

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** COHORT\_SELECTION

**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](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** MAIN INFORMED CONSENT

**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](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/26/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** DEMOGRAPHY

**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](#)

**Demography**

1.	Subject ID	[10871228]
2.	Birth Date:	(b) (6)/1948
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

**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	Aug/26/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1087

**Subject No:** 10871228

**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	Aug/26/2020
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: 10871228

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:	[HYPERTENSION]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GROUT]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BENIGN PROSTATIC HYPERPLASIA]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CORONARY ARTERY DISEASE]
	Start Date:	Feb/UNK/2020
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BILATERAL FOOT PAIN]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CONGESTIVE HEART FAILURE]
	Start Date:	Feb/UNK/2020
	Ongoing:	YES

090177e196ae4035\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:** 10871228

**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

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CHRONIC KIDNEY DISEASE]
	Start Date:	Feb/UNK/2020
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Triple Bypass]
	Start Date:	Feb/UNK/2020
	Ongoing:	NO End Date: Feb/UNK/2020

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**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

**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:	Aug/26/2020
2.	Weight:	[92.5]
3.	Unit:	kg
4.	Height:	[182.9]
5.	Unit:	cm
6.	Body Mass Index:	[27.7]

**Vital Signs Details**

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

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<b>Header Text:</b> c4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1087) PMG Research of Wilmington, LLC
<b>Site No:</b> 1087	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10871228	<b>Generated Time (GMT):</b> 29-Mar-2021 10:22
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/26/2020
2.	Randomization Number:	[241392]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[CRC WAS ONLY ABLE TO DRAW 1 OF 3 REQUIRED TUBES DUE TO HARD STICK AND VEIN BLOWING. PATIENT REFUSED A SECOND STICK FOR REMAINING 2 TUBES.]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9ZPJ]
5.b	Sample ID	[BMRPL1]

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**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**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**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/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	[BP9ZMG]
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**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

**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:	Aug/26/2020 13:02
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

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

**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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>

090177e196ae4035\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:** 10871228

**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

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ [ ]	<a href="#">Comments</a>
	Unit:	Not Done _____	<a href="#">Comments</a>
	Temperature Location:	Not Done _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**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](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ [ ]
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090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Vaccination**

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

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

**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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<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V4_MONTH6_L	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1087) PMG Research of Wilmington, LLC
<b>Site No:</b> 1087	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10871228	<b>Generated Time (GMT):</b> 29-Mar-2021 10:22
<b>Generated By:</b> (b) (4)	

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:** 10871228

**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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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1087

**Subject No:** 10871228

**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:** 10871228

**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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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1087

**Subject No:** 10871228

**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	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1087

**Subject No:** 10871228

**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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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/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:** 10871228

**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/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  
Sep/16/2020

**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:** 10871228

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Sep/16/2020
2.	Date of First Symptom Started:	Sep/3/2020
3.	Symptoms Ongoing?	NO
		Date of Last Symptom Resolved: Sep/6/2020

**Symptoms**

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

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae4035\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:** 10871228

**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.	Sep/3/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Sep/3/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[Cepheid Xpert Express SARS-CoV-2 test]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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:** 10871228

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Telehealth visit not performed. Subject did not notify site of symptoms. Site became aware after receiving records for SAE hospitalization]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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:** 10871228

**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	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Telehealth visit not performed. Subject did not notify site of symptoms. Site became aware after receiving records for SAE hospitalization.]	

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

**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
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?	YES
		Has the subject been in intensive care due to potential COVID-19 illness?
		NO

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Sep/3/2020	NO Discharge Date: Sep/8/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** HOSPITALIZATION DETAILS

**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:** 10871228

**Subject Initials:** ---

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

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

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[Form Audit Trail](#)

**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Sep/3/2020
4.	Ongoing?	NO Discharge Date: Sep/8/2020

**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:** 10871228

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020      **Form:** RESPIRATORY TREATMENT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**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?	YES Respiratory Illness Diagnosis: [Worsening of chronic congestive heart failure]  Date of Diagnosis: Sep/3/2020
3.	Toxicity Grade:	2

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: 10871228

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.	SEVERE COVID-19 ILLNESS	SIGNIFICANT ACUTE RENAL DYSFUNCTION	YES <i>Diagnosis:</i>  acute kidney injury  Start Date:  Sep/3/2020  Ongoing?:  NO  End Date:  Sep/7/2020	3	<a href="#">Repeating Pages</a>

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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[Form Audit Trail](#)

**Illness Details**

1.	Category of Clinical Event:	SEVERE COVID-19 ILLNESS
2.	Subcategory of Clinical Event:	SIGNIFICANT ACUTE RENAL DYSFUNCTION
3.	Was a diagnosis obtained?	YES Diagnosis: [acute kidney injury]  Start Date: Sep/3/2020  Ongoing?: NO End Date: Sep/7/2020
4.	Toxicity Grade:	3

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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: 10871228

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.	CLINICAL CHEMISTRY	New Hanover Regional Medical Center Laboratory Services, 2131 S. 17th St., Wilmington, NC 28401	Sep/3/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	[ ]	
					30	Alanine Aminotransferase_PX30	[ ]	
					28	Aspartate Aminotransferase_PX28	[ ]	
					35	Alkaline Phosphatase_PX35	[ ]	
					21	Bilirubin_PX21	[ ]	
					47	Blood Urea Nitrogen_PX47	35 mg/dL	
					48	Creatinine_PX48	2.61	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[New Hanover Regional Medical Center Laboratory Services, 2131 S. 17th St., Wilmington, NC 28401]
3.	Collection Date:	Sep/3/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[35 mg/dL]
	Not Done:	
	LNMT	Low [9] High [23] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[2.61]
	Not Done:	
	LNMT	Low [.70] High [1.30] Unit mg/dL

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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: 10871228

