

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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 Sep/1/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10871286]
2.	Birth Date:	(b) (6) 1948
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871286

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	Sep/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1087

Subject No: 10871286

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 _____
----	--	-------------------------

Exclusion Criteria Met

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

090177e196ae4039\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: 10871286

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	Sep/1/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Allergy to nonsteroidal anti-inflammatory drugs]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Diverticulitis]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

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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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Vitamin D3 deficiency]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Anemia]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

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](#)

Vital Signs

1.	Date:	Sep/1/2020
2.	Weight:	[87.6]
3.	Unit:	kg
4.	Height:	[170.2]
5.	Unit:	cm
6.	Body Mass Index:	[30.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1087**Subject No:** 10871286**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

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 :	Sep/1/2020
2.	Randomization Number:	[248540]
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: 10871286

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: Sep/1/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8BPV]
5.b	Sample ID	[BMRPRH]
5.c	Sample ID	[BMRPRS]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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: Sep/1/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8BRF]
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090177e196ae4039\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: 10871286

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:	Sep/1/2020 13:36
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1087

Subject No: 10871286

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: DATE OF VISIT

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: 10871286

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	Sep/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

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](#)

Vital Signs

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

2.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1087**Subject No:** 10871286**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)**Lab Urinalysis**

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

Lab Result

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

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: 10871286

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: Sep/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM963P]
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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:	Sep/22/2020 12:12
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

090177e196ae4039\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:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10871286 **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	Oct/20/2020
2.	Erroneous Visit	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10871286 **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/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2DXY]
5.b	Sample ID	[BSJ8PH]
5.c	Sample ID	[BSJ8P0]

090177e196ae4039\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: 10871286

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 Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

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	[]
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090177e196ae4039\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: 10871286

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 Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

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	[]
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090177e196ae4039\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: 10871286

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 Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

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	[]
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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	Oct/16/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/16/2020
2.	Date of First Symptom Started:	Oct/15/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/16/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	YES
Symptoms - Other		
5.a	Symptoms - Other Text:	[NAUSEA]
5.b	Symptoms - Other Text:	[Fatigue upon exertion]
5.c	Symptoms - Other Text:	[Tachycardia]
5.d	Symptoms - Other Text:	[Dyspnea upon exertion]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings /Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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_SELF
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV05960]
5.b	Sample ID	[RR08069]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Nasal Self Swab collected. Please refer to SELF SWAB eCRF.]

Aliquot

Please enter barcode for each aliquot.

5-a	Sample ID	[CV05960]
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

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

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Category f or Lab Tes t	Vendor Nam e (DERIVED)	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	Repeating Pages

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

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

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1087

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

Subject No: 10871286

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

Form Version: 06-Jul-2020 21:55

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

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.	Start Date:	//
6.	Ongoing?	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/26/2020
2.	Erroneous Visit	ERRONEOUS VISIT

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1087**Subject No:** 10871286**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Data Complete, Frozen**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Form Comments](#)[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Date of First Symptom Started:	Not Applicable _____ //	Comments
3.	Symptoms Ongoing?	Not Applicable _____	Comments

Symptoms

4.a	Symptoms:	FEVER	
	Was symptom present?	Not Applicable _____	Comments
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	Not Applicable _____	Comments
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

4.d	Symptoms:	CHILLS	
	Was symptom present?	Not Applicable _____	Comments
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	Not Applicable _____	Comments
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	Not Applicable _____	Comments
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	Not Applicable _____	Comments
4.h	Symptoms:	DIARRHEA	
	Was symptom present?	Not Applicable _____	Comments
4.i	Symptoms:	VOMITING	
	Was symptom present?	Not Applicable _____	Comments
Symptoms - Other			
5.a	Symptoms - Other Text:	Not Applicable _____ []	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Symptoms - Other Text:	Not Applicable _____ []	Comments
5.c	Symptoms - Other Text:	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings /Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, 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](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	Not Applicable _____ []	Comments
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Data Complete, 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](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871286**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Form Comments](#)[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	Not Applicable _____	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	Not Applicable _____	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	Not Applicable _____	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	Not Applicable _____	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	Not Applicable	Comments

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	Not Applicable []	Comments
----	-------------------------------------	-----------------------	--------------------------

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	Not Applicable	Comments
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete, 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](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	Not Applicable _____	Comments
3.	Toxicity Grade:	Not Applicable _____	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020**Form:** LOCAL LABORATORY DATA - REPEATING
CHEMISTRY**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871286**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 2 -
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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 2 -
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CHEMISTRY

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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result :	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020**Form:** LOCAL LABORATORY DATA - REPEATING
Hematology**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871286**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 2 -
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Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1087

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

Subject No: 10871286

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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	Nov/16/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

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

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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: Nov/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8Y92]
5.b	Sample ID	[BSH9CM]
5.c	Sample ID	[BLG42D]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Sep/24/2020

Form: DATE OF VISIT

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: 10871286

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	Sep/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Sep/24/2020

Form: UNPLANNED VISIT

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Sep/24/2020

Form: CONTACT OUTCOME - UNPLANNED

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Sep/24/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Reported onset symptoms starting 9/22/2020. Subject had second vax on the same day 9/22/2020 of onset symptoms. Reported feeling much better on 9/24/2020. Per P.I COVID Illness visit is not needed.]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled
Visit on Oct/15/2020

Form: DATE OF VISIT

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: 10871286

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	Oct/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled
Visit on Oct/15/2020

Form: UNPLANNED VISIT

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled
Visit on Oct/15/2020

Form: CONTACT OUTCOME - UNPLANNED

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/15/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Pt reported COVID symptoms including vomiting, diarrhea & nausea starting 15Oct2020. Based on symptoms PI determined self-swab was necessary.]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 3 - Unscheduled
Visit on Oct/16/2020

Form: DATE OF VISIT

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: 10871286

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	Oct/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 3 - Unscheduled
Visit on Oct/16/2020

Form: UNPLANNED VISIT

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 3 - Unscheduled
Visit on Oct/16/2020

Form: CONTACT OUTCOME - UNPLANNED

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/16/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Pt called back to report symptoms resolved from 15Oct2020. Reports feeling better. COVID Illness Visit was still conducted & self-swab was sent to Pfizer labs.]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 4 - Unscheduled
Visit on Oct/26/2020

Form: DATE OF VISIT

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: 10871286

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	Oct/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 4 - Unscheduled
Visit on Oct/26/2020

Form: UNPLANNED VISIT

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
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Header Text: c4591001

Visit: Unplanned 4 - Unscheduled
Visit on Oct/26/2020

Form: CONTACT OUTCOME - UNPLANNED

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/26/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Pt reports severe fatigue upon exertion & tachycardia during these episodes. PI to complete telehealth call. Pt confirms no other changes in health/meds. Symptoms onset was 3 days ago.]

