI has assessed a causal relationship to IP in this case. As this subject would not have had "exposure during pregnancy" had she not been vaccinated with IP. We are open to changing the response if needed.
Nov-11-2020 11:23:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reiss ued:Op ened	CLINQUERY: The question is asking in regard to whether the study treatment had a causal relationship to the event (pregnancy). Please review if current entry is correct
Nov-10-2020 16:59:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Ans wered	please advise how this should be assessed
Nov-10-2020 06:54:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Open ed	CLINQUERY: Exposure during Pregnancy has been reported as Related to study treatment. Please review and update as appropriate
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data E ntry: RELAT ED	Initial Entry

10. Latest Action Taken with Study Treatment:

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 06:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-12-2020 02:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 16:17:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please advise? as there is not an end date but the subject is still pregnant so is still marked yes.
Nov-11-2020 16:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE EXPOSURE DURING PREGNANCY: 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".
Nov-11-2020 16:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Updated per query.
Nov-11-2020 16:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Updated per 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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-11-2020 05:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020433197, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Based on the latest EDP guidance, outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 09:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-06-2020 09:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-06-2020 09:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-06-2020 09:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 09:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is PREGNANCY but "Specify Status" is Provided.

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (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, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-06-2020 09:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PREGNANCY	Initial Entry
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4. Specify Status:

Date	Location	User	Value	Reason
Nov-06-2020 09:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Nov-06-2020 09:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IP Permanently withdr awn as it was discover ed on 05NOV2020 that subject is pregnant	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-19-2021 14:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

090177e196ae403a\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871557

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Date	Location	User	Value	Reason
Feb-19-2021 14:47:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willi ng to return for Vaccinat ion 3 OR otherwise not e ligible	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Subject Status

Date	Location	User	Value	Reason
Nov-06-2020 09:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-19-2020 10:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMI ZED	Initial Entry
Oct-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-06-2020 09:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Initial Entry
Oct-19-2020 10:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Oct-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry

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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871557

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail
History

Form Status: Data Complete, Signed, Verified

Site Name: (1087) PMG Research of Wilmington, LLC

Subject Initials: ---

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