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.	HEMATOLOGY	New Hanover Regional Medical Center Laboratory Services, 2131 S. 17th St., Wilmington, NC 28401	Sep/3/2020	BLOOD	<table border="1"> <thead> <tr> <th data-bbox="1010 474 1143 562">Sponsor-Defined Identifier</th> <th data-bbox="1148 474 1260 562">Test:</th> <th data-bbox="1265 474 1330 562">Result:</th> </tr> </thead> <tbody> <tr> <td data-bbox="1010 569 1143 636">1</td> <td data-bbox="1148 569 1260 636">Hemoglobin_PX1</td> <td data-bbox="1265 569 1330 636">11.6 g/dL</td> </tr> <tr> <td data-bbox="1010 642 1143 709">2</td> <td data-bbox="1148 642 1260 709">Hematocrit_PX2</td> <td data-bbox="1265 642 1330 709">39.5</td> </tr> <tr> <td data-bbox="1010 716 1143 783">3</td> <td data-bbox="1148 716 1260 783">Erythrocytes_PX3</td> <td data-bbox="1265 716 1330 783">[ ]</td> </tr> <tr> <td data-bbox="1010 789 1143 856">5</td> <td data-bbox="1148 789 1260 856">Platelets_PX5</td> <td data-bbox="1265 789 1330 856">200 K/uL</td> </tr> <tr> <td data-bbox="1010 863 1143 930">7</td> <td data-bbox="1148 863 1260 930">Leukocytes_PX7</td> <td data-bbox="1265 863 1330 930">[ ]</td> </tr> <tr> <td data-bbox="1010 936 1143 1003">608</td> <td data-bbox="1148 936 1260 1003">Neutrophils_PX608</td> <td data-bbox="1265 936 1330 1003">[ ]</td> </tr> <tr> <td data-bbox="1010 1010 1143 1077">609</td> <td data-bbox="1148 1010 1260 1077">Eosinophils_PX609</td> <td data-bbox="1265 1010 1330 1077">[ ]</td> </tr> <tr> <td data-bbox="1010 1083 1143 1150">612</td> <td data-bbox="1148 1083 1260 1150">Monocytes_PX612</td> <td data-bbox="1265 1083 1330 1150">[ ]</td> </tr> <tr> <td data-bbox="1010 1157 1143 1224">610</td> <td data-bbox="1148 1157 1260 1224">Basophils_PX610</td> <td data-bbox="1265 1157 1330 1224">[ ]</td> </tr> <tr> <td data-bbox="1010 1230 1143 1297">611</td> <td data-bbox="1148 1230 1260 1297">Lymphocytes_PX611</td> <td data-bbox="1265 1230 1330 1297">[ ]</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	11.6 g/dL	2	Hematocrit_PX2	39.5	3	Erythrocytes_PX3	[ ]	5	Platelets_PX5	200 K/uL	7	Leukocytes_PX7	[ ]	608	Neutrophils_PX608	[ ]	609	Eosinophils_PX609	[ ]	612	Monocytes_PX612	[ ]	610	Basophils_PX610	[ ]	611	Lymphocytes_PX611	[ ]	<a href="#">Repeating Pages</a>
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	11.6 g/dL																																					
2	Hematocrit_PX2	39.5																																					
3	Erythrocytes_PX3	[ ]																																					
5	Platelets_PX5	200 K/uL																																					
7	Leukocytes_PX7	[ ]																																					
608	Neutrophils_PX608	[ ]																																					
609	Eosinophils_PX609	[ ]																																					
612	Monocytes_PX612	[ ]																																					
610	Basophils_PX610	[ ]																																					
611	Lymphocytes_PX611	[ ]																																					

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[New Hanover Regional Medical Center Laboratory Services, 2131 S. 17th St., Wilmington, NC 28401]
3.	Collection Date:	Sep/3/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[11.6 g/dL]
	Not Done:	
	LNMT	Low [13.7] High [17.5] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[39.5]
	Not Done:	
	LNMT	Low [40.1] High [51.0] Unit %

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[200 K/uL]
	Not Done:	
	LNMT	Low [163] High [369] Unit /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

090177e196ae4035\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:** 10871228

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	146	81	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Not Done //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[146]
	Diastolic:	[81]
	Respiratory Rate in respirations/minute:	[21]
	Heart Rate in beats/minute:	[53]

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**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:** 10871228

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

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/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:** 10871228

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	//
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**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:** 10871228

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/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:** 10871228

**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:** 10871228

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**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.	Start Date:	//
6.	Ongoing?	

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**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:** 10871228

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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:** 10871228

**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\_CONVA - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Unplanned Assessments**

1.	Assessments	
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**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:** 10871228

**Subject Initials:** ---

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

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

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**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Sep/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

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

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Sep/16/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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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: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Worsening of Chronic Congestive Heart Failure	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/8/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Accelerated Hypertension	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/6/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Acute Kidney Injury	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/7/2020 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Acute Respiratory Failure	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/4/2020 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Dizziness	Sep/5/2020 UNK:UNK	NO End Date Time:  Sep/8/2020 UNK:UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	Hypotension	Sep/5/2020 UNK:UNK	NO End Date Time:  Sep/7/2020 UNK:UNK	<a href="#">Repeating Pages</a>
7.	ADVERSE EVENT	7	Urinary Tract Infection	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/8/2020 08:08	<a href="#">Repeating Pages</a>
8.	ADVERSE EVENT	8	HYPOKALEMIA	Sep/4/2020 UNK:UNK	NO End Date Time:  Sep/6/2020 UNK:UNK	<a href="#">Repeating Pages</a>
9.	ADVERSE EVENT	9	WORSENING OF BILATERAL FOOT PAIN	Sep/5/2020 UNK:UNK	NO End Date Time:  Sep/6/2020 UNK:UNK	<a href="#">Repeating Pages</a>

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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
10.	ADVERSE EVENT	10	LOW-GRADE FEVER	Sep/5/2020 UNK:UNK	NO End Date Time:  Sep/6/2020 UNK:UNK	<a href="#">Repeating Pages</a>
11.	ADVERSE EVENT	11	PAROXYSMAL ATRIAL Fibrillation	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/8/2020 UNK:UNK	<a href="#">Repeating Pages</a>
12.	ADVERSE EVENT	12	SHORTNESS OF BREATH	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/4/2020 UNK:UNK	<a href="#">Repeating Pages</a>
13.	ADVERSE EVENT	13	BILATERAL PULMONARY EDEMA	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/5/2020 UNK:UNK	<a href="#">Repeating Pages</a>
14.	ADVERSE EVENT	14	DEHYDRATION	Sep/3/2020 UNK:UNK	NO End Date Time:  Sep/4/2020 UNK:UNK	<a href="#">Repeating Pages</a>

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

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Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of Chronic Congestive Heart Failure]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/8/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event 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: [worsening of pre-existing condition]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES

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**Form Status:** Data Complete, Frozen

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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?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020359869]

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1087**Subject No:** 10871228**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Accelerated Hypertension]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/6/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [worsening of pre-existing condition]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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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)	[Acute Kidney Injury]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/7/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [Dehydration]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1087**Subject No:** 10871228**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Respiratory Failure]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/4/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [due to congestive heart failure]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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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)	[Dizziness]
4.	Start Date Time:	Sep/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/8/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [due to UTI]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

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**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hypotension]
4.	Start Date Time:	Sep/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/7/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [due to diuresis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

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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)	[Urinary Tract Infection]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/8/2020 08:08
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [spontaneous]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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**Header Text:** c4591001

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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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 No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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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)	[HYPOKALEMIA]
4.	Start Date Time:	Sep/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/6/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [DUE TO DIURESIS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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**Header Text:** c4591001

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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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)	[WORSENING OF BILATERAL FOOT PAIN]
4.	Start Date Time:	Sep/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/6/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [WORSENING OF PRE-EXISTING CONDITION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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**Form:** ADVERSE EVENT REPORT

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

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

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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)	[LOW-GRADE FEVER]
4.	Start Date Time:	Sep/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/6/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [URINARY TRACT INFECTION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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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)	[PAROXYSMAL ATRIAL Fibrillation]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/8/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [URINARY TRACT INFECTION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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

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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:	[12]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SHORTNESS OF BREATH]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/4/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [CONGESTIVE HEART FAILURE]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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

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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:	[13]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[BILATERAL PULMONARY EDEMA]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/5/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [CONGESTIVE HEART FAILURE]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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

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

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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:	[14]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[DEHYDRATION]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/4/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [DUE TO DIURETICS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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

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**Subject No:** 10871228

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

**Form:** ADVERSE EVENT REPORT

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

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

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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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**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:** 10871228

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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

**Site No:** 1087

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

**Subject No:** 10871228

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1087

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

**Subject No:** 10871228

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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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?	