090177e196ae4039\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, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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 :	Oct/20/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

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

1 - Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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	Oct/26/2020
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	COVID_AR1
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
1 - Unscheduled Visit on Oct/26/2020 SWAB

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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_SELF
3.	Sample Collected?	YES Date of Collection: Oct/26/2020
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	[RR08069]
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090177e196ae4039\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: 10871286

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. DELETED	ADVERSE EVENT	1	TACHYCARDIA	Oct/20/2020 19:00	YES	Repeating Pages
2. DELETED	ADVERSE EVENT	2	DYSPNEA	Oct/20/2020 19:00	YES	Repeating Pages
3. DELETED	ADVERSE EVENT	3	NAUSEA	Oct/15/2020 UNK: UNK	NO End Date Time : Oct/16/2020 UNK:UNK	Repeating Pages
4. DELETED	ADVERSE EVENT	4	FATIGUE UPON EXERTION	Oct/20/2020 19:00	YES	Repeating Pages
5. DELETED	ADVERSE EVENT	5	DIARRHEA	Oct/15/2020 UNK: UNK	NO End Date Time : Oct/16/2020 UNK:UNK	Repeating Pages
6. DELETED	ADVERSE EVENT	6	VOMITING	Oct/15/2020 UNK: UNK	NO End Date Time : Oct/16/2020	Repeating Pages

090177e196ae4039\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: 10871286

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
					UNK:UNK	
7.	ADVERSE EVENT	7	Gastrointestinal Bleed	Nov/4/2020 UNK:UNK	NO End Date Time : Nov/6/2020 UNK:UNK	Repeating Pages
8.	ADVERSE EVENT	8	Hematochezia	Nov/4/2020 UNK:UNK	NO End Date Time : Nov/7/2020 UNK:UNK	Repeating Pages
9.	ADVERSE EVENT	9	Gastric Antral Vascular Ectasia	Nov/6/2020 UNK:UNK	NO End Date Time : Nov/7/2020 UNK:UNK	Repeating Pages
10.	ADVERSE EVENT	10	Arteriovenous Malformation of the Colon	Nov/6/2020 UNK:UNK	NO End Date Time : Nov/7/2020 UNK:UNK	Repeating Pages

090177e196ae4039\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: 10871286

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
11.	ADVERSE EVENT	11	Acute Blood Loss Anemia	Nov/4/2020 UNK: UNK	NO End Date Time: Nov/5/2020 UNK:UNK	Repeating Pages
12.	ADVERSE EVENT	12	Decreased Hemoglobin	Nov/4/2020 UNK: UNK	YES	Repeating Pages

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[±]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[TACHYCARDIA]
4.	Start Date Time:	Oct/20/2020 19:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify:</p> <p>[CARDIAC FOLLOW UP WITH PCP]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[DYSPNEA]
4.	Start Date Time:	Oct/20/2020 19:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify:</p> <p>[? CARDIAC FOLLOW UP WITH PCP]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[NAUSEA]
4.	Start Date Time:	Oct/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	2

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT

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Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [LIKELY VIRAL]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[FATIGUE UPON EXERTION]
4.	Start Date Time:	Oct/20/2020 19:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

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

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify:</p> <p>[CARDIAC TO FOLLOW UP WITH PCP]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[DIARRHEA]
4.	Start Date Time:	Oct/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	2

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7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify:</p> <p>[LIKELY VIRAL ILLNESS]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[VOMITING]
4.	Start Date Time:	Oct/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/16/2020 UNK:UNK
6.	Toxicity Grade:	2

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7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify:</p> <p>[LIKELY VIRAL ILLNESS]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Gastrointestinal Bleed]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/6/2020 UNK:UNK
6.	Toxicity Grade:	3

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7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [AVM of the colon]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020455286]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hematochezia]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/7/2020 UNK:UNK
6.	Toxicity Grade:	2

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

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [AVM of the colon]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Gastric Antral Vascular Ectasia]
4.	Start Date Time:	Nov/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/7/2020 UNK:UNK
6.	Toxicity Grade:	3

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Arteriovenous Malformation of the Colon]
4.	Start Date Time:	Nov/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/7/2020 UNK:UNK
6.	Toxicity Grade:	3

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Idiopathic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[11]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Blood Loss Anemia]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/5/2020 UNK:UNK
6.	Toxicity Grade:	3

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7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Gastrointestinal Bleed]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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:	[12]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Decreased Hemoglobin]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Gastrointestinal Bleed]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4039\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: 10871286

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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Medication Error

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

090177e196ae4039\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: 10871286

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: 10871286

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:	//

090177e196ae4039\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: 10871286

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

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

090177e196ae4039\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: 10871286

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: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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?	

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.	PACKED RBC	Nov/4/2020	Repeating Pages

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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1.	Transfusion Type:	PACKED RBC
2.	Date of Transfusion:	Nov/4/2020

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: 10871286

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: 10871286

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:	

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: 10871286

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:	

090177e196ae4039\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: 10871286

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?	

090177e196ae4039\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: 10871286

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: 10871286

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 - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1087

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

Subject No: 10871286

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: 10871286

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: 10871286

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

090177e196ae4039\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: 10871286

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

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

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: 10871286 **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/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

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: 10871286 **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 willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/15/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

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

Subject No: 10871286

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: 10871286

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/20/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1087

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

Subject No: 10871286

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: 10871286

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-04-2021 11:36:40 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Sep-01-2020 17:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

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Site No: 1087

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

Subject No: 10871286

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Generated By: (b) (4)

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

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Item	Date	User	Comment
6.a	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

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Generated By: (b) (4)

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

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Item	Date	User	Comment
6.a	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6.a	Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

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

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Item	Date	User	Comment
1	Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

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Item	Date	User	Comment
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Item	Date	User	Comment
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Generated Time (GMT): 29-Mar-2021 10:22

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Item	Date	User	Comment
6.a	Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not a woman of childbearing potential <hr/> Not Done

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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

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Item	Date	User	Comment
3	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

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Form Version: 06-Jul-2020 21:54

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

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

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: DATE OF VISIT - ILLNESS ONSET - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Nov-04-2020 09:37:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Site initially believed there was a COVID-B event, however as the date of of the new symptoms was on the 4th day of the end date of COVID-A, per protocol information was combined with COVID-A event.

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Oct-30-2020 16:13:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Oct-30-2020 16:13:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

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

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Item	Date	User	Comment
3	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Oct-30-2020 16:13:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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Subject No: 10871286

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Item	Date	User	Comment
4.a	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.a	Oct-30-2020 16:13:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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Item	Date	User	Comment
4.b	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.b	Oct-30-2020 16:13:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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Subject No: 10871286

Subject Initials: ---

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Item	Date	User	Comment
4.c	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.c	Oct-30-2020 16:14:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4.d	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.d	Oct-30-2020 16:14:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4.e	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.e	Oct-30-2020 16:14:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4.f	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.f	Oct-30-2020 16:14:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4.g	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.g	Oct-30-2020 16:14:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

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Site No: 1087

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

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Item	Date	User	Comment
4.h	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.h	Oct-30-2020 16:14:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4.i	Mar-03-2021 09:39:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4.i	Oct-30-2020 16:14:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.a	Oct-30-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-30-2020 16:15:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

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

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Item	Date	User	Comment
5.c	Oct-30-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

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Item	Date	User	Comment
1	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

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Item	Date	User	Comment
2	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

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

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site Name: (1087) PMG Research of Wilmington, LLC

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Item	Date	User	Comment
4	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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5	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

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6	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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7	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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8	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Subject Initials: ---

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9	Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Unscheduled Visit on Oct/26/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Nov-04-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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Subject No: 10871286

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Item	Date	User	Comment
2	Nov-04-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

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Item	Date	User	Comment
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Header Text: c4591001

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Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

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Item	Date	User	Comment
4	Nov-04-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Item	Date	User	Comment
5.a	Nov-03-2020 16:59:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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Generated By: (b) (4)

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Item	Date	User	Comment
Form	Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
1	Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

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

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Item	Date	User	Comment
2	Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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Item	Date	User	Comment
3	Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Generated By: (b) (4)

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Item	Date	User	Comment
Form	Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Item	Date	User	Comment
1.a	Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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Item	Date	User	Comment
1.b	Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Item	Date	User	Comment
1.c	Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Item	Date	User	Comment
1.d	Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Item	Date	User	Comment
1.e	Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
1.f	Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
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Visit: POT_COVID_ILL 2 -
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Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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Generated By: (b) (4)

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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Header Text: c4591001

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Header Text: c4591001

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Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

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

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Form: ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52

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Visit: POT_COVID_ILL 2

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Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

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Header Text: c4591001

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

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5.h	Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 2 -
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Generated By: (b) (4)

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Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

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Form Status: Data Complete, Signed, Verified

Site No: 1087

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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-04-2021 11:36:40 (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.

