

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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 Sep/1/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10871289]
2.	Birth Date:	(b) (6)/1952
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:	

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1087

Subject No: 10871289

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
----	---	----------------

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to Sulfa]
	Start Date:	UNK/UNK/1955
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to Adhesive Tape]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Recurrent Infection of Right Total Knee Replacement]
	Start Date:	Jun/UNK/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tremors]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bipolar Disorder]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/1993
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyponatremia]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Muscle pain]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis - Shoulder]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis - Knee]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES
1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis - ankle]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to vancomycin]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bleeding Ulcer]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hemarthrosis]
	Start Date:	Jan/UNK/2020
	Ongoing:	NO End Date: Jan/UNK/2020
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Inguinal Hernia - Left]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1990
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Inguinal Hernia - Right]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1990

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign Prostate Hyperplasia]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cyst - right testicle]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hospitalization due to bleeding ulcer]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Total Shoulder Arthroplasty]
	Start Date:	Jun/16/2020
	Ongoing:	NO End Date: Jun/16/2020

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Synovectomy - Right Knee]
	Start Date:	Jun/UNK/2020
	Ongoing:	NO End Date: Jun/UNK/2020
1.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Knee arthroplasty - right]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hospitalization due to infection of right knee]
	Start Date:	Jul/UNK/2018
	Ongoing:	NO End Date: Jul/UNK/2018
1.z	Line/MH Number:	[26]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hospitalization due to infection of right knee]
	Start Date:	Aug/UNK/2018
	Ongoing:	NO End Date: Aug/UNK/2018

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.aa	Line/MH Number:	[27]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hospitalization due to infection of right knee]
	Start Date:	Nov/UNK/2018
	Ongoing:	NO End Date: Nov/UNK/2018
1.ab	Line/MH Number:	[28]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hospitalization due to infection of right knee]
	Start Date:	Jan/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.ac	Line/MH Number:	[29]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Knee Arthroplasty - Right]
	Start Date:	Nov/UNK/2019
	Ongoing:	NO End Date: Nov/UNK/2019
1.ad	Line/MH Number:	[30]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Ankle Fusion - Left]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.ae	Line/MH Number:	[31]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hospitalization for left leg compound fracture due to trauma]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.af	Line/MH Number:	[32]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hernia repair - bilateral]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.ag	Line/MH Number:	[33]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Orchiectomy - right testicle]
	Start Date:	Mar/UNK/2018
	Ongoing:	NO End Date: Mar/UNK/2018
1.ah	Line/MH Number:	[34]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[transurethral resection]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.ai	Line/MH Number:	[35]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left leg compound fracture]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/1/2020
2.	Weight:	[128.36]
3.	Unit:	kg
4.	Height:	[172.7]
5.	Unit:	cm
6.	Body Mass Index:	[43.0]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/1/2020
2.	Randomization Number:	[248751]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8BP9]
5.b	Sample ID	[BMRPT4]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8BRL]
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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 15:17
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1087

Subject No: 10871289

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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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

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

2.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM963V]
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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/22/2020 13:31
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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2DY5]
5.b	Sample ID	[BSJ8PR]
5.c	Sample ID	[BSJ8RJ]

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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: 10871289

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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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

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_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

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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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

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: 10871289

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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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/20/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - 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: 10871289

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:	
----	-----------------------	--

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: 10871289

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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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1087

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

Subject No: 10871289

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 Recurrent Infection of Right Total Knee Replacement	Nov/16/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Right Knee Pain	Nov/16/2020 UNK:UNK	NO End Date Time: Nov/24/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Severe Soft Tissue Swelling of Right Lower Extremity	Nov/16/2020 UNK:UNK	NO End Date Time: Nov/24/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Fragmentation of the Patella	Nov/16/2020 UNK:UNK	NO End Date Time: Nov/24/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Cortical Irregularity of medial distal femur	Nov/16/2020 UNK:UNK	NO End Date Time: Nov/24/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Enlarged right inguinal lymph nodes	Nov/16/2020 UNK:UNK	NO End Date Time: Nov/24/2020 UNK:UNK	Repeating Pages