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**Form:** RADIATION TREATMENT

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

**Site No:** 1087

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**Subject Initials:** ---

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

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#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae4035\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:** 10871228

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**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:** 10871228

**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:** 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:** 10871228

**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?	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

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

**Subject Initials:** ---

**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:** 10871228

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**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:** 10871228

**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:** 10871228

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

**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:** 10871228

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - 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:** 10871228

**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:** Potential ReVax Initial Contact - Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

**Form Status:** Not Started

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**Treatment Unblinded**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

**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:** 10871228

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/16/2020



**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:** 10871228

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

**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:** 10871228

**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	Jan-22-2021 16:16:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Aug-27-2020 08:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** DATE OF VISIT - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-25-2020 10:34:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** DATE OF VISIT - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Sep-25-2020 10:34:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** DATE OF VISIT - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Sep-25-2020 10:34:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2.
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2.a	Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2.a	Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2.a	Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2.
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2.
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2.
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
7	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
8	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
9	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
10	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
11	Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	To update after subject completes Visit 2. Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

**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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Item	Date	User	Comment
3	Nov-06-2020 13:31:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Nov-05-2020 08:29:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
3	Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Nov-05-2020 08:32:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
4	Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5	Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
5	Nov-06-2020 09:06:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
6	Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Nov-06-2020 09:06:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Nov-05-2020 09:00:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject not seen for covid illness visit
			Not Done

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: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Kevin Cannon	Approved	Jan-22-2021 16:16:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-04-2020 11:09:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Kevin Cannon	Approved	Nov-16-2020 12:41:50 (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-09-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Kevin Cannon	Approved	Nov-06-2020 16:45:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001  
**Visit:** Investigator Signature - Unscheduled  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1087  
**Subject No:** 10871228  
**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - Signature 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

**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-06-2020 16:12:15 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
 N/A

Kevin Cannon	Approved	Nov-06-2020 13:42:43 (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-06-2020 11:40:18 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
 N/A

Kevin Cannon	Approved	Nov-06-2020 10:34:03 (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-05-2020 08:07:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**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:** 10871228

**Subject Initials:** ---

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

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

**Affidavit:**

N/A

Kevin Cannon	Approved	Nov-02-2020 17:45:45 (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	Oct-30-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Kevin Cannon	Approved	Oct-21-2020 19:52:30 (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.

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-27-2020 08:47:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:47:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** MAIN INFORMED CONSENT - 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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**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-27-2020 08:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/26/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**I. Subject ID**

Date	Location	User	Value	Reason
Sep-24-2020 05:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event entered in AE CRF
Sep-22-2020 05:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	event removed in SDB data
Sep-22-2020 05:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	event removed in SDB data
Sep-18-2020 06:33:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020359869 SHORTNESS OF BREATH(onset date:03Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-18-2020 06:33:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020359869 BILATERAL PULMONARY EDEMA(onset date:03Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-18-2020 06:32:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020359869 ACUTE ON CHRONIC CONGESTIVE HEART FAILURE(onset date:03Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a

090177e196ae4035\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: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

				follow-up SAE Form.
Aug-27-2020 08:46:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10871228	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-27-2020 08:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) 1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-27-2020 08:47:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-27-2020 08:47:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:47:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae4035\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:** 10871228

**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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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-27-2020 08:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

**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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-27-2020 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-27-2020 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-27-2020 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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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**I.a**

Date	Location	User	Value	Reason
Aug-27-2020 08:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> HYPERTENSIO N <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> YES	Initial Entry

**I.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-27-2020 08:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HYPERTENSION	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-27-2020 08:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-27-2020 08:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Aug-27-2020 08:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> GROUT	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			<b>Start Date:</b>	UNK/UNK/2017
			<b>Ongoing:</b>	YES

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

Date	Location	User	Value	Reason
Aug-27-2020 08:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> GROUT	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-27-2020 08:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-27-2020 08:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Aug-27-2020 08:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> BENIGN PROSTATIC HYPERPLASIA <b>Start Date:</b> Jan/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-27-2020 08:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BENIGN PROSTATIC HYPERPLASIA	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-27-2020 08:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2020	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-27-2020 08:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-27-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 4 <b>ber:</b> <b>Medical Histor</b> CORONARY ARTER <b>y Term:</b> Y DISEASE <b>Start Date:</b> Feb/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Aug-27-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CORONARY ARTERY DISEASE	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Aug-27-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2020	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Oct-05-2020 12:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 11:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Med Hx eCRF updated accordingly. Thank you!
Sep-25-2020 13:43:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: MH to be updated with information related to AE entries
Sep-25-2020 11:49:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: MH to be updated with information related to AE entries
Aug-27-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Oct-05-2020 11:45:36	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	<b>Line/MH Number:</b> 5 <b>Medical History Term:</b> BILATERAL FOOT PAIN <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES
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*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Oct-05-2020 11:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BILATERAL FOOT PAIN	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Oct-05-2020 11:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Oct-05-2020 11:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Oct-05-2020 11:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> CONGESTIVE HEART FAILURE <b>Start Date:</b> Feb/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

**I.f Line/MH Number:**

Date	Location	User	Value	Reason
Oct-05-2020 11:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONGESTIVE HEART FAILURE	Initial Entry

**I.f Start Date:**

Date	Location	User	Value	Reason
Oct-05-2020 11:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2020	Initial Entry

**I.f Ongoing:**

Date	Location	User	Value	Reason
Oct-05-2020 11:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.g**

Date	Location	User	Value	Reason
Oct-05-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History</b> CHRONIC KIDNEY <b>Term:</b> DISEASE <b>Start Date:</b> Feb/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Oct-05-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHRONIC KIDNEY DISEASE	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Oct-05-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2020	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Oct-05-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.h***

Date	Location	User	Value	Reason
Dec-04-2020 11:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> Triple Bypass <b>Start Date:</b> Feb/UNK/2020 <b>Ongoing:</b> NO End Date: Feb/UNK/2020 0	Initial Entry

090177e196ae4035\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: 10871228

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Dec-04-2020 11:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 01:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	duplicated query
Jan-21-2021 01:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINCAL please submit this relevant history of 3-vessel CABG to the SAE medical history section, in a SAE safety update
Dec-04-2020 11:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Triple Bypass	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Dec-04-2020 11:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2020	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Dec-04-2020 11:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Feb/UNK/2020	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 92.5	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 182.9	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.7	Initial Entry

**7.a**

Date	Location	User	Value	Reason
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090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> C <b>Temperature Location</b> ORAL CAVIT <b>::</b> Y	Initial Entry
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-27-2020 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae4035\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:** 10871228

**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
Aug-27-2020 08:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-27-2020 08:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 241392	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871228**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 08:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-27-2020 08:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-27-2020 16:33:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 08:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 08:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/26/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Aug-27-2020 08:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CRC WAS ONLY ABLE TO DRAW 1 OF 3 REQUIRED TUBES DUE TO HA RD STICK AND VEIN BLOWING. PA TIENT REFUSED A SECOND STICK FOR REMAINING 2 TUBES.	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 22-Apr-2020 21:03  
 Site No: 1087  
 Subject No: 10871228  
 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

Aug-27-2020 16:33:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP9ZPJ	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 16:33:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9ZPJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-27-2020 16:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BMRPL1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 16:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMRPL1	Initial Entry