(b) (6)	N/A	Feb-02-2021 10:41:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Kevin Cannon	Approved	Jan-26-2021 08:46:00 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
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Form Status: Data Complete, Signed, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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.

(b) (6)	N/A	Jan-25-2021 16:35:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Kevin Cannon	Approved	Jan-22-2021 16:27:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Kevin Cannon	Approved	Nov-17-2020 16:33:26 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

(b) (6)	N/A	Nov-17-2020 09:40:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Kevin Cannon	Approved	Nov-04-2020 11:20:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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.

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-01-2020 17:31:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:31:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 17:31:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 17:30:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10871286	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 17:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-01-2020 17:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR L ATINO(A) OR OF SP ANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-01-2020 17:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICA N AMERICAN	Initial Entry

090177e196ae4039\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: 10871286

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 17:31:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - 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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-01-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Sep-01-2020 17:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 1 H Num ber: Medica Allergy to no l Histor nsteroidal ant y Term i-inflammator : y drugs Start D UNK/UNK/2 ate: 012 Ongoin YES g:	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-01-2020 17:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergy to nonsteroidal anti-inflammatory drugs	Initial Entry
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1.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-01-2020 17:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His Divertic tory Term: ulitis	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

			Start Date: UNK/ NK/201 2	
			Ongoing: YES	

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:09 (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
Sep-02-2020 13:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Sep-02-2020 11:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Thank you for your query. Per Inclusion/Exclusion, subject has met all Inclusion criteria, including Inclusion #3.
Sep-02-2020 08:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please confirm ongoing status. Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				symptoms within 6 weeks of enrolment and no acute event within 48h before study intervention administration
Sep-01-2020 17:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diverticulitis	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-01-2020 17:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 3 Medical History Term: Hypertension Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:24 (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
Sep-01-2020 17:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:24	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4039\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: 10871286

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)

1.d

Date	Location	User	Value	Reason
Sep-01-2020 17:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 4 umber: Medical His Anxiety tory Term: Start Date: UNK/U NK/201 7 Ongoing: YES	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:37:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4039\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: 10871286

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)

I.e

Date	Location	User	Value	Reason
Sep-01-2020 17:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical H Vitamin D istory Ter 3 deficien m: cy Start Date UNK/UN : K/2015 Ongoing: YES	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vitamin D3 deficiency	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:38:36	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4039\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: 10871286

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)

If

Date	Location	User	Value	Reason
Sep-01-2020 17:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 6 umber: Medical His Anemia tory Term: Start Date: UNK/U NK/200 0 Ongoing: YES	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 08:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Sep-03-2020 15:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject has not received any blood products in the past 60 days.
Sep-02-2020 10:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please can you confirm if subject has received any blood products in the past 60 days for this medhx?

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-01-2020 17:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anemia	Initial Entry
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If Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4039\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: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 87.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae4039\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: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 170.2	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (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
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.9	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

			Temperature Unit: Temperature Location: CAVITY
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae4039\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: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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
Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4039\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: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae4039\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: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:30 (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: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

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
Sep-01-2020 17:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 248540	Initial Entry

090177e196ae4039\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: 10871286

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 17:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 17:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 00:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-23-2020 09:45:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Updated

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				
Sep-22-2020 22:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Serum barcode BMRPRS has been received by the lab for Visit 1. Please review and update or submit SCF.
Sep-02-2020 18:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 07:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:33:49 (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

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Sep-01-2020 17:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 18:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BP8B ID: PV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 18:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BPV	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 18:01:41 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BMRP	Initial Entry

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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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)			ID: RH	
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 18:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMRPRH	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 09:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BMRP ID: RS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 09:41:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMRPRS	Initial Entry

090177e196ae4039\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: 10871286

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
Sep-01-2020 17:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 17:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-02-2020 18:02:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 07:13:26 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 18:02:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BP8B ID: RF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-02-2020 18:02:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BRF	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

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
Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:04 (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
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090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 13:36	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

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
Sep-01-2020 17:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENIC ITY E-DIARY NOT C OLLECTED FOR THI S SUBJECT	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871286

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-29-2020 08:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-28-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	POT_COVID_ILL reflects self swab and barcode CV05960.
Oct-23-2020 00:52:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	HOLDS: Nasal self- swab barcode CV05960 was received by the lab for COVID_A. Please review and update accordingly or submit an updated SCF.
Oct-09-2020 13:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	per response UNPL updated.
Oct-08-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	After speaking

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

16:26:44 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	red	with subject and per P.I a COVID Illness was not necessary. Inform has been updated with the unplanned phone call visit.
Oct-07-2020 09:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness edinary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 05OCT2020. But there is no COVID Illness visit reported in the database.
Sep-23-2020 10:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1087

Subject No: 10871286

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

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1. Date:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 10:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.4 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:29 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:29 (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
Sep-23-2020 10:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae4039\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: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4039\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: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae4039\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: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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6.a Test:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-23-2020 10:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae4039\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: 10871286

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
Sep-23-2020 10:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 10:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 18:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 10:13:02 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 10:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 18:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BM96 ID: 3P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 18:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM963P	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

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
Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-23-2020 10:13:30 (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
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090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 12:12	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 10:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10871286 **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
Oct-23-2020 13:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10871286 **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-23-2020 13:25:35 (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-23-2020 13:25:35 (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-25-2020 13:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-24-2020 04:36:08 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871286**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-23-2020 13:25:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candi date	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-23-2020 13:25:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collec tion: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-25-2020 13:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR2DX D: Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10871286 **Subject Initials:** ---

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

Oct-25-2020 13:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR2DXY	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-25-2020 13:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BSJ8P : H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 13:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJ8PH	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-25-2020 13:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BSJ8P : 0	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10871286 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 13:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJ8P0	Initial Entry

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, 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-20-2020 03:18:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Clo sed	Response satisfies query
Nov-19-2020 15:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: An swere d	Changed data per query
Nov-19-2020 06:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Op ened	SAE RECON:AER#2020455286 gastrointestinal bleed(onset date:04Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-23-2020 13:29:06 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Del eted	Close Auto Query

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-23-2020 13:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-23-2020 13:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-23-2020 13:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Oct/16/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Oct-23-2020 13:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry
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Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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 Assessment:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-30-2020 07:34:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-23-2020 09:42:37 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

Eastern Time (US & Canada)				
Nov-23-2020 09:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO Date of Last Symptom Re solved: Oct/16/202 0	updated
Nov-23-2020 09:06:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reiss ued:Opened	Unfreeze now, kindly amend data as appropriate. Thanks.
Nov-20-2020 11:51:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reiss ued:Candidate	DM please unfreeze CRF for site to make update.
Nov-20-2020 08:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answ ered	Please unfreeze.
Nov-20-2020 01:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Open ed	CLINQUERY: Please clarify whether the reported symptoms are still ongoing?