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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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 Recurrent Infection of Right Total Knee Replacement]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020475253]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right Knee Pain]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/24/2020 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 osteoarthritis]

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Severe Soft Tissue Swelling of Right Lower Extemity]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/24/2020 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 infection]

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fragmentation of the Patella]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/24/2020 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 infection]

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cortical Irregularity of medial distal femur]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/24/2020 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 infection]

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Enlarged right inguinal lymph nodes]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/24/2020 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 infection]

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

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Radiation Treatment

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

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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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: 10871289

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: 10871289

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: 10871289

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?	

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

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: 10871289

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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

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: 10871289

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: 10871289

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: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/21/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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 :	//
----	------------------------------	----

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Kevin Cannon	Approved	Mar-04-2021 11:37:49 (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.

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1087

Subject No: 10871289

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 17:12:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Kevin Cannon	Approved	Mar-04-2021 11:37:49 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-10-2021 16:38:03 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Kevin Cannon	Approved	Jan-25-2021 11:02:49 (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	Jan-25-2021 10:44:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Kevin Cannon	Approved	Jan-22-2021 16:29:36 (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	Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Kevin Cannon	Approved	Oct-30-2020 11:27:32 (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.

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1087

Subject No: 10871289

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
Sep-01-2020 17:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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
Sep-01-2020 17:11:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1087

Subject No: 10871289

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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1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 17:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10871289	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1952	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 17:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-01-2020 17:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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: ---

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 17:12:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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
Sep-01-2020 17:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 17:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 17:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

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1.a

Date	Location	User	Value	Reason
Sep-01-2020 17:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Allergy to Sulfa Start Date: UNK/UNK/1955 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergy to Sulfa	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1955	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

Date	Location	User	Value	Reason
Sep-01-2020 17:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor Allergy to Adhes y Term: ive Tape Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergy to Adhesive Tape	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-01-2020 17:21:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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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Time (US & Canada)			Medical History Term:	Insomnia
			Start Date:	UNK/UNK/2000
			Ongoing:	YES

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Insomnia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Feb-10-2021 16:38:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4 Medical History Term: Chronic Recurrent Infection of Right Total Knee Replacement	updated per query.

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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			Start Date: Jun/UNK/2018 Ongoing: YES	
Sep-01-2020 17:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Bacterial Infection - Leg, Right Start Date: Jun/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1087

Subject No: 10871289

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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I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 12:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 16:38:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query.
Feb-10-2021 16:38:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Recurrent Infection of Right Total Knee Replacement	updated per query.
Feb-03-2021 10:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please clarify if this is the same condition as referenced in the AE "Chronic Recurrent Infection of Right Total Knee Replacement" and update term accordingly so consistent terms are used.
Sep-01-2020 17:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bacterial Infection - Leg, Right	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/UNK/2018	Initial Entry

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Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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I.d Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 14:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-03-2020 15:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per patient verbal, since ongoing.
Sep-02-2020 11:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Please confirm that bacterial infection - leg right is ongoing since 2018/06/UNK.
Sep-01-2020 17:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-01-2020 17:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History T Tremors erm: Start Date: UNK/UNK/2 005 Ongoing: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

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Site No: 1087

Subject No: 10871289

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.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tremors	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-01-2020 17:23:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Bipolar Disorder Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Subject Initials: ---

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1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:23:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bipolar Disorder	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2009	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Sep-01-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Hypercholesterolemia Start Date: UNK/UNK/1993 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1087

Subject No: 10871289

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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1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypercholesterolemia	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1993	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Sep-01-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: GERD Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1087

Subject No: 10871289

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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1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: GERD	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Sep-01-2020 17:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Hyponatremia Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10871289