090177e196ae4035\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:** 10871228**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 08:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-27-2020 08:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-27-2020 16:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 08:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 08:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-27-2020 16:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP9ZMG	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 16:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9ZMG	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871228

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
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020 13:02	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae4035\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:** 10871228

**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

Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-27-2020 08:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

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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**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-08-2020 04:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-07-2020 16:21:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As of 30SEP2020 subject is waiting to hear from PCP if they are willing to take part in their second vaccination due to having a recent SAE.
Oct-06-2020 06:24:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.
Oct-05-2020 08:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.
Oct-05-2020 08:25:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Reissued under Candidate status due to site's response is visit has not occurred yet.
Sep-26-2020 07:20:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Previous response states 'pending approval to proceed with Visit 2'. Please update once approval received and visit done. Please respond to the query once data is updated OR it is confirmed that Visit 2 will never be done. Thank you.
Sep-25-2020 10:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject recent hospitalization. Upon review of hospital

090177e196ae4035\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: 10871228

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

				records, subject has now had a change in a pre-existing condition. Pending approval to proceed with Visit 2.
Sep-25-2020 10:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Sep-25-2020 04:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Sep-25-2020 10:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae4035\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: 10871228

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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**I. Date:**

Date	Location	User	Value	Reason
Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Temperature:</b> Not Done <b>Temperature Unit:</b> Not Done <b>Temperature Location::</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-25-2020 10:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae4035\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: 10871228

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-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Sep-25-2020 10:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871228

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-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-10-2020 15:38:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 12:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was discontinued prior to receiving a second injection, no visit 2 performed.
Nov-09-2020 15:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5325515;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871228

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

Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1087

**Subject No:** 10871228

**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

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

Date	Location	User	Value	Reason
Sep-25-2020 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-07-2020 02:35:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	per reason on swab form
Nov-06-2020 13:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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.
Nov-06-2020 04:35:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query present on SWAB
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-05-2020 08:10:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Transcription Error
Nov-05-2020 08:07:38 (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.
Nov-05-2020 08:07:38 (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.
Nov-05-2020 08:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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:** 10871228

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-05-2020 08:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> COVID_A	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Nov-09-2020 12:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 09:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is discontinued from study. DISP FUP completed.
Nov-07-2020 10:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Visit is not erroneous just because it was not performed. Since there's potential COVID-19 symptom reported, a convalescent visit needs to occur. Is the subject discontinued only from treatment or also from study? If from study, please complete DISP FUP
Nov-06-2020 16:16:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Potential COVID illness visit is erroneous so no convalescent visit is scheduled. Should illness visit be deleted in EDC since it was not performed by the site? Subject is now

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

				discontinued as of 9/16/2020.
Nov-06-2020 14:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Subject has completed illness Visit and symptoms are resolved, however corresponding Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Sep/6/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW OR INCREASE D COUGH	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom Present:	NO
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4.b Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom s: NEW OR INCREASED S HORTNESS OF BREATH Symptom YES Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/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

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 08:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-06-2020 19:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 08:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query.
Nov-06-2020 08:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cepheid Xpert Express SARS-CoV-2 test	updated per query.
Nov-06-2020 06:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	As per FDA List of Trade names and CRF CR, data should be updated as Cepheid Xpert Express SARS-CoV-2 test, Kindly update data as requested, else clarify, Thank you. (b) (4)
Nov-05-2020 08:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Xpert Express SARS-CoV-2 test	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1087**Subject No:** 10871228**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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 08:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-05-2020 08:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-06-2020 13:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirming swab was not collected by site or subject. Subject had swab collected by hospital only.
Nov-06-2020 02:29:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM:Per CCG either Nasal Swab Self or Nasal Swab is required to be collected. Kindly verify & update the data as appropriate; else clarify. Thanks
Nov-05-2020 08:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-05-2020 08:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Telehealth visit not performed. Subject did not notify site of symptoms. Site became aware after receiving records for SAE hospitalization	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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: 10871228

Subject Initials: ---

Generated By: (b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-06-2020 13:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-06-2020 13:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-06-2020 15:52:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 13:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Nov-06-2020 13:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-06-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 13:21:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: This form is unfrozen. Please update per query. Thank you.
Nov-06-2020 10:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze
Nov-06-2020 10:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Sample Collected is not expected to be Not Done. If the sample was not collected 'Please mark 'Sample collected' as 'NO' and provide the

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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:** 10871228

**Subject Initials:** ---

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

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

				reason sample was not done in Field #4. Thank you.
Nov-06-2020 08:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please refer to self swab per COVID Illness visit.
Nov-06-2020 02:29:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM:Per CCG either Nasal Swab Self or Nasal Swab is required to be collected. Kindly verify & update the data as appropriate; else clarify. Thanks
Nov-05-2020 08:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-06-2020 13:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Telehealth visit not performed. Subject did not notify site of symptoms. Site became aware after receiving records for SAE hospitalization.	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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*I.a*

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIAL IST <b>Occurrence of Visits or C ontacts:</b>	Initial Entry
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIAL IST <b>Occurrence of Visits or C ontacts:</b>	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENC Y ROOM <b>Occurrence of Visits NO or Contacts:</b>	Initial Entry
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENC Y ROOM <b>Occurrence of Visits or Contacts:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**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
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b>	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b>	Initial Entry

***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***I.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b>	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871228**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***I.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Cont NO acts:</b>	Initial Entry

***I.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***I.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 08:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-05-2020 08:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: HOSPITALIZATION DETAILS - 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: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Nov-05-2020 08:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Nov-05-2020 08:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Nov-09-2020 15:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-09-2020 12:57:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Following up with clinical team.
Nov-09-2020 09:07:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Nov-09-2020 09:07:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry
Nov-07-2020 10:47:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Item incomplete
Nov-06-2020 16:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 16:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	This patient was hospitalized due to chronic diastolic Congestive Heart Failure. Not Covid-19
Nov-06-2020 16:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	This patient was hospitalized due to chronic diastolic

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** HOSPITALIZATION DETAILS - 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:** 10871228

**Subject Initials:** ---

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

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

				Congestive Heart Failure. Not Covid-19
Nov-06-2020 14:03:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (pulse oxymet, respiratory treatment, imaging...). Please make every effort to obtain these information.
Nov-05-2020 08:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Nov-05-2020 08:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date: Sep/8/2020	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 10:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-10-2020 08:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Nov-10-2020 07:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Please apply form level comment NOT APPLICABLE.
Nov-06-2020 15:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 11:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please consider mark this form as Not applicable by selecting form level comment.
Nov-06-2020 09:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 03:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

				Not applicable by selecting form level comment. Thank you.
Nov-05-2020 08:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-10-2020 08:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-06-2020 09:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-06-2020 09:06:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

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-05-2020 08:33:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Nov-05-2020 08:33:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Worsening of chronic congestive heart failure  Date of Diagnosis:  Sep/3/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-05-2020 08:33:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** ILLNESS DETAILS - SEVERE - Audit Trail

**Form Version:** 17-Jul-2020 21:55

**Form Status:**

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-05-2020 08:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