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Nov-19-2020 10:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Oct-30-2020 14:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-23-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

13:27:18 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6) [REDACTED]	NO Date of Last Symptom Re solved: Oct/16/202 0	
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4.a

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms FEV : ER Symptom NO Present:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time
(US & Canada)

4.b

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR toms: INCREA SED CO UGH Symp NO tom P resen t:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCRE ASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW OR I pto NCREAS ms: ED SHOR TNESS O F BREAT H	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom Present:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESSES OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Characteristics: Symptom Present:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW OR ptom INCREA s: SED MU SCLE PAI N Sym NO ptom Prese nt:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCRE ASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW LO toms: SS OF TA STE OR SMELL Symp NO tom Prese nt:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW OR ptom INCREA s: SED SOR E THROA T Sym NO ptom Prese nt:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCRE ASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: DIAR RHE A Symptom Present: YES	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: VOMITING Symptom Present: YES	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-23-2020 13:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-23-2020 13:27:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NAU s - Other: SEA	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-23-2020 13:27:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NAUSEA	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

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

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

5.b

Date	Location	User	Value	Reason
Oct-30-2020 11:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Fatigue upon exertion	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 11:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue upon exertion	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 11:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Tachycardia	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 11:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tachycardia	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-30-2020 11:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Dyspnea upon exertion	Initial Entry

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 11:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dyspnea upon exertion	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 06-Jul-2020 21:54

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, 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. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 06-Jul-2020 21:54

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-23-2020 13:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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-23-2020 13:38:48 (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-23-2020 13:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 10:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 3: Close d	As per the update
Nov-04-2020 09:20:36 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 3: Answ ered	Done. Thank you

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Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				
Nov-04-2020 01:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reiss ued:Opened	DM: Thanks for response, however no COV RSWAB visit entered. Please enter the DOV as 10/26/20 when repeat performed and add RR08069 to Sample form and link to COVID_ARI within the COV RSWAB visit.
Nov-03-2020 19:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answ ered	Answer Auto Query
Nov-03-2020 18:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reiss ued:Opened	Please move barcode RR08069 to the COV RSWAB visit within this casebook.

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Header Text: c4591001

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

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
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Site Name: (1087) PMG Research of Wilmington, LLC

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				Please enter the DOV as 10/26/20 when repeat performed and add RR08069 to Sample form and link to COVID_ARI within the COV RSWAB visit. This is to the right on the visit bar.
Nov-03-2020 17:20:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Self swab from 10/26/2020 added to COVID A visit per instructions: all other data moved from B to A, including the barcode – into repeat swab visit (DOV is self-swab collection date, linked as COVID AR1 to COVID A

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

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				visit)
Nov-03-2020 17:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Open ed	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Nov-03-2020 17:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Close d	Close Auto Query
Nov-03-2020 17:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Open ed	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Oct-23-2020 13:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Delet ed	Close Auto Query
Oct-23-2020 13:38:48	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candi date	'Sample Collected?' is

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

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Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-23-2020 13:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Colle ction: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-23-2020 13:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample CV059 ID: 60	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-23-2020 13:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV05960	Initial Entry

5.b

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
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Form Status: Data Complete, Frozen, Verified

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

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Date	Location	User	Value	Reason
Nov-03-2020 19:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I RR080 D: 69	Transcription Error (DELETED)
Nov-03-2020 17:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I RR080 D: 69	Initial Entry
Nov-03-2020 17:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Nov-03-2020 17:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I RR080 D: 69	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
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Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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5.b Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 19:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RR08069	Transcription Error (DELETED)
Nov-03-2020 17:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RR08069	Initial Entry
Nov-03-2020 17:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-03-2020 17:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RR08069	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Subject No: 10871286

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-23-2020 13:29:06 (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-23-2020 13:29:06 (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-23-2020 13:40:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Close d	Close Auto Query
Oct-23-2020 13:39:43 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opene d	'Sample Collected?' is marked as No

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Visit: POT_COVID_ILL 1 -
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Site No: 1087

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

Subject No: 10871286

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Generated By: (b) (4)

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Eastern Time (US & Canada)				and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-23-2020 13:39:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-23-2020 13:39:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Oct-23-2020 13:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: ELECTRONIC SAMPLE TRACKING - NASAL
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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Oct-23-2020 13:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 13:29:06 (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.
Oct-23-2020 13:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-23-2020 13:40:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nasal Self Swab collected. Please refer to SELF SWAB eCRF.	Initial Entry

5.a

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-23-2020 13:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample CV05 ID: 960	Transcription Error (DELETED)
Oct-23-2020 13:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample CV05 ID: 960	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-24-2020 08:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Close d	Response satisfies query
Oct-23-2020 13:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV05960	Transcription Error (DELETED)
Oct-23-2020 13:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answ ered	Confirming sample barcode of CV05960 is correct as entered

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
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Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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Oct-23-2020 13:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Open ed	Barcode is not 6 characters in length. Please review and correct as appropriate.
Oct-23-2020 13:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV05960	Initial Entry

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Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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I.a

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr SPE actitioner: CIA LIS T Occurren NO ce of Visit s or Conta cts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

1.b

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of EMER Practitio GENC ner: Y RO OM Occure NO nce of Vi sits or C ontacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY R OOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

I.c

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of PRIMA Practiti RY CA oner: RE PH YSICI AN Occurr NO ence of Visits o r Conta cts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAR E PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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1.d

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P URG ractice ENT r: CAR E Occurren NO ce of Visit s or Cont acts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: HEALTH CARE UTILIZATION - eCRF Audit
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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of TELEP Practiti HONE oner: CONS ULTAT ION Occurr NO ence of Visits o r Conta cts:	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE C ONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: HEALTH CARE UTILIZATION - eCRF Audit
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Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: HE R Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

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

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

13:28:20 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6) [REDACTED]	NO	
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Header Text: c4591001

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

Form Version: 06-Jul-2020 21:52

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, 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. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 13:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-23-2020 13:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, 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
Mar-03-2021 13:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	sod form updated,
Mar-03-2021 09:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Done
Mar-03-2021 05:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	DM: Visit is marked as Erroneous; and data was cleared from all the initiated forms. However, form level comment is not present on SOD form. Kindly add Form level comment as Not applicable

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				on all the initiated forms of this visit. Thank you.
Nov-04-2020 11:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Deleted	Query is invalid or does not apply
Nov-04-2020 11:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-04-2020 09:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Form level comment added to this page.
Nov-04-2020 09:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 09:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-03-2020 19:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-03-2020 16:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-03-2020 12:39:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Visit was conducted, however, as the new symptoms started on day 4 after

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				COVID-A symptoms ended, Site was instructed to move the reported symptoms from COVID-A to COVID-B and mark all forms in this visit as "Not Applicable."
Nov-03-2020 07:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Please review and clarify if this visit was conducted. If yes, please update all the applicable forms at this visit. If not, please clarify if this is an erroneous visit and update as appropriate.
Oct-27-2020 13:52:50 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-27-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-27-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-27-2020 13:49:31 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time
(US & Canada)

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-03-2020 19:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-27-2020 13:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

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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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-30-2020 16:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				and update as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-30-2020 16:13:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 16:05:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 14:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	All updates complete.
Oct-30-2020 14:13:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUERY: Please respond via query once all updates are made per initial

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				query that the subject developed symptoms within 4 days from symptoms end date of COVID_A visit, in this case per PA7, 2nd COVID visit is not required.
Oct-30-2020 09:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Deleted per query. Details will be added to COVID_A visit as appropriate.
Oct-30-2020 09:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. Details will be added to COVID_A visit as appropriate.
Oct-30-2020 07:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Forms appear unfrozen. Please update.
Oct-29-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

15:53:33 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	ered	first COVID visit CRFs so that I may update.
Oct-28-2020 10:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Open ed	CLINQUERY: Given that the subject developed symptoms within 4 days from symptoms end date of COVID_A visit, in this case per PA7, 2nd COVID visit is not required. Please move the details of this visit from all CRFs to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

3. Symptoms Ongoing?

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 16:23:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 16:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	done
Oct-30-2020 16:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 16:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Please mark the fields on this CRF as Not Applicable.
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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4.a

Date	Location	User	Value	Reason
Oct-30-2020 16:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Not A m Present: pplica ble	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FE VE R Symptom Present:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FE VE R Symptom NO Present:	Initial Entry

4.a Symptoms:

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Oct-30-2020 16:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom s: NEW O R INCR EASED COUGH Symptom Present: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom s: NEW O R INCR EASED COUGH Symptom Present:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom s: NEW O R INCR EASED COUGH Symptom Present: NO	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCRE ASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 16:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sym NEW OR pto INCREA ms: SED SH ORTNES S OF BR EATH Sym Not Appli pto cable m P rese nt:	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sym NEW OR pto INCREA ms: SED SH ORTNES S OF BR EATH Sym pto m P rese nt:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sym NEW OR pto INCREA ms: SED SH ORTNES S OF BR	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

			EATH Sym NO pto m P rese nt:	
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCRE ASED SHORTN ESS OF BREAT H	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-30-2020 16:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Present: Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHI LLS Symptom Present:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHI LLS Symptom Present:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:14:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 16:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW O pto R INCR ms: EASED MUSCL E PAIN Sym Not Appl pto icable m Pr esen t:	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW O pto R INCR ms: EASED MUSCL E PAIN Sym pto m Pr esen t:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW O pto R INCR ms: EASED MUSCL E PAIN	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

			Sym NO pto m Pr esen t:	
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCRE ASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 16:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sym NEW L ptom OSS OF s: TASTE OR SME LL Sym Not Appl ptom icable Pres ent:	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sym NEW L ptom OSS OF s: TASTE OR SME LL Sym ptom Pres ent:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sym NEW L ptom OSS OF s: TASTE OR SME LL Sym NO ptom Pres ent:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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4.f Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

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Header Text: c4591001

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 16:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW O pto R INCR ms: EASED SORE T HROAT Sym Not Appl pto icable m Pr esen t:	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW O pto R INCR ms: EASED SORE T HROAT Sym pto m Pr esen t:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW O pto R INCR ms: EASED SORE T HROAT	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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Header Text: c4591001

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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4.g Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCRE ASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

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Header Text: c4591001

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 16:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom DIARR s: HEA Symptom Not App Present: licable	Initial Entry

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Header Text: c4591001

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Subject Initials: ---

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4.h

Date	Location	User	Value	Reason
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIA RRH EA Symptom Present:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIA RRH EA Symptom Present: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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4.h Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

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Header Text: c4591001

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 16:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom: VOMITING Symptom Present: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom: VOMITING Symptom Present:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom: VOMITING Symptom Present: NO	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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4.i Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 16:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

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Header Text: c4591001

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Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-30-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: cable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 14:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom - Other: ERTION	Transcription Error
Oct-27-2020 13:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: E	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 16:15:17	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)				
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 14:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE UP ON EXERTIO N	Transcription Error
Oct-27-2020 13:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-30-2020 16:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympto Not A ms - Ot plica her: ble	Initial Entry
Oct-30-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

09:29:21 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Symptoms - Other:	query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - YCA Other: RDIA	Initial Entry

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Header Text: c4591001

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 16:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TACHYCARD IA	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympto Not A ms - Ot pplica her: ble	Initial Entry
Oct-30-2020 09:29:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)			Symptoms - Other:	details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:51:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp DYSPN toms EA UP - Oth ON EX er: ERTIO N	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 16:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-30-2020 09:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Deleted per query. All details will be added to COVID_A visit as appropriate.
Oct-27-2020 13:51:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DYS/PNEA UP ON EXERTIO N	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, 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. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-27-2020 13:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, 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. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-27-2020 13:52:50 (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-04-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Transcription

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

09:29:18 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)		Error
Oct-27-2020 13:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SEL F	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Close d	Close Auto Query
Nov-04-2020 09:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-04-2020 09:04:57 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Open ed	'Sample Collected?' is Yes, however

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Eastern Time (US & Canada)		(b) (4), (b) (6)		no barcodes are entered. Please review and correct as appropriate.
Nov-03-2020 16:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candi date	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-27-2020 13:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Delet ed	Close Auto Query
Oct-27-2020 13:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candi date	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-27-2020 13:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Colle ction:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

			Oct/26/2020	
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-04-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 07:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-03-2020 17:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	swab information transferred to COVID A visit. Please unfreeze DOV ILL so this visit can be marked as erroneous.
Oct-30-2020 16:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLIQUEY: If subject was enrolled under PA 7, please move the Swab

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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				information to the COV RSWAB visit and complete this CRF with NO as per CCG's. If not then the site should enter a comment that the swab was taken in error and should be destroyed.
Oct-30-2020 16:12:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLIQUEY: If subject was enrolled under PA 7, please move the Swab information to the COV RSWAB visit and complete this CRF with NO as per CCG's. If not then the site should enter a comment that the swab was taken in error and should be destroyed.

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Oct-30-2020 16:12:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	error
Oct-30-2020 16:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUERY: As this visit should not have occurred, please move the Swab information to the COV RSWAB visit and complete this CRF with NO as per CCG's.

5.a

Date	Location	User	Value	Reason
Nov-03-2020 16:59:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sampl Not App e ID: licable	Initial Entry
Nov-03-2020 16:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	deleted per query. Data will be applied to COVID A

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

				visit.
Oct-27-2020 13:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: RR080 69	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 16:59:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-03-2020 16:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	deleted per query. Data will be applied to COVID A visit.
Oct-27-2020 13:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RR08069	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, 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. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, 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
Oct-27-2020 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of SPE Practitioner: CIA LIS T Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Nov-04-2020 10:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: P SPE CIA LIS T Occurrence of Visits or Contacts: Changed Information	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: P SPE CIA LIS T	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 10:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

1.b

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of EME Practitioner: NCY ROO M Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Nov-04-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of EME Practitioner: NCY ROO M Occurrence of Visits or Contacts:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of EME Practitioner: NCY	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

(US & Canada)			ROOM M Occurrence of Visits or Contacts:	
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY R OOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 10:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

<p>Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Type of Practitioner: PRIMARY CARE : PHYSICIAN Occurrence of Visits or Contacts: Not Applicable</p>	<p>Initial Entry</p>
<p>Nov-04-2020 10:56:27 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Type of Practitioner: PRIMARY CARE : PHYSICIAN Occurrence of Visits or Contacts:</p>	<p>Changed Information</p>
<p>Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Type of Practitioner: PRIMARY CARE : PHYSICIAN</p>	<p>Initial Entry</p>

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

			Occur NO rence of Visi ts or C ontact s:	
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAR E PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 10:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of URG Practitio ENT ner: CAR E Occurre Not nce of Vi Appl sits or C icabl ontacts: e	Initial Entry
Nov-04-2020 10:56:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of URG Practitio ENT ner: CAR E Occurre nce of Vi sits or C ontacts:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of URG Practitio ENT ner: CAR E Occurre NO nce of Vi sits or C ontacts:	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 10:56:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONIC CONSULTATION Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Nov-04-2020 10:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONIC CONSULTATION Occurrence of Visits or Contacts:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONIC CONSULTATION	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

			Occur NO rence o f Visits or Con tacts:	
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE C ONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 10:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HER Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Nov-04-2020 10:57:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 10:57:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-04-2020 10:57:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 10:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 13:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Status: Data Complete, 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. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-04-2020 09:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-04-2020 09:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 09:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 09:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Nov-04-2020 09:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 09:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-04-2020 09:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Information combined with COVID A
Oct-27-2020 13:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID -19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 09:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Information

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

09:38:40 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		combined with COVID A
Oct-27-2020 13:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-04-2020 09:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Information combined with COVID-A visit
Oct-27-2020 13:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-04-2020 09:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-04-2020 09:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-04-2020 09:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 09:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 21-Aug-2020 02:49

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, 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. Lab Panel:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 21-Aug-2020 02:49

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Eastern Time (US
& Canada)

5.a Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 21-Aug-2020 02:49

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, 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-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