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

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1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyponatremia	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-01-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History T Muscle pain erm: Start Date: UNK/UNK/2 018 Ongoing: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

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Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Subject Initials: ---

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle pain	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.k

Date	Location	User	Value	Reason
Sep-01-2020 17:27:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 11 er: Medical History Osteoarthritis - S Term: houlder Start Date: UNK/UNK/1986 Ongoing: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

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Subject No: 10871289

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

Subject Initials: ---

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

I.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:27:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:27:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis - Shoulder	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:27:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1986	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:27:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.l

Date	Location	User	Value	Reason
Sep-01-2020 17:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: Osteoarthritis - Knee Start Date: UNK/UNK/198 6 Ongoing: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

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Subject No: 10871289

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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-01-2020 17:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis - Knee	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1986	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Feb-22-2021 15:11:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number 13 r: Medical History Osteoarthritis - Term: ankle Start Date: UNK/UNK/19 86 Ongoing: YES	Transcription Error
Sep-01-2020 17:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 13 :	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

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			Medical History Term: Start Date: UNK/UNK/1986 Ongoing: YES
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I.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:11:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis - ankle	Transcription Error
Sep-01-2020 17:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1986	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Feb-22-2021 10:51:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 14	Initial Entry

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Subject No: 10871289

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

Time (US & Canada)			er: Medical History Allergy to vanco Term: mycin Start Date: Jan/UNK/2020 Ongoing: YES
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1.n Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 10:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 10:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergy to vancomycin	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 10:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 10:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Feb-22-2021 15:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 15 r: Medical History Bleeding Ulcer Term:	Initial Entry

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Header Text: c4591001

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Subject No: 10871289

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

			Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	
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I.o Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding Ulcer	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.p

Date	Location	User	Value	Reason
Feb-22-2021 15:12:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 16	Initial Entry

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Site No: 1087

Subject No: 10871289

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

Time (US & Canada)			:	
			Medical History Term:	Hemarthrosis
			Start Date:	Jan/UNK/2020
			Ongoing:	NO
			End Date:	Jan/UNK/2020

1.p Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemarthrosis	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/UNK/2020	Initial Entry

1.q

Date	Location	User	Value	Reason
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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

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Subject No: 10871289

Generated By: (b) (4)

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

Subject Initials: ---

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

Feb-22-2021 15:14:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 17 er: Medical History Inguinal Hernia Term: - Left Start Date: UNK/UNK/1989 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry
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1.q Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:14:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:14:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inguinal Hernia - Left	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:14:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:14:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

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Header Text: c4591001

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Site No: 1087

Subject No: 10871289

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

L.r

Date	Location	User	Value	Reason
Feb-22-2021 15:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 er: Medical History Inguinal Hernia - Term: Right Start Date: UNK/UNK/1989 Ongoing: NO End Date: UNK/UNK/1 990	Initial Entry

L.r Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

L.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Feb-22-2021 15:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inguinal Hernia - Right	Initial Entry

L.r Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

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1.r Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

1.s

Date	Location	User	Value	Reason
Feb-22-2021 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 19 mber: Medical Histo Benign Prostate H ry Term: yperplasia Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2013	Initial Entry

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Subject Initials: ---

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

I.s Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Benign Prostate Hyperplasia	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2013	Initial Entry

I.t

Date	Location	User	Value	Reason
Feb-22-2021 15:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 20 r: Medical History Term: Cyst - right testicle Start Date: UNK/UNK/2018	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

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			Ongoing:	NO End Date: UNK/UNK/ 2018
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1.t Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cyst - right testicle	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

1.u

Date	Location	User	Value	Reason
Feb-22-2021 15:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu mber: 21	Initial Entry

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			Medical History Term: Hospitalization due to bleeding ulcer Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	
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I.u Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospitalization due to bleeding ulcer	Initial Entry

I.u Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.u Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.v

Date	Location	User	Value	Reason
Mar-01-2021 11:18:29 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Nu 22	Transcription Error