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-05-2020 08:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE COVID-19 ILLNESS	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-05-2020 08:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SIGNIFICANT ACUTE RENAL DYS FUNCTION	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-05-2020 08:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-05-2020 08:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Diagnosis:</i>  acute kidney injury  Start Date:  Sep/3/2020  Ongoing?:  NO  End Date:  Sep/7/2020	New Information
Nov-05-2020 08:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Yes is selected, however, either the diagnosis details or Start date, Ongoing is missing. Please correct.
Nov-05-2020 08:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Start Date:	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

			Sep/3/2020	
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**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-05-2020 08:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

**Form Version:** 21-Aug-2020 02:49

**Form Status:**

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> New Hanover Regional Medical Center Laboratory Services, 2131 S. 17th St., Wilmington, NC 28401	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Protein _PX329 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range</b> :	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
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090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry
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**5.a Test:**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined 28</b> <b>Identifier:</b> <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

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Subject Initials: ---

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX28	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

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Header Text: c4591001

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Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_PX 21 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

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Header Text: c4591001

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Subject No: 10871228

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Subject Initials: ---

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-06-2020 13:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 47 <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 35 mg/dL <b>Not Done::</b> <b>Lab Normal Range:</b> Low 9 High 23 Unit mg/dL	New Information
Nov-06-2020 13:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 47 <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 35 mg/dL <b>Not Done::</b>	New Information

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			<b>Lab Normal Range:</b> <i>Low</i> not displayed  <i>High</i> not displayed	
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 35 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> not displayed  <i>High</i> not displayed	Initial Entry

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Header Text: c4591001

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-06-2020 13:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 13:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-06-2020 13:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 35 mg/dL	New Information
Nov-06-2020 06:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for your response. Please check to update lab normal range (low, high, units) as per available unit.
Nov-05-2020 08:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	lab range and unit are not displayed in hospital records
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 35	Initial Entry

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Header Text: c4591001

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5.f LNMT

Date	Location	User	Value	Reason
Nov-06-2020 13:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 9  <i>High</i> 23  <i>Unit</i> mg/dL	New Information
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> not displaed  <i>High</i> not displayed	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-10-2020 08:02:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Creatinine_P X48 <b>Result::</b> 2.61 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> .70  <i>High</i> 1.30  <i>Unit</i> mg/dL	New Information
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Creatinine_P X48 <b>Result::</b> 2.61 <b>Not Done::</b>	Initial Entry

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			<b>Lab Normal Range:</b> <i>Low</i> not displayed	
			<i>High</i> not displayed	

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-06-2020 09:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 08:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	lab range and unit are not displayed in hospital records
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2.61	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-10-2020 10:08:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 08:02:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-10-2020 08:02:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low .70	New Information

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**Header Text:** c4591001

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**Subject No:** 10871228

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

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**Form Status:** Data Complete, Frozen

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			<i>High</i> 1.30	
			<i>Unit</i> mg/dL	
Nov-10-2020 06:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Low range, high range and unit is missing. Please update, else add comment as UNK.
Nov-05-2020 08:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> not displayed  <i>High</i> not displayed	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Subject Initials: ---

Generated By: (b) (4)

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> New Hanover Regional Medical Center Laboratory Services, 2131 S. 17th St., Wilmington, NC 28401	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-06-2020 13:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobin_PX1 <b>Result::</b> 11.6 g/dL <b>Not Done::</b>	New Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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**Subject No:** 10871228

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Subject Initials:** ---

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			<p><b>Lab Normal Range:</b> <i>Low</i> 13.7</p> <p><i>High</i> 17.5</p> <p><i>Unit</i> g/dL</p>	
Nov-06-2020 13:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Sponsor-Defined Identifier:</b></p> <p><b>Test::</b> Hemoglobin_PX1</p> <p><b>Result::</b> 11.6 g/dL</p> <p><b>Not Done::</b></p> <p><b>Lab Normal Range:</b></p> <p><i>High</i> not displayed</p> <p><i>Unit</i> g/dL</p>	New Information
Nov-06-2020 11:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Sponsor-Defined Identifier:</b></p> <p><b>Test::</b> Hemoglobin_PX1</p> <p><b>Result::</b> 11.6</p> <p><b>Not Done::</b></p> <p><b>Lab Normal Range:</b></p> <p><i>High</i> not displayed</p> <p><i>Unit</i> g/dL</p>	New Information
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<p><b>Data Entry:</b></p> <p><b>Sponsor-Defined Identifier:</b></p> <p><b>Test::</b> Hemoglobin_PX1</p> <p><b>Result::</b> 11.6</p> <p><b>Not Done::</b></p>	Initial Entry

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			<b>Lab Normal Range:</b> <i>Low</i> not displayed  <i>High</i> not displayed	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-06-2020 13:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 13:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11.6 g/dL	New Information
Nov-06-2020 11:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-06-2020 01:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Result is present, but lab normal range (Low, high or Unit) is missing. Please review and update the data else clarify.
Nov-05-2020 08:59:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not displayed on hospital records

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Generated By: (b) (4)

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

Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11.6	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-06-2020 13:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 13.7 <i>High</i> 17.5 <i>Unit</i> g/dL	New Information
Nov-06-2020 11:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>High</i> not displayed <i>Unit</i> g/dL	New Information
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> not displayed <i>High</i> not displayed	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-06-2020 13:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_P X2 <b>Result::</b> 39.5 <b>Not Done::</b>	New Information

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - 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

			<b>Lab Normal Range:</b> <i>Low</i> 40.1 <i>High</i> 51.0 <i>Unit</i> %	
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 2 <b>Test::</b> Hematocrit_P X2 <b>Result::</b> 39.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> not displayed <i>High</i> not displayed	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-06-2020 16:34:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 13:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-06-2020 13:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 39.5	New Information
Nov-06-2020 01:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Result is present, but lab normal range (Low, high or Unit) is missing. Please review and update the data else clarify.
Nov-05-2020 08:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not displayed on hospital records
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 39.5	Initial Entry

5.b LNMT

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-06-2020 13:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.1  <i>High</i> 51.0  <i>Unit</i> %	New Information
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> not displayed  <i>High</i> not displayed	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Erythrocytes_PX3 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-06-2020 13:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5 <b>Result::</b> 200 K/uL <b>Not Done::</b> <b>Lab Normal Range:</b> Low 163 High 369 Unit /uL	Changed Information
Nov-06-2020 13:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5 <b>Result::</b> 200 K/uL <b>Not Done::</b>	New Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - 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

			<b>Lab Normal Range:</b> <i>Low</i> 163 <i>High</i> 369	
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_PX 5 <b>Result::</b> 200 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> not displayed <i>High</i> not displayed	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-06-2020 13:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 13:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-06-2020 13:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 200 K/uL	New Information
Nov-06-2020 08:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for your response. Please check to update lab normal range (low, high, units) as per available unit.
Nov-05-2020 08:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not displayed on hospital records
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 200	Initial Entry

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Header Text: c4591001

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Site No: 1087

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

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Subject Initials: ---

Generated By: (b) (4)

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5.d LNMT

Date	Location	User	Value	Reason
Nov-06-2020 13:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 163  <i>High</i> 369  <i>Unit</i> /uL	Changed Information
Nov-06-2020 13:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 163  <i>High</i> 369	New Information
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> not displayed  <i>High</i> not displayed	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Leukocytes_P X7  <b>Result::</b> <b>Not Done::</b> NOT DONE  <b>Lab Normal Range:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_P X609 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_PX 612 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_PX 610 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