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

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

5.b LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Form Version: 21-Aug-2020 02:49

Site No: 1087

Subject No: 10871286

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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - 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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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& Canada)

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

5.c LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

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Form Version: 21-Aug-2020 02:49

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

Subject Initials: ---

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Site No: 1087

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

Subject No: 10871286

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)		
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5.d LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

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Header Text: c4591001

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Form Version: 21-Aug-2020 02:49

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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CHEMISTRY - eCRF Audit Trail History

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

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
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& Canada)

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

5.e LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
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Subject Initials: ---

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5.f Sponsor ID:

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Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

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

5.f LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Nov-04-2020 09:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Visit: POT_COVID_ILL 2 -
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Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, 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. Lab Panel:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: LOCAL LABORATORY DATA - REPEATING
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Site No: 1087

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

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

Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

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5.c

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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)

5.c LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Site No: 1087

Subject No: 10871286

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Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

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Generated By: (b) (4)

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

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

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

5.d LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae4039\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 Initials: ---

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Site No: 1087

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

Subject No: 10871286

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Generated By: (b) (4)

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

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

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

5.e LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Form Status: Data Complete, Frozen, Verified

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

Subject No: 10871286

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)

5.f LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Header Text: c4591001

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Subject No: 10871286

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

Subject Initials: ---

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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& Canada)

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

5.g LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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)

5.h LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Header Text: c4591001

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Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
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5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.i LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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

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

			Lab Normal Range:	Not Applicable	
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Header Text: c4591001

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

Subject Initials: ---

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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5.j LNMT

Date	Location	User	Value	Reason
Nov-04-2020 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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-04-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-04-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in respirations/minute: Not Applicable Heart Rate in beats/minute: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:49	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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)		
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2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-04-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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-04-2020 09:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-04-2020 09:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-04-2020 09:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Status: Data Complete, 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-04-2020 09:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS - eCRF Audit
Trail History

Form Status: Data Complete, 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 Time of Assessment:

Date	Location	User	Value	Reason
Nov-04-2020 09:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-04-2020 09:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-04-2020 09:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, 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. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-04-2020 09:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-04-2020 09:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-04-2020 09:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-04-2020 09:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-04-2020 09:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 09:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: IMAGING - eCRF Audit Trail History

Form Status: Data Complete, 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 Assessment:

Date	Location	User	Value	Reason
Nov-04-2020 09:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-04-2020 09:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-04-2020 09:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 09:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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
Nov-17-2020 09:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-17-2020 09:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, 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. Data Origin

Date	Location	User	Value	Reason
Nov-17-2020 09:41:14 (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-17-2020 09:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-17-2020 09:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Delete d	Close Auto Query
Nov-17-2020 09:41:14 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candi date	'Sample Collected?' is Yes, however

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-17-2020 09:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collec tion: Nov/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-17-2020 09:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BR8Y ID: 92	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 09:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR8Y92	Initial Entry

5.b

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, 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-17-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSH9 CM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 09:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSH9CM	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-17-2020 09:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLG4 2D	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 09:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLG42D	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/24/2020

Form: DATE OF VISIT - 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: 10871286

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
Oct-08-2020 16:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/24/2020	Initial Entry

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/24/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: UNPLANNED 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. Assessments

Date	Location	User	Value	Reason
Oct-08-2020 16:25:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 16:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-08-2020 16:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTC OME	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/24/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Oct-08-2020 16:25:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-08-2020 16:25:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Sep/24/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Oct-08-2020 16:25:34	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reported onset symp	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Sep/24/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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

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

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

toms starting 9/22/2020. Subject had second vax on the same day 9/22/2020 of onset symptoms. Reported feeling much better on 9/24/2020. Per P.I. COVID Illness visit is not needed.

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled
Visit on Oct/15/2020

Form: DATE OF VISIT - 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: 10871286

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
Oct-23-2020 13:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/15/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: UNPLANNED 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. Assessments

Date	Location	User	Value	Reason
Oct-23-2020 13:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-23-2020 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001**Visit:** Unplanned 2 - Unscheduled Visit on Oct/15/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1087**Subject No:** 10871286**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - 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[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-23-2020 13:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-23-2020 13:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact : Oct/15/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 2 - Unscheduled
Visit on Oct/15/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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

Oct-23-2020 13:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pt reported COVID symptoms including vomiting, diarrhea & nausea starting 15Oct2020. Based on symptoms PI determined self-swab was necessary.	Initial Entry
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 3 - Unscheduled
Visit on Oct/16/2020

Form: DATE OF VISIT - 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: 10871286

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
Oct-23-2020 13:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 3 - Unscheduled Visit on Oct/16/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: UNPLANNED 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. Assessments

Date	Location	User	Value	Reason
Oct-23-2020 13:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 13:44:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-23-2020 13:44:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 3 - Unscheduled Visit on Oct/16/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Oct-23-2020 13:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-23-2020 13:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact : Oct/16/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 3 - Unscheduled
Visit on Oct/16/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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

Oct-23-2020 13:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pt called back to report symptoms resolved from 15 Oct 2020. Reports feeling better. COVID Illness Visit was still conducted & self-swab was sent to Pfizer labs.	Initial Entry
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Unplanned 4 - Unscheduled
Visit on Oct/26/2020

Form: DATE OF VISIT - 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: 10871286

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
Oct-27-2020 13:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 4 - Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: UNPLANNED 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. Assessments

Date	Location	User	Value	Reason
Oct-27-2020 13:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 13:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-27-2020 13:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001**Visit:** Unplanned 4 - Unscheduled
Visit on Oct/26/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1087**Subject No:** 10871286**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - 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[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-27-2020 13:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-27-2020 13:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact : Oct/26/2020 Contact Outcom e: VISIT NOT R EQUIRED, IN VESTIGATO R DECISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 4 - Unscheduled
Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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

Oct-27-2020 13:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pt reports severe fatigue upon exertion & tachycardia during these episodes. PI to complete telehealth call. Pt confirms no other changes in health/meds. Symptoms onset was 3 days ago.	Initial Entry
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090177e196ae4039\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, Locked, Frozen, Verified

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

Subject No: 10871286 **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-23-2020 13:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-23-2020 13:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-23-2020 13:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB - eCRF Audit
1 - Unscheduled Visit on Oct/26/2020 Trail History

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

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
Nov-04-2020 09:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

3. COVID-19 Repeat Swab:

Date	Location	User	Value	Reason
Nov-04-2020 09:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_AR1	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
1 - Unscheduled Visit on Oct/26/2020 SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 10871286 **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-04-2020 09:18:29 (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-04-2020 09:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SEL F	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 09:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 09:18:29 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
1 - Unscheduled Visit on Oct/26/2020 SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57 **Form Status:** Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 09:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-04-2020 09:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: RR08069	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 09:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RR08069	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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

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Date	Location	User	Value	Reason
Nov-03-2020 12:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Captured in COVID A symptoms
Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-03-2020 15:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Captured on COVID ILL form
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

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Date	Location	User	Value	Reason
Nov-03-2020 12:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Captured on COVID-A CRF
Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-03-2020 15:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	captured on COVID ILL form
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

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Date	Location	User	Value	Reason
Oct-29-2020 17:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Deleted per query. Will add to COVID illness CRF only.
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

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Date	Location	User	Value	Reason
Oct-29-2020 17:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Deleted	Deleted per query. Will be added to COVID illness CRF only.
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

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Form Status:

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

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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, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (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
Oct-27-2020 14:06:46 (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
Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TACHYCARDIA	Initial Entry

4. Start Date Time:

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020 19:0 0	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (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
Oct-27-2020 14:06:46 (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

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (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
Oct-27-2020 14:06:46 (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 d ue to: OTHER	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

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

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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

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

			<p><i>If Other, specify:</i></p> <p>CARDIAC FOLLOW UP WITH P CP</p>	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (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
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVER ED/NOT RESOL VED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\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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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
Oct-27-2020 14:07:57 (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
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-03-2020 21:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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Nov-03-2020 15:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Captured on COVID ILL form
Nov-03-2020 13:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per protocol section 8.13., COVID-19 listed symptom DYSPNEA should have please captured only on the CRF SOD form already completed (Visit Date of Assessment: 16Oct2020)
Oct-29-2020 19:19:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PI assessed that this was a possible cardiac issue. The subject has no other

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Site Name: (1087) PMG Research of Wilmington, LLC

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Generated By: (b) (4)

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				cardiac pre existing cardiac conditions other than Hypertension. PI confirms at this point this is not considered an important medical event.
Oct-29-2020 13:01:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Open ed	clinical: Causality attributed to cardiac dz. Pt has an AE of tachycardia. Does pt have hx of cardiac dz other than HTN-if so pls update MedHx CRF confirm PI does not consider this is IME (important medical event) which would require reporting as

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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				SAE
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DYSYPNEA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020 19:0 0	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (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
Oct-27-2020 14:07:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

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(UTC-05:00)
Eastern Time
(US & Canada)

(b) (4), (b) (6)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (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:

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Header Text: c4591001

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Site Name: (1087) PMG Research of Wilmington, LLC

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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Date	Location	User	Value	Reason
Oct-29-2020 14:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATE D If Not Related to study treatm ent(s), this eve nt is due to: OTHER <i>If Other, sp ecify:</i> ? CARDI AC FOLL OW UP WITH PC P	Transcription Error
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATE D If Not Related to study treatm ent(s), this eve nt is due to: OTHER <i>If Other, sp ecify:</i>	Initial Entry

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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			CARDIA C FOLLO W UP WI TH PCP	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICAB LE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (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
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site Name: (1087) PMG Research of Wilmington, LLC

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Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVER ED/NOT RESOL VED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (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
Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-03-2020 14:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

***** THIS REPEATING FORM HAS BEEN DELETED *****

Nov-03-2020 12:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Captured on COVID-A CRF
Nov-03-2020 02:25:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Query 1: Opened	CLINQUERY: NAUSEA has been captured as a potential covid symptom within the COV ILL CRF (SOD page). There is no need to capture this duplicate entry also in the AE log.
Nov-02-2020 11:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: NAUSEA has been captured as a potential covid symptom within the COV ILL CRF (SOD page). There is no need to capture this duplicate entry also in the AE log.

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NAUSEA	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020 UN K:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/16/2020 U NK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Form Status: Data Complete, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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Eastern Time
(US & Canada)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (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
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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

<p>Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> LIKELY VIRAL</p>	<p>Initial Entry</p>
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
<p>Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NOT APPLICABLE</p>	<p>Initial Entry</p>

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
<p>Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NO</p>	<p>Initial Entry</p>

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (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
Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/R ESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (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
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE UPON EXERTION	Initial Entry

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Header Text: c4591001

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (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
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (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
Oct-27-2020 14:11:10 (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 d ue to:	Initial Entry

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Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

			OTHER <i>If Other, specify:</i> CARDIAC-TO FOLLO W UP WIT H PCP	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (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
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090177e196ae4039\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, Deleted

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

***** THIS REPEATING FORM HAS BEEN DELETED *****

Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVER ED/NOT RESOL VED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (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
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-30-2020 07:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

***** THIS REPEATING FORM HAS BEEN DELETED *****

Oct-29-2020 17:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Deleted per query. Will add to COVID illness CRF only.
Oct-29-2020 15:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: As DIARRHEA was added to Symptom of Disease Form in COVID ILL visit, the condition should not be on the AE CRF form. Please confirm if this AE was related to COVID illness? If so it should be removed as an AE.
Oct-29-2020 14:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirming AE DIARRHEA is correct as entered on AE

090177e196ae4039\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, Deleted, Frozen**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871286**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22***** THIS REPEATING FORM HAS BEEN DELETED *****

				CRF form
Oct-28-2020 14:58:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLIQUERY: As DIARRHEA was added to Symptom of Disease Form in COVID ILL visit, the condition should not be on the AE CRF form. Please update.
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: DIARRHEA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/15/2020 UN K:UNK	Initial Entry

5. Is the adverse event still ongoing?

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/16/2020 U NK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (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
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

(US & Canada)

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (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
Oct-27-2020 14:12:30 (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 d ue to: OTHER <i>If Other, spec ify:</i> LIKELY VI RAL ILLN ESS	Initial Entry

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (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
Oct-27-2020 14:12:30 (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
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090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

***** THIS REPEATING FORM HAS BEEN DELETED *****

Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/R ESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (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
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-30-2020 07:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

***** THIS REPEATING FORM HAS BEEN DELETED *****

Oct-29-2020 17:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Deleted per query. Will be added to COVID illness CRF only.
Oct-29-2020 15:02:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: As VOMITING was added to Symptom of Disease Form in COVID ILL visit, the condition should not be on the AE CRF form. Please confirm if this AE was related to COVID illness? If so it should be removed as an AE.
Oct-29-2020 14:47:24 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirming AE Vomiting correct as entered on AE

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

(US & Canada)				CRF form
Oct-28-2020 14:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: As VOMITING was added to Symptom of Disease Form in COVID ILL visit, the condition should not be on the AE CRF form. Please update.
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020 UN K:UNK	Initial Entry

5. Is the adverse event still ongoing?

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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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/16/2020 U NK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (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
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

(US & Canada)

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (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
Oct-27-2020 14:13:51 (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 d ue to: OTHER <i>If Other, spec ify:</i> LIKELY VI RAL ILLN ESS	Initial Entry

090177e196ae4039\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, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (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
Oct-27-2020 14:13:51 (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
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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

*** THIS REPEATING FORM HAS BEEN DELETED ***

Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/R ESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 14:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (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-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastrointestinal Bleed	Initial Entry

4. Start Date Time:

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Header Text: c4591001

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/6/2020 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1087

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-23-2020 09:12:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-23-2020 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	A safety follow up was sent explaining that while in the hospital the patient did not receive a COVID test.
Nov-21-2020 17:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	CLINICAL - Please enter date of COVID test in hospital if known
Nov-20-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	follow up SAE form sent.
Nov-20-2020 03:19:49 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10871286

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)				
Nov-19-2020 15:54:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2020455286] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Gastrointestinal Bleed: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-19-2020 15:25:16 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious ev	Initial Entry

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Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Eastern Time (US & Canada)			ent associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO	
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Header Text: c4591001

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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: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Other medically important serious event	
			NO	

**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (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
Dec-06-2020 11:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-04-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated per query.
Dec-04-2020 12:30:37 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related t	updated per query.

090177e196ae4039\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: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Eastern Time (US & Canada)			o study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> AVM of the colon	
Nov-25-2020 09:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Safety reviewing case history
Nov-25-2020 00:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Please clarify which lesion is being identified, either the AVM of the colon or gastric ectasia.
Nov-23-2020 10:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	GIB/hematochezia prompted endoscopy on 06NOV2020 which is when AVM was found.
Nov-23-2020 08:22:48	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: It is reported that the

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-05:00) Eastern Time (US & Canada)				possible causality of gastrointestinal bleed is 'Gastric AVM'. However, the bleed is reported to start prior to the AVM per CRF. Please review dates and update; else, clarify
Nov-19-2020 15:25:16 (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 <i>If Other, specify:</i> Gastric AVM	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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Form Status: Data Complete, Frozen

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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& Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Nov-19-2020 15:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-20-2020 03:19:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020455286	Initial Entry

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (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-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematochezia	Initial Entry

4. Start Date Time:

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/7/2020 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (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

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (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
Dec-09-2020 13:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-06-2020 11:12:10 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	CLINICAL Thank you. Please submit a SAE safety update with

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)				this information that AVM of colon was responsible for GI bleed
Dec-04-2020 12:31:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated per query.
Dec-04-2020 12:31:26 (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 <i>If Other, specify:</i> AVM of the colon	updated per query.
Nov-25-2020 09:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Safety reviewing case history
Nov-25-2020 00:59:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Please clarify which

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

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)		lesion is being identified, either the AVM of the colon or gastric ectasia.
Nov-23-2020 10:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	GIB/hematochezia prompted endoscopy on 06NOV2020 which is when AVM was found.
Nov-23-2020 08:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: It is reported that the possible causality of hematochezia is 'Gastric AVM'. However, the event of hematochezia is reported to start prior to the AVM per CRF. Please review dates and update; else, clarify
Nov-19-2020 15:26:32 (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:	Initial Entry

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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			OTHER <i>If Other, specify:</i> Gastric AV M	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (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-19-2020 15:26:32 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Eastern Time (US & Canada)

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-19-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site No: 1087

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (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-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-23-2020 09:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-23-2020 08:45:08	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No AE terms 9 and 10 were

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Header Text: c4591001

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Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		not known prior to signing of ICF.
Nov-21-2020 13:50:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: were AE terms 9 and 10 known prior to signing of ICF? Thanks
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastric Antral Vascular Ectasia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Initial Entry

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Site No: 1087

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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& Canada)			Nov/7/2020 UNK :UNK	
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to st udy treatment(s), th is event is due to: OTHER <i>If Other, specify:</i> Idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-20-2020 08:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-19-2020 16:06:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-19-2020 16:06:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Nov-19-2020 15:52:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Please clarify whether Ectasia and/or AVM events had non-drug treatment during

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Subject Initials: ---

Generated By: (b) (4)

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				endoscopy (answer is 'YES' for GI bleed SAE itself).
Nov-19-2020 15:28:51 (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-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-19-2020 15:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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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: 10871286

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-19-2020 15:33:22 (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-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-03-2021 22:50:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for requested information.
Feb-02-2021 11:13:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SAE follow up report faxed.

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Subject Initials: ---

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(UTC-05:00) Eastern Time (US & Canada)				
Jan-27-2021 21:15:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL SAE report Lab data section on line 2 06Nov20 endoscopy still has final term 'gastric AVM of colon', which is included in the SAE narrative; please remove the 'gastric' modifier in a SAE safety update
Jan-27-2021 21:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	update
Dec-09-2020 13:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL SAE report test section for 06Nov20 endoscopy still has 'gastric AVM of colon',

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				which is included in the SAE narrative; please update the 'gastric' modifier in a SAE safety update
Dec-09-2020 13:45:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-09-2020 12:11:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated per query.
Dec-09-2020 12:11:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Arteriovenous Malformation of the Colon	updated per query.
Dec-06-2020 11:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued :Opened	CLINICAL - The AE term has re-added 'Gastric' however, 'gastric' and 'colon' are different

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				locations. AVM has been clarified as in colon; please remove 'gastric' in both AE and SAE for this lesion.
Dec-02-2020 14:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-02-2020 14:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastric Arteriovenous Malformation of the Colon	Transcription Error
Nov-23-2020 09:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Event of AVM of the Colon is reported; however SAE report has Gastric AVM of the Colon. Please review, harmonize reporting, and update in the applicable location

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Nov-21-2020 18:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-20-2020 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-20-2020 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Arteriovenous Mal formation of the C olon	Changed Information
Nov-20-2020 08:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Clinical - please clarify location as 'gastric' conflicts with 'colon'; both in AE and SAE (with a safety update)
Nov-19-2020 16:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query.
Nov-19-2020 16:02:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastric Arterioven	updated per query.

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)			ous Malformation of the Colon	
Nov-19-2020 15:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Event term is Gastric AVM; however, in SAE report the term is 'Gastric AVM of the Colon'. Please review, harmonize reporting, and update in the appropriate location.
Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastric Arterioven ous Malformation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020 UNK:U NK	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

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-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/7/2020 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-25-2021 04:49:24 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)				
Jan-22-2021 16:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as entered per source
Dec-03-2020 12:25:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm that the AE does not meet protocol criteria for serious AE including important medical event, given information provided in SAE number 2020455286.
Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-19-2020 15:33:22 (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 <i>If Other, specify:</i> Idiopathic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

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Generated By: (b) (4)

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Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-19-2020 16:15:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Nov-19-2020 15:33:22 (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-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-19-2020 15:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

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-19-2020 15:34:46 (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-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute Blood Loss A nemia	Initial Entry

4. Start Date Time:

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Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/5/2020 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

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Generated By: (b) (4)

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medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-03-2020 12:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-02-2020 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Dr. Cannon has assessed that this is not an SAE and is secondary to the SAE
Nov-23-2020 11:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm that AE does not meet protocol criteria for serious adverse event including important medical event, given toxicity grade 3 and nondrug treatment.
Nov-19-2020 15:34:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-05:00)
Eastern Time
(US & Canada)

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-19-2020 15:34:46 (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-19-2020 15:34:46 (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 <i>If Other, specify:</i> Gastrointestina l Bleed	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (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
Feb-02-2021 15:22:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Feb-02-2021 10:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated per query.
Nov-25-2020 07:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: If blood products were given, please

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& Canada)				capture on the TRANSFUSE page under Logs tab of the CRF
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-19-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (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-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Decreased Hemoglo bin	Initial Entry

4. Start Date Time:

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Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (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-19-2020 15:35:49 (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

090177e196ae4039\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

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

prevent above outcomes).

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (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-19-2020 15:35:49 (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 <i>If Other, specify:</i> Gastrointestina	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			I Bleed	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (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-19-2020 15:35:49 (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
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RES OLVING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-19-2020 15:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Feb-02-2021 10:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871286

Generated By: (b) (4)

Form: TRANSFUSIONS - eCRF Audit Trail History

Form Status: Data Complete, 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. Transfusion Type:

Date	Location	User	Value	Reason
Feb-02-2021 10:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PACKED RBC	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Feb-02-2021 10:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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: 10871286 **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-23-2021 09:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled 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: 10871286 **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-23-2021 09:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccinat ion 3 Participant is: eligible per local/ national recomme ndations and conf irmed to have rec eived only placeb o at Vaccination 1 /2	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-25-2021 16:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-23-2021 16:54:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Feb-23-2021 09:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-22-2021 21:26:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 1: Opened	DM: Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL

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Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

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Site No: 1087

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Subject Initials: ---

Generated By: (b) (4)

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				VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-25-2021 16:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Oct-23-2020 13:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 17:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 17:32:11 (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
Jan-08-2021 01:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-07-2021 10:56:07	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject reports having no

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)				COVID symptoms. States she must have pressed "yes" accidentally.
Dec-18-2020 15:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 15DEC2020. But there is no COVID Illness visit reported in the database. Please clarify.
Nov-19-2020 15:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-19-2020 15:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-19-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Event

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1087

Site Name: (1087) PMG Research of Wilmington, LLC

Subject No: 10871286

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

14:29:58 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		of GI Bleed reported as SAE (#2020455286); however, it does not appear on the AE CRF. Please review for safety and update AE log CRF accordingly.
Oct-23-2020 13:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Initial Entry
Sep-01-2020 17:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
Sep-01-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	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: 10871286

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: ---

Generated Time (GMT): 29-Mar-2021 10:22

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-04-2020 11:20:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kevin Cannon (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae4039\Final\Final On: 01-Apr-2021 05:33 (GMT)