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Header Text: c4591001

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

Time (US & Canada)		(b) (4), (b) (6)	mber: Medical History Term: Total Shoulder Arthroplasty Start Date: Jun/16/2020 Ongoing: NO End Date: Jun/16/2020	
Feb-22-2021 15:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 22 mber: Medical History Term: Total Shoulder Arthroplasty Start Date: Jun/16/2020 Ongoing: YES	Initial Entry

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Header Text: c4591001

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

I.v Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Total Shoulder Arthroplasty	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/16/2020	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Mar-02-2021 10:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 11:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-01-2021 11:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jun/16/2020	Transcription Error
Mar-01-2021 01:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Total Shoulder Arthroplasty is noted from 16Jun2020 to ongoing. However, this is a procedure and should only be 1

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

				day in duration. Please confirm the END DATE and update the CRF as appropriate
Feb-24-2021 11:30:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Total Shoulder Arthroplasty is noted from 16Jun2020 to ongoing. However, this is a procedure and should only be 1 day in duration. Please confirm the END DATE and update the CRF as appropriate
Feb-22-2021 15:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.w

Date	Location	User	Value	Reason
Feb-22-2021 15:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 23 Medical History Term: Synovectomy - Right Knee Start Date: Jun/UNK/2020 Ongoing: NO End Date: Jun/UNK/2020	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.w Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Synovectomy - Right Knee	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/UNK/2020	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jun/UNK/2020	Initial Entry

I.x

Date	Location	User	Value	Reason
Feb-22-2021 15:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Num 24 ber: Medical Histor Knee arthroplast y Term: y - right Start Date: UNK/UNK/2016	Transcription Error

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

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

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			Ongoing: NO End Date: UNK/UNK/2016	
Feb-22-2021 15:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 24 r: Medical History Term: Knee arthroplasty Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.x Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Knee arthroplasty - right	Transcription Error
Feb-22-2021 15:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Knee arthroplasty	Initial Entry

I.x Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.x Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

I.y

Date	Location	User	Value	Reason
Feb-22-2021 15:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 25 Number: Medical Hi Hospitalization due to story Term infection of right knee : Start Date: Jul/UNK/2018	Initial Entry

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1087**Subject No:** 10871289**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

			Ongoing: NO End Date: Jul/UNK/2018	
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I.y Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospitalization due to infection of r ight knee	Initial Entry

I.y Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2018	Initial Entry

I.y Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/UNK/2018	Initial Entry

I.z

Date	Location	User	Value	Reason
Feb-22-2021 15:31:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 26 Number:	Initial Entry

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Subject No: 10871289

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			Medical Hi Hospitalization due to story Term infection of right knee : Start Date: Aug/UNK/2018 Ongoing: NO End Date: Aug/UNK/2018	
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1.z Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:31:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:31:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospitalization due to infection of r ight knee	Initial Entry

1.z Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:31:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/UNK/2018	Initial Entry

1.z Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:31:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Aug/UNK/2018	Initial Entry

1.aa

Date	Location	User	Value	Reason
Feb-22-2021 15:31:36	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: c4591001

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Subject No: 10871289

Generated By: (b) (4)

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Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH 27 Number: Medical Hi Hospitalization due to story Term infection of right knee : Start Date: Nov/UNK/2018 Ongoing: NO End Date: Nov/UNK/2018	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10871289

Generated By: (b) (4)

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Subject Initials: ---

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1.aa Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospitalization due to infection of r ight knee	Initial Entry

1.aa Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/UNK/2018	Initial Entry

1.aa Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Nov/UNK/2018	Initial Entry

1.ab

Date	Location	User	Value	Reason
Feb-22-2021 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 28 Number: Medical Hi Hospitalization due to story Term infection of right knee : Start Date: Jan/UNK/2019	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1087**Subject No:** 10871289**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

			Ongoing: NO End Date: UNK/UNK/2019	
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1.ab Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospitalization due to infection of r ight knee	Initial Entry