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

**Site No:** 1087

**Subject No:** 10871228

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - 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.j Sponsor ID:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Nov-05-2020 08:58:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 21-Aug-2020 02:50

**Form Status:**

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-06-2020 13:17:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen**Site No:** 1087**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject No:** 10871228**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**I. Date:**

Date	Location	User	Value	Reason
Nov-09-2020 12:53:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-09-2020 09:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Vitals from hospital records as COV illness visit not performed by site.
Nov-09-2020 01:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM1: Please verify and confirm if Vital signs was performed for this visit, else clarify.
Nov-06-2020 15:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 13:17:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 04:03:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Since Vital sign is Not done, kindly update Reason incomplete for form level comment as Not Done from dropdown list.
Nov-05-2020 09:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-06-2020 13:17:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 14 6 <b>Diastolic::</b> 81 <b>Respiratory Rate in respirations /minute:</b> 21 <b>Heart Rate in beats/minute:</b> 53	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

Nov-05-2020 09:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> <b>Diastolic::</b> <b>Respiratory Rate in respirations/minute:</b> <b>Heart Rate in beats/minute:</b>	Initial Entry
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2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-05-2020 09:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-06-2020 16:02:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 13:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It is noted in MH that subject has Hypertension. Due to admission for Respiratory Distress, elevated BP is not abnormal.
Nov-06-2020 13:17:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 146 is outside of Normal Range 90 - 140.
Nov-06-2020 13:17:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 146	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-06-2020 13:17:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 81	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
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090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Sep/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

Nov-06-2020 13:17:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 21	Initial Entry
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**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-06-2020 13:17:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 53	Initial Entry

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: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-06-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-06-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-13-2020 10:06:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Nov-13-2020 09:40:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-13-2020 09:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Nov-13-2020 09:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated per query.
Nov-13-2020 09:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	updated per query.
Nov-13-2020 01:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINQUERY: Please update status to be ADVERSE EVENT in line with the AE, worsening CHF, line entry.
Nov-12-2020 13:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Candidate	CLINQUERY: Please update status to be ADVERSE EVENT in line with the AE,

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<b>Header Text:</b> c4591001				
<b>Visit:</b> End of Treatment - Unscheduled		<b>Form:</b> DISPOSITION - TREATMENT - eCRF Audit Trail History		
<b>Form Version:</b> 15-Sep-2020 21:55		<b>Form Status:</b> Data Complete, Locked, Frozen, Verified		
<b>Site No:</b> 1087		<b>Site Name:</b> (1087) PMG Research of Wilmington, LLC		
<b>Subject No:</b> 10871228		<b>Subject Initials:</b> ---		
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 10:22		
				worsening CHF, line entry.
Nov-12-2020 12:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Nov-12-2020 02:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Per request Worsening of CHF on AE log CRF is unfreeze. Kindly update as appropriate. Thanks
Nov-11-2020 16:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please unfreeze Worsening of CHF on AE log.
Nov-11-2020 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: It appears subject's MH worsened leading to AE entries. If this is how inclusion 3 is no longer met, please review this status to link instead to ADVERSE EVENT (status) and update the AEs involved in the decision to cease Rx (DRUG WITHDRAWN)
Nov-11-2020 06:56:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Candidate	CLINQUERY: It appears subject's MH worsened leading to AE entries. If this is how inclusion 3 is no longer met, please review this status to link instead to ADVERSE EVENT (status) and update the AEs involved in the decision to cease Rx (DRUG WITHDRAWN)
Nov-06-2020 16:21:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is NO LONGER MEETS ELIGIBILITY

**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:** 10871228

**Subject Initials:** ---

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

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

				CRITERIA but "Specify Status" is missing.
Nov-06-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO LONGER MEETS ELIGIBILITY CRITERIA	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Nov-13-2020 09:40:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	updated per query
Nov-13-2020 09:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Worsening of CHF	updated per query
Nov-06-2020 16:21:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> inclusion criteria 3	Initial Entry

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-09-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-09-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-12-2020 13:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-12-2020 12:40:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-12-2020 12:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-12-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Nov-12-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Nov-12-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)



**Header Text:** c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1087**Subject No:** 10871228**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - 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-12-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	Transcription Error
Nov-12-2020 05:31:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: To link the AE event (worsening CHF) to end of study, please update this status to be ADVERSE EVENT
Nov-11-2020 16:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Worsening of CHF is the AE involved. Please unfreeze.
Nov-11-2020 06:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: It appears subject's MH worsened leading to AE entries. If this is how IC3 is no longer met, please review this status to link instead to ADVERSE EVENT (status) and update the AEs involved in decision to end study (Yes, for study discount)
Nov-09-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO LONGER MEETS ELIGIBILITY CRITERIA	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Nov-12-2020 12:40:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-09-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> inclusion criteria 3	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (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 Version:** 22-Apr-2020 21:02

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

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Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Subject No:** 10871228

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Subject No:** 10871228

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

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

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**Subject No:** 10871228

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Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1087

**Subject No:** 10871228

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**Form Status:**

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

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Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

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Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

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**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

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Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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**Header Text:** c4591001

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**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

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Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:**

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

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Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-16-2021 18:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Jan-26-2021 17:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	SAE follow up sent.
Dec-07-2020 02:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	CLINICAL please report the triple bypass (Feb 2020) to the SAE Med Hx section, as SAE safety update
Dec-06-2020 13:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Candidate	CLINICAL please report the triple bypass (Feb 2020) to the SAE Med Hx section, as SAE safety update
Dec-06-2020 13:29:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	move to a non-locked AE location
Nov-23-2020 20:26:55	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:	CLINICAL please report the triple bypass (Yr) to the

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Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Subject Initials: ---

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(UTC-05:00) Eastern Time (US & Canada)			Opened	SAE Med Hx section, a SAE safety update, and add to subject's past Med Hx CRF
Nov-23-2020 14:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Med History states subject had triple bypass and hospital records confirm CABG.
Nov-23-2020 09:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	CLINICAL SAE report (#2020359869) for chest XRAY states subject has sternotomy wires; however, Med history does not include any surgery which requires sternotomy. Please submit the cardio/thoracic surgical procedure for which the wires were place to SAE
Nov-23-2020 04:35:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	FU report has been recorded. Issue = resolved.
Nov-21-2020 17:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Candidate	CLINICAL SAE report (#2020359869) for chest XRAY states subject has sternotomy wires; however, Med history does not include any surgery which requires sternotomy. Please submit the cardio/thoracic surgical procedure for which the wires were place to SAE
Nov-20-2020 03:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Candidate	To confirm with Clinician if required information was provided
Nov-19-2020 16:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SAE follow up report has been sent.
Nov-19-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4:	SAE

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09:08:54 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Opened	RECON:AER#2020359869 , per Clinical review, please provide the diagnostic work-up including imaging, labs and treatment added to the narrative.
Oct-30-2020 21:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-30-2020 21:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-30-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Term has been updated and submitted to safety as well
Oct-30-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Term has been updated and submitted to safety as well
Oct-30-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Worsening of Chronic Congestive Heart Failure	Term has been updated and submitted to safety as well
Oct-26-2020 16:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	Clinical - please submit a SAE safety update now with the information now available on the AE log for AEs that occurred during the hospitalization; further updates may follow
Oct-24-2020 03:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 2: Reissued: Opened	If the reported event is the worsening of reported event on medical history if yes kindly update wording worsening before Acute on Chronic Congestive Heart Failure or else clarify.

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Oct-23-2020 18:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	current term is the discharge diagnosis. We believes that this is interchangeable with "worsening of" as the chronic condition has become acute
Oct-23-2020 18:19:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Current SAE term was discharge dx. Acute on chronic essentially means worsening of. Will send updated SAE report to encompass complications.
Oct-21-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL please submit a SAE safety update for complications occurring during Hosp (Afib, kidney failure, inc HTN, hypotension, dehydration, UTI/fever, dizzy, dec K)
Oct-06-2020 03:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	The AE Acute on Chronic Congestive Heart Failure was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Oct-05-2020 12:51:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 11:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirming Med Hx eCRF updated with CONGESTIVE HEART FAILURE condition.
Sep-28-2020 08:30:00 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued: Opened	CLINQUERY: Confirming MH page is unfrozen and updates can be applied

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(US & Canada)				
Sep-25-2020 10:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject failed to report condition CONGESTIVE HEART FAILURE at V1. Confirmed this condition with hospital records. Please unfreeze Med Hx eCRF and term will be updated.
Sep-24-2020 09:47:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: AE term, and causality entry of 'worsening of pre-existing condition' suggests congestive heart failure is part of MedHx. However, it was not listed at V1. Please clarify if this a new event, or if CHF was part of MH prior to trial.
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute on Chronic Congestive Heart Failure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/8/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

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(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-26-2020 16:12:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with requested COVID test info
Oct-23-2020 18:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	WILL REQUEST FURTHER TEST INFORMATION AND UPDATE EDC AND SAFETY. HOSPITAL RECORD JUST LISTS "COVID-19 NEGATIVE"
Oct-21-2020 10:00:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Please add date for hospital COVID test to SAE report, if known (during hospitalization, so Sept 3 to 8), in a SAE safety update
Sep-24-2020 05:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute on Chronic Congestive Heart Failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO	Initial Entry

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			<p>Did this serious event result in death ?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  worsening of pre-existing condition	Initial Entry

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

Date	Location	User	Value	Reason
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Subject No: 10871228

Generated By: (b) (4)

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Nov-17-2020 08:15:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	action taken updated in SDB. Issue resolved
Nov-16-2020 18:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	Pending SDB update
Nov-16-2020 15:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE follow up report sent 16NOV2020 at 15:33
Nov-16-2020 10:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	SAE RECON 1: Per Confirmation from PSSR no follow up receive indicating update in action taken. Please confirm if follow up AEM form was submitted indicating DRUG WITHDRAWN as the correct action taken.
Nov-14-2020 10:30:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	Pending SDB update
Nov-13-2020 16:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE follow up report submitted.
Nov-13-2020 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_AE001_32

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-13-2020 06:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Op ened	DMW5369594;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Nov-13-2020 04:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	SAE RECON:AER#2020359869,action taken was updated to DRUG WITHDRAWN in AE CRF while NOT APPLICABLE in Safety database.Please confirm correct action taken. If safety update is required, please submit a follow up form
Nov-12-2020 13:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Clo sed	Response satisfies query
Nov-12-2020 12:16:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information
Nov-12-2020 12:16:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : DRU G WI THD RAW N	Changed Information
Nov-12-2020 02:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	CLINQUERY: Per EOT page comment please review the entry on this AE to determine if event contributed to end of treatment decision

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Nov-11-2020 16:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Can didate	CLINQUERY: Per EOT page comment please review the entry on this AE to determine if event contributed to end of treatment decision
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NOT APPL ICAB LE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 13:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-12-2020 12:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-12-2020 12:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Changed Information

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Nov-12-2020 10:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Per FUP tab, please review this field if the Worsening CHF contributed to decision to end study
Sep-23-2020 11:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 05:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020359869	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-16-2021 18:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 17:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE follow up sent.
Nov-23-2020 20:35:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL The event Accelerated HTN is reported; however, SAE report does not include any BP report documenting this event. Please review and submit information pertinent to this event.
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Accelerated Hypertension	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time:  Sep/6/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:	Initial Entry

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Header Text: c4591001

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Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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			worsening of pre-existing condition	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1087**Subject No:** 10871228**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute Kidney Injury	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/7/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

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

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If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 04:11:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	as per the update
Oct-05-2020 11:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE of DEHYDRATION updated in Inform
Sep-24-2020 14:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Dehydration]. Any symptoms, AEs or other key data should be collected on the appropriate page. If this is already in the predefined list above please

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				choose the appropriate value. Please review and update as necessary. (b) (4)
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Dehydration	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	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
Sep-23-2020 11:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Jan-21-2021 01:44:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	oxygen treatment noted in SAE
Nov-23-2020 20:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL The event acute Resp Failure is reported; however, SAE report does not include any report on oxygenation or other observation documenting this event. Please review and submit information pertinent to this event.
Nov-06-2020 00:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-05-2020 09:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	covid illness visit has been updated
Nov-03-2020 21:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Medical monitor: Please regardless of the etiology and despite a Covid-19 visit was not conducted. Please capture all the information available

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				on the potential COVID-19 illness CRF from. Nasal swab not collected
Nov-02-2020 17:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was in hospital due to Acute Chronic Diastolic Congestive Heart Failure and was tested for COVID in the hospital. The test came back negative and the AE was due to hospitalization. Subject was discontinued due to this their hospitalization.
Nov-02-2020 03:01:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Per Prot Sect 8.1, at any time, a participant develops acute respiratory illness (see Section 8.13), for the purposes of the study he or she will be considered to potentially have COVID-19 illness. Please complete the potential COVID-19 CRF forms
Nov-02-2020 00:35:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Candidate	Clin: Per Prot Sect 8.1, at any time, a participant develops acute respiratory illness (see Section 8.13), for the purposes of the study he or she will be considered to potentially have COVID-19 illness. Please complete the potential COVID-19 CRF forms
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute Respiratory Failure	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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Generated By: (b) (4)

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Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/4/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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Subject Initials: ---

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			OTHER  If Other, specify:  due to congestive heart failure	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1087**Subject No:** 10871228**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dizziness	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/8/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

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

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Subject No: 10871228

Generated By: (b) (4)

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Subject Initials: ---

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If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  due to UTI	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



Header Text: c4591001

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-02-2021 21:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 17:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE follow up sent.
Nov-23-2020 20:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL The event Hypotension is reported; however, SAE report does not include any BP report documenting this event. Please review and submit information pertinent to this event.
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypotension	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/2020 UNK:UNK	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time:  Sep/7/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

			due to diuresis	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Subject No: 10871228

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-17-2021 22:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 17:27:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE follow up sent.
Nov-23-2020 20:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL The event UTI is reported; however, SAE report does not include any culture or urine test documenting this event. Please review and submit information pertinent to this event.
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Urinary Tract Infection	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-05-2020 16:58:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