1.ab Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2019	Initial Entry

1.ab Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

1.ac

Date	Location	User	Value	Reason
Feb-22-2021 15:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 29 ber: Medical Histor Knee Arthroplast y Term: y - Right	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1087

Subject No: 10871289

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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			Start Date: Nov/UNK/2019 Ongoing: NO End Date: Nov/UNK/2019 9	
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I.ac Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Knee Arthroplasty - Right	Initial Entry

I.ac Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/UNK/2019	Initial Entry

I.ac Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Nov/UNK/2019	Initial Entry

I.ad

Date	Location	User	Value	Reason
Feb-22-2021 15:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 30	Initial Entry

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Header Text: c4591001

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Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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			Medical History Ankle Fusion - Term: Left Start Date: UNK/UNK/201 4 Ongoing: NO End Date: UNK/UNK/ 2014	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.ad Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 17:20:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 10:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This was due to osteoarthritis of the ankle
Feb-25-2021 02:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Per CRF completion requirements (8.7), please document the condition or diagnosis that led to the surgery/procedure as a separate MH entry.
Feb-24-2021 17:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Per CRF completion requirements (8.7), please document the condition or diagnosis that led to the surgery/procedure as a separate MH entry.
Feb-22-2021 15:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Ankle Fusion - Left	Initial Entry

I.ad Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:33:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	UNK/UNK/2014
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1.ad Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

1.ae

Date	Location	User	Value	Reason
Mar-02-2021 13:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M H Numb er: Medical History Hospitalization for left leg compound fracture Term: due to trauma Start Date: UNK/UNK/2009 Ongoing NO : End Date: UNK/UNK/2009	New Information
Feb-22-2021 15:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 31 Medical History Term: Hospitalization due to left leg compound fracture Start Date: UNK/UNK/2009 e: Ongoing: NO End Date: UNK/UNK/2009	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.ae Line/MH Number:

Date	Location	User	Value	Reason
Mar-03-2021 09:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-03-2021 08:56:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-02-2021 17:08:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery2: Thanks for responding. This CRF is unfrozen. Please update as appropriate.
Mar-02-2021 13:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze Medical History.
Feb-25-2021 02:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Hospitalization due to Left Leg Compound Fracture is noted. However, the Fracture is not listed as a separate entry. Please consider adding the compound fracture as a separate MH entry as appropriate.
Feb-24-2021 17:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Hospitalization due to Left Leg Compound Fracture is noted. However, the Fracture is not listed as a separate entry. Please consider adding the compound fracture as a separate MH entry as appropriate.
Feb-22-2021 15:35:22	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

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Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-03-2021 09:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-03-2021 08:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated; "due to trauma" added and a separate entry made for "Left leg compound fracture"
Mar-02-2021 17:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery2: Thanks for responding. This CRF is unfrozen. Please update as appropriate.
Mar-02-2021 13:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospitalization for left leg compound fracture due to trauma	New Information
Mar-02-2021 13:23:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze.
Feb-25-2021 02:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please clarify if there was any underlying medical condition to this Left Leg Compound fracture, or if due to trauma. If there is a corresponding medical condition please add to the MH listing as a separate entry.
Feb-24-2021 17:17:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Please clarify if there was any underlying medical condition to

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

				this Left Leg Compound fracture, or if due to trauma. If there is a corresponding medical condition please add to the MH listing as a separate entry.
Feb-22-2021 15:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospitalization due to left leg compound fracture	Initial Entry

I.ae Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2009	Initial Entry

I.ae Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

I.af

Date	Location	User	Value	Reason
Feb-22-2021 15:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 32 Medical History: Hernia repair - bilateral Term: lateral Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.af Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hernia repair - bilateral	Initial Entry

1.af Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.af Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

1.ag

Date	Location	User	Value	Reason
Feb-22-2021 15:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 33 ber: Medical Histo Orchiectomy - rig ry Term: ht testicle Start Date: Mar/UNK/2018	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

				Ongoing: NO End Date: Mar/UNK/2018
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1.ag Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Orchiectomy - right testicle	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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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1.ag Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/UNK/2018	Initial Entry

1.ag Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/UNK/2018	Initial Entry

1.ah

Date	Location	User	Value	Reason
Feb-22-2021 15:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 34 er: Medical History transurethral res Term: ection Start Date: UNK/UNK/201 3 Ongoing: NO End Date: UNK/UNK/2 013	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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.ah Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 15:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 15:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: transurethral resection	Initial Entry

1.ah Start Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.ah Ongoing:

Date	Location	User	Value	Reason
Feb-22-2021 15:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2013	Initial Entry

1.ai

Date	Location	User	Value	Reason
Mar-02-2021 13:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 35 ber: Medical Histor Left leg compound y Term: fracture Start Date: UNK/UNK/2009	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

			Ongoing: NO End Date: UNK/UNK/2009	
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1.ai Line/MH Number:

Date	Location	User	Value	Reason
Mar-02-2021 13:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 13:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left leg compound fracture	Initial Entry

1.ai Start Date:

Date	Location	User	Value	Reason
Mar-02-2021 13:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2009	Initial Entry

1.ai Ongoing:

Date	Location	User	Value	Reason
Mar-02-2021 13:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871289

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
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 128.36	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 172.7	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 43.0	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1087

Subject No: 10871289

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

7.a

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Locat ion:: ORAL CAVI TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 17:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-01-2020 17:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 248751	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 17:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 17:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-02-2020 18:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 07:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-02-2020 18:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8BP9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 18:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BP9	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 18:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMRPT4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 18:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMRPT4	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 17:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 17:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-02-2020 18:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 07:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-02-2020 18:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8BRL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 18:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BRL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 15:17	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871289

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

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:15:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1087

Subject No: 10871289

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
Sep-01-2020 17:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIA RY 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: 10871289

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
Sep-23-2020 10:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-23-2020 10:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 10:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.8 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 10:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 10:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 10:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-23-2020 10:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 10:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 10:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 18:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 10:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 10:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 18:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM963V	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (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: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 18:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM963V	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 13:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1087

Subject No: 10871289

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

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 10:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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-22-2020 18:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 18:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-22-2020 18:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-25-2020 13:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-24-2020 04:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 18:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 18:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-25-2020 13:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR2DY5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 13:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR2DY5	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-25-2020 13:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ8PR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 13:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJ8PR	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-25-2020 13:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ8RJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 13:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSJ8RJ	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - 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
Oct-22-2020 18:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 18:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 18:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (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: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (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: 10871289

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
Dec-02-2020 10:39:09 (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: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (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: 10871289

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
Dec-02-2020 10:42:00 (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: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-16-2021 07:58:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed per data updated
Feb-15-2021 11:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Data clarification
Feb-15-2021 11:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry: Worsenin g of Chro nic Recurr ent Infecti on of Rig ht Total K nee Repla cement	Data clarification
Feb-15-2021	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD	Query 2:	The AE Chronic

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

<p>05:01:08 (UTC-05:00) Eastern Time (US & Canada)</p>		(b) (4)	Opened	<p>Recurrent Infection of Right Total Knee Replacement 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)</p>
<p>Feb-03-2021 10:39:06 (UTC-05:00) Eastern Time (US & Canada)</p>	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	<p>GPD CLINQUERY: Closing AE query and re-issuing against specific Med His condition.</p>
<p>Dec-03-2020 14:20:59 (UTC-05:00) Eastern Time (US & Canada)</p>	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	<p>GPD CLINQUERY: As the nature of the event is chronic & recurrent, please confirm if prior medical history of same and update Medical History page as appropriate.</p>

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Recurrent Infection of Right Total Knee Replacement	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-11-2020 09:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

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				test info
Dec-09-2020 11:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE safety follow up faxed.
Dec-06-2020 11:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical – Thank you. While awaiting additional records, please submit 'Awaiting Med Records to Determine if COVID testing was Performed' as a SAE safety followup.
Dec-04-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	unknown. Records have been requested.
Dec-04-2020 05:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-02-2020 16:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2020475253] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Chronic Recurrent Infection of Right Total Knee Replacement: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1087**Subject No:** 10871289**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1087) PMG Research of Wilmington, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <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>	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
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: NO</p>	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: Worsening of Pre-existing c ondition	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 05:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 16:38:10 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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Subject No: 10871289

Generated By: (b) (4)

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Eastern Time (US & Canada)				
Dec-04-2020 16:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Transcription Error
Dec-04-2020 05:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020475253,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RES OLVING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-04-2020 05:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020475253	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right Knee Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-09-2020 12:55:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 16:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-08-2020 16:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: worsening of osteoarthritis	Changed Information

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Dec-03-2020 14:07:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: When recording AE, medical terminology must be consistent for re-occurrence of the same event. Please clarify which pre-existing medical condition relates to AE (e.g. worsening osteoarthritis - knee) and update term or MedHx accordingly.
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> worsening of pre-existing condition	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Severe Soft Tissue Swelling of Right Lower Extremity	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-04-2020 13:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 11:38:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-04-2020 11:38:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: due to infection	Transcription Error

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Dec-03-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: When recording AE, medical terminology must be consistent for re-occurrence of the same event. Please clarify which pre-existing medical condition relates to AE and update term or Med History accordingly.
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Worsening of pre-existing condition	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fragmentation of the Patella	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-04-2020 14:00:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 11:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-04-2020 11:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: due to infection	Transcription Error

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Subject Initials: ---

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Dec-03-2020 14:12:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: When recording AE, medical terminology must be consistent for re-occurrence of the same event. Please clarify which pre-existing medical condition relates to AE and update term or MedHx accordingly.
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Worsening of pre-existing condition	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cortical Irregularity of medial distal femur	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-04-2020 14:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 11:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-04-2020 11:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: due to infection	Transcription Error

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

Dec-03-2020 14:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: When recording AE, medical terminology must be consistent for re-occurrence of the same event. Please clarify which pre-existing medical condition relates to AE and update term or MedHx accordingly.
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> worsening of pre-existing condition	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Enlarged right inguinal lymph no des	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1087

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

Subject No: 10871289

Subject Initials: ---

Generated By: (b) (4)

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

Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-04-2020 14:02:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 11:35:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-04-2020 11:35:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: due to infection	Transcription Error

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

Dec-03-2020 14:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: When recording AE, medical terminology must be consistent for re-occurrence of the same event. Please clarify which pre-existing medical condition relates to the AE and update term or MedHx accordingly.
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> worsening of pre-existing condition	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1087

Subject No: 10871289

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

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

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1087

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

Subject No: 10871289

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
Jan-25-2021 10:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Jan-25-2021 10:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible and NOT confirmed to h ave received only placebo at Vac cination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-25-2021 02:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-24-2021 15:41:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Site misunderstood which date was being used as the un-blinding date. Date has been corrected to the date the subject was unblinded.
Feb-24-2021 15:41:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Jan/21/2021	Site misunderstood which date was being used as the un-blinding date. Date has been corrected to the date the subject was unblinded.
Feb-23-2021 07:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7351962;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-25-2021 10:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Jan/15/2021	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-25-2021 10:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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I. Subject Status

Date	Location	User	Value	Reason
Oct-22-2020 18:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 17:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 17:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-03-2020 15:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-02-2020 09:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-02-2020 09:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020475253 chronic recurrent infection of right total knee replacement(onset date:16Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a ffup form
Oct-22-2020 18:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Initial Entry

090177e196ae403c\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1087

Subject No: 10871289

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

Sep-01-2020 17:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
Sep-01-2020 17:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

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: 10871289

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-30-2020 11:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kevin Cannon (b) (4)	Data Entry: Click Here to Enable	Initial Entry