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Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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Oct-05-2020 15:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-05-2020 15:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Transcription Error
Oct-05-2020 14:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Per prior query response, site to review start date of UTI entry
Oct-05-2020 12:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: Per prior query response, site to review start date of UTI entry
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 12:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/8/2020 08:08	Transcription Error
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
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Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**8. Is this adverse event the result of a study Medication Error?**  
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  spontaneous	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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Date	Location	User	Value	Reason
Sep-23-2020 12:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Urinary Tract Infection: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

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Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HYPOKALEMIA	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/4/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/6/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

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

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If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  DUE TO DIURESIS	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

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Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1087**Subject No:** 10871228**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WORSENING OF BILATERAL FOOT PAIN	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/6/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

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

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Generated By: (b) (4)

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If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-05-2020 12:52:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 11:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirming Med Hx eCRF updated with BILATERAL FOOT PAIN condition.
Sep-28-2020 08:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Confirming MH page is unfrozen and updates can be applied
Sep-25-2020 10:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject failed to report condition BILATERAL FOOT PAIN at V1. Confirmed this condition with hospital records. Please unfreeze Med Hx eCRF and term will be updated.
Sep-24-2020 09:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Causality notes 'worsening of pre-existing

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Header Text: c4591001

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Site No: 1087

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Generated By: (b) (4)

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				condition'. However, Bilateral Foot Pain was not reported at medical history of V1. Please review and clarify.
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  WORSENING OF PRE-EXISTING CONDITION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

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

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

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Sep-23-2020 13:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Oct-25-2020 18:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Oct-23-2020 18:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PI FEELS THAT GIVEN THE CLINICAL PICTURE A COVID ILLNESS VISIT WAS NOT INDICATED
Sep-25-2020 18:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per protocol Section 8.1., please COVID-19 listed symptom FEVER should have triggered a potential COVID Illness Visit irrespective of the diagnosis of URINARY TRACT INFECTION. A NASAL SWAB will not be collected, symptom ended- 6Sep2020.
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LOW-GRADE FEVER	Initial Entry

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Header Text: c4591001

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Subject No: 10871228

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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4. Start Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time:  Sep/6/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-26-2020 13:56:33	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)				
Sep-25-2020 10:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to AE#7 "Urinary Tract Infection"
Sep-24-2020 14:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [urinary tract infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. If this is already in the predefined list above please choose the appropriate value. Please review and update as necessary. (b) (4)
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  URINARY TRACT INFECTION	Initial Entry

10. Latest Action Taken with Study Treatment:

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Header Text: c4591001

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Subject No: 10871228

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Sep-23-2020 18:25:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-23-2020 15:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-23-2020 15:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAROXYSMAL AT TRIAL Fibrillation	Transcription Error
Sep-23-2020 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify PAROXYSMAL ATRIAL FIBRILATION as follows. Please confirm if spelling should be PAROXYSMAL ATRIAL FIBRILLATION and edit term. Or further clarify and edit. Thank you.

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Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAROXYSMAL AT RIAL FIBRILATIO N	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/8/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-05-2020 16:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 11:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Start date for AE of URINARY TRACT INFECTION is 03-Sep-2020. Transcription error. Kindly unfreeze the eCRF for AE of URINARY TRACT INFECTION and date will be updated. Thank you!
Sep-26-2020 13:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as relevant Clinical query is present
Sep-25-2020 10:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Related to AE#7 "Urinary Tract Infection"
Sep-24-2020 13:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [urinary tract infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. If this is already in the predefined list

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Header Text: c4591001

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Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

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Subject Initials: ---

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				above please choose the appropriate value. Please review and update as necessary. (b) (4)
Sep-24-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: PAROXYSMAL AF is reported to be due to UTI. However, paroxysmal AF (03Sep20) is reported to start prior to the start of the UTI (05Sep20). Please review.
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  URINARY TRACT INFECTION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Form Status: Data Complete, Frozen

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

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Nov-06-2020 00:11:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-05-2020 09:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	covid illness visit has been updated
Nov-03-2020 21:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	medical monitor: Please regardless of the etiology and despite a Covid-19 visit was not conducted. Please capture all the information available on the potential COVID-19 illness CRF from. Nasal swab not collected
Nov-02-2020 17:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was hospitalized due to Acute Chronic Diastolic Congestive Heart Failure. This SAE was the onset of shortness of breath. A COVID test was performed while the subject was hospitalized and it came back negative. Subject was discontinued do to SAE.

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Nov-02-2020 00:30:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per protocol section 8.13., COVID-19 listed symptom SHORTNESS OF BREATH should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance and captured only on the CRF SOD form
Oct-29-2020 15:05:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI discretion no Potential COVID Illness visit necessary.
Oct-25-2020 18:19:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please complete the potential COVID-19 Illness Visit CRF forms with all information available.
Oct-23-2020 18:26:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT DID NOT REPORT SYMPTOM TO SITE. THIS WAS LEARNED AS THE RESULT OF AN SAE (HOSPITALIZATION). HOSPITAL RECORDS INDICATED THAT SUBJECT WAS TESTED FOR COVID AND WAS NEGATIVE. PI DID NOT FEEL IT WAS NECESSARY TO COLLECT SELF SWAB
Sep-25-2020 18:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per protocol Section 8.1., please COVID-19 listed symptom SHORTNESS OF BREATH should have triggered a potential COVID Illness Visit irrespective of the diagnosis of URINARY TRACT INFECTION. A NASAL SWAB will not be collected, symptom ended-5Sep2020.

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Header Text: c4591001

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Generated By: (b) (4)

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Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SHORTNESS OF BREATH	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/4/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-26-2020 13:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-25-2020 10:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to AE#1: SAE "Acute on Chronic Congestive Heart Failure"
Sep-24-2020 14:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [congestive heart failure]. Any symptoms, AEs or other key data should be collected on the appropriate page. If this is already in the predefined list above please choose the appropriate value. Please review and update as necessary. (b) (4)
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  CONGESTIVE HEART	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

			FAILURE	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BILATERAL PULMONARY EDEMA	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/5/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

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

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-26-2020 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-25-2020 10:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to AE#1: SAE "Acute on Chronic Congestive Heart Failure"
Sep-24-2020 14:12:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [congestive heart failure]. Any symptoms, AEs or other key data should be collected on the appropriate page. If this is already in the predefined

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

				list above please choose the appropriate value. Please review and update as necessary. (b) (4)
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  CONGESTIVE HEART FAILURE	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

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

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

**Subject Initials:** ---

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

Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	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
Sep-23-2020 13:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1087**Subject No:** 10871228**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DEHYDRATION	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/4/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871228

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER  If Other, specify:  DUE TO DIURETICS	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:** Data Complete, Locked, 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-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1087

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

Subject No: 10871228

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-13-2020 09:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	updated per query.
Nov-12-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Nov-09-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Nov-06-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Aug-27-2020 08:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-13-2020 09:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	updated per query.
Nov-12-2020 10:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Transcription Error
Nov-09-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Initial Entry
Nov-06-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Initial Entry
Aug-27-2020 08:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/26/2020	Initial Entry
Aug-27-2020 08:48:26	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1087

**Subject No:** 10871228

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

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

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

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

(autocalc)

Aug/26/2020

090177e196ae4035\Final\Final On: 01-Apr-2021 05:33 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1087

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

**Subject No:** 10871228

**Subject Initials:** ---

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

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 19:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kevin Cannon (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry