

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/24/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11341153]
2.	Birth Date:	(b) (6) /1976
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/24/2020
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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[breast cancer]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergic rhinitis]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Attention deficit hyperactivity disorder]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[post menopausal]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1993
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1993
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral mastectomy]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral mastectomy]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholecystectomy]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillectomy]
	Start Date:	UNK/UNK/1993
	Ongoing:	NO End Date: UNK/UNK/1993

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/24/2020
2.	Weight:	[127.0]
3.	Unit:	LB
4.	Height:	[61.5]
5.	Unit:	in
6.	Body Mass Index:	[23.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

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

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/24/2020
2.	Randomization Number:	[64342]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BP1L04]
5.b	Sample ID	[BP1L05]
5.c	Sample ID	[BP1L06]
5.d	Sample ID	[BPHC7N]
5.e	Sample ID	[BPHC7P]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BP1KXC]
-----	-----------	----------

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/24/2020 16:10
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

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

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

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
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	[BM915P]
-----	-----------	----------

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Vaccination

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

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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	[BRBYCJ]
5.b	Sample ID	[BLG04H]
5.c	Sample ID	[BLG06J]

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
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	[BS1HNN]
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/12/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/12/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/12/2021
2.	Date of First Symptom Started:	Jan/10/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/15/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/12/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Symptoms - Other

5.a	Symptoms - Other Text:	[headache]
5.b	Symptoms - Other Text:	[runny nose]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Microbiology Specimen

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

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/12/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
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	[CV16623]
-----	-----------	-----------

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/12/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SUBJECT DID THE SELF SWAB]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/12/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/12/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/12/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/12/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/12/2021

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Lab Chemistry Details

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

Lab Result

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

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/12/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/12/2021

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/12/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/12/2021

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/12/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Concomitant Medications

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

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Jan/12/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Feb/09/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/09/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
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	[BRBC5M]
5.b	Sample ID	[BSMSHG]
5.c	Sample ID	[BSMSKN]

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Aug/25/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	headache	Aug/25/2020 UNK: UNK	NO End Date Time: Aug/25/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	diarrhea	Aug/25/2020 UNK: UNK	NO End Date Time: Aug/25/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	headache	Aug/25/2020 UNK: UNK	NO End Date Time: Aug/25/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	right eye pain	Aug/25/2020 UNK: UNK	NO End Date Time: Sep/21/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	muscle weakness	Aug/25/2020 UNK: UNK	NO End Date Time: Sep/21/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	fatigue	Aug/25/2020 UNK: UNK	NO End Date Time: Sep/21/2020 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	upset stomach	Aug/25/2020 UNK: UNK	NO End Date Time: Sep/21/2020 UNK:UNK	Repeating Pages
8.	ADVERSE EVENT	8	loose stools	Aug/25/2020 UNK: UNK	NO End Date Time: Sep/21/2020 UNK:UNK	Repeating Pages

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/25/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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)	[diarrhea]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/25/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
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

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Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

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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)	[right eye pain]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN

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Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

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)	[muscle weakness]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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

Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fatigue]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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

Header Text: c4591001

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Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[upset stomach]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
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

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[loose stools]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Medication Error

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Concomitant Medications

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

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Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

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Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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?	

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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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/15/2021
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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/15/2021
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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Aug/25/2020

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	--------------------------------------

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jonathan Wilson	Approved	Mar-11-2021 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JonathanWilson, 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.

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Aug-24-2020 19:11:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
2	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
5	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
6.a	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
6.a	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
6.a	Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
2	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
5	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
6.a	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
6.a	Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
2	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
4	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
5	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
6	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
7	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
8	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
9	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
10	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
11	Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject refused 2nd of vaccination due to AE's
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
2	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
5	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
6	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
7	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
8	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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Item	Date	User	Comment
9	Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jonathan Wilson	Approved	Mar-11-2021 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JonathanWilson, 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	Mar-10-2021 20:13:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Mar-01-2021 15:53:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, JonathanWilson, 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-17-2021 13:35:07 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Jonathan Wilson	Approved	Feb-12-2021 11:51:39 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, Jonathan Wilson, 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-09-2021 16:39:18 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Jan-21-2021 16:13:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, Jonathan Wilson, 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-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Jan-15-2021 16:42:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Affidavit:

By my dated signature below, I, JonathanWilson, 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-14-2021 17:28:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Nov-17-2020 20:34:39 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-17-2020 18:43:54 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Nov-11-2020 13:11:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Affidavit:

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

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

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

(b) (6)	N/A	Nov-11-2020 12:56:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Oct-27-2020 16:19:10 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, JonathanWilson, 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.

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-24-2020 19:09:48 (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
Aug-24-2020 19:09:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-24-2020 19:10:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtain ed Aug/24/2020	Initial Entry

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Aug-24-2020 19:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-24-2020 19:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11341153	New Information
Aug-24-2020 19:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Subject ID is expected to be in 8 digits. Please review.
Aug-24-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 134115	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1976	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-24-2020 19:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-24-2020 19:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO (A) OR OF SPANISH ORIGI N	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Aug-24-2020 19:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-24-2020 19:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-24-2020 19:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-24-2020 19:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-24-2020 19:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-24-2020 19:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History breast cancer Term: Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/ 2017	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 19:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: breast cancer	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Aug-24-2020 19:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry
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1.b

Date	Location	User	Value	Reason
Aug-24-2020 19:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: anxiety Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 19:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> anxiety	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2000	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-24-2020 19:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 3 : Medical History Term: allergic rhinitis Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:18:32 (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
Aug-24-2020 19:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: allergic rhinitis	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-25-2020 16:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 4 Number: Medical Hi Attention deficit h story Term yperactivity disor : der Start Date: UNK/UNK/2000 Ongoing: YES	Transcription Error
Aug-24-2020 19:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			Number:	
			Medical History Term: Attention deficit hyperactivity disorder	
			Start Date: UNK/UNK/2020	
			Ongoing: YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 19:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Attention deficit hyperactivity disorder	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 16:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 16:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2000	Transcription Error
Aug-24-2020 19:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 24/Aug/2020. Please review and update as appropriate.
Aug-24-2020 19:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2020	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.e

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Aug-24-2020 19:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History Term: post menopausal Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 19:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: post menopausal	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.f

Date	Location	User	Value	Reason
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

<p>Aug-26-2020 08:49:41 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b)(6)</p>	<p>Data Entry: Line/MH Number: 6 Medical History Term: tonsillitis Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1993</p>	<p>Transcription Error (DELETED)</p>
<p>Aug-24-2020 19:22:51 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Number: 6 Medical History Term: tonsillitis Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1993</p>	<p>Initial Entry</p>

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

If Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 08:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> 6	Transcription Error (DELETED)
Aug-24-2020 19:22:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 08:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> tonsillitis	Transcription Error (DELETED)
Aug-24-2020 19:22:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> tonsillitis	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 08:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> UNK/UNK/1990	Transcription Error (DELETED)
Aug-24-2020 19:22:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1990	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 08:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> NO End Date: UNK/UNK/1993	Transcription Error (DELETED)
Aug-24-2020 19:22:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			UNK/UNK/1993	
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I.g

Date	Location	User	Value	Reason
Aug-24-2020 19:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History: tonsillitis Term: Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/ 1993	Initial Entry

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Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 16:36:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-26-2020 08:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Duplicate entry delted.
Aug-25-2020 20:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN - TONSILLITIS is reported twice with the same dates. Please review and if a duplication, please update.
Aug-24-2020 19:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> tonsillitis	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1990	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: UNK/UNK/1993	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

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Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.h

Date	Location	User	Value	Reason
Aug-24-2020 19:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 er: Medical History Term: bilateral mastectomy Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/ 2017	Initial Entry

I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 19:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral mastectomy	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1.h Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-26-2020 08:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Line/MH Number: 9 Medical History Term: bilateral mastectomy Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	Transcription Error (DELETED)
Aug-24-2020 19:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: bilateral mastectomy Start Date: UNK/UNK/2017	Initial Entry

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Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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			Ongoing:	NO	
				End Date:	
				UNK/UNK/ 2017	

Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 08:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> 9	Transcription Error (DELETED)
Aug-24-2020 19:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 08:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> bilateral mastectomy	Transcription Error (DELETED)
Aug-24-2020 19:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> bilateral mastectomy	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 08:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2017	Transcription Error (DELETED)
Aug-24-2020 19:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2017	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 08:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: UNK/UNK/2017	Transcription Error (DELETED)
Aug-24-2020 19:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:	Initial Entry

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Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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			UNK/UNK/2017	
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I,j

Date	Location	User	Value	Reason
Aug-24-2020 19:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History: cholecystectomy Term: y Start Date: UNK/UNK/2008 Ongoing: NO End Date: UNK/UNK/2008	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 19:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cholecystectomy	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2008	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2008	Initial Entry

I.k

Date	Location	User	Value	Reason
Aug-24-2020 19:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: tonsillectomy Start Date: UNK/UNK/1993	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			Ongoing:	NO	
				End Date:	
				UNK/UNK/ 1993	

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 19:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tonsillectomy	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1993	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 19:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1993	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 127.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 61.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.6	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 98.5 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (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
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 19:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry Not Appli cable Not Appli cable Not Appli cable Not Appli cable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-24-2020 19:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-24-2020 19:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-24-2020 19:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 64342	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-25-2020 07:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 07:49:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BP1L04	Changed Information

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Aug-25-2020 07:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BP1KXD	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:49:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BP1L04	Changed Information
Aug-25-2020 07:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BP1KXD	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-25-2020 07:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BP1L05	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BP1L05	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 07:49:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BP1L06	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:49:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BP1L06	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.d

Date	Location	User	Value	Reason
Aug-25-2020 07:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPHC7N	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPHC7N	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-25-2020 07:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPHC7P	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BPHC7P	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 07:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 07:48:04 (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
Aug-25-2020 07:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 07:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 07:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 07:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BPIKXC	Initial Entry

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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BP1KXC	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 19:16:42 (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
Aug-24-2020 19:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-24-2020 19:16:42 (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
Aug-24-2020 19:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020 16:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 19:16:42 (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
Aug-24-2020 19:16:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 19:16:42 (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
Aug-24-2020 19:16:42 (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
Aug-24-2020 19:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-24-2020 19:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 19:17:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 15:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.2 Temperature Unit F : Temperature Loc FOREHE ation:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:18 (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-21-2020 15:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry Not Appli cable Not Appli cable Not Appli cable Not Appli cable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-21-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 20:03:28 (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-16-2020 20:03:28 (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-16-2020 20:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 20:03:28 (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-16-2020 20:03:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 20:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BM915P	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 20:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BM915P	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 15:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-20-2020 17:34:33 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Oct-20-2020 17:34:41 (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-20-2020 17:34:41 (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-21-2020 15:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	thank you for the confirmation. Query will post on EOT page when unfrozen for your update.
Oct-21-2020 14:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Confirmed subject did not withdraw consent.
Oct-21-2020 14:19:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Please confirm the subject did not withdraw consent in September.
Oct-21-2020 10:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please unfreeze disposition treatment row 2 so comment can be updated- subject has agreed to stay in the study.
Oct-21-2020 09:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Sample was collected on 20 Oct

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

				20 at Visit 3. However, per EOT disposition, subject refused further study procedures on 15 Sep 20. Please clarify or update as appropriate.
Oct-20-2020 17:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 17:34:41 (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-20-2020 17:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 17:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRBYCJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BRBYCJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 17:34:59	ACV0PFEINFP6000	(b) (6)	Data Entry:	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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b)(4), (b)(6)	Sample ID: BLG04H	
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BLG04H	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 17:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BLG06J	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BLG06J	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 06:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Mar-10-2021 20:13:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 20:13:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 20:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 20:13:00 (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.
Mar-10-2021 20:13:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-10-2021 20:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BS1HNN	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

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

Form Status: Data Complete, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 20:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BS1HNN	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 04:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-20-2021 16:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Jan-20-2021 01:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Date of Visit is completed but Nasal Swab (SWAB PFE) CRF is not initiated. Please review and update the data as appropriate. Thanks
Jan-19-2021 01:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-18-2021 01:29:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-18-2021 01:29:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

				Swab are missing. Please review and update as appropriate.
Jan-14-2021 17:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-14-2021 17:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-14-2021 17:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-14-2021 17:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/10/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-15-2021 15:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-12-2021 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-12-2021 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/15/2021	New Information
Feb-11-2021 15:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Convalescent Visit Source, symptoms ended on 1/15/2021. Please reconcile.
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

4.a

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
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090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry
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4.g Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-20-2021 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-21-2021 02:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-20-2021 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-20-2021 01:09:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for Data item#4h and 4i are missing. Kindly review and update.

4.i

Date	Location	User	Value	Reason
Jan-20-2021 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO	Initial Entry
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present:	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-19-2021 01:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 01:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other headache	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: headache	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-19-2021 01:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other runny nose	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-19-2021 01:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: runny nose	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/12/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-02-2021 10:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 17:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	CRC will contact the subject to confirm this
Jan-28-2021 12:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	per source, subject made an appointment to urgent care for rapid test on 1/12/2021. Please confirm if rapid test performed and results of test.
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/12/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-20-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 01:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 01:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 01:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 01:06:04 (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.
Jan-19-2021 01:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 01:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV16623	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 01:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> CV16623	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/12/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 16:25:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 16:25:35 (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
Jan-20-2021 16:25:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 16:25:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT DID THE SELF SWA B	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/12/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1.a

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/12/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/12/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Jan-19-2021 13:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Transcription Error
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-19-2021 13:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Number of Visits or Contacts: 1	Transcription Error
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULT	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/12/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			ATION	
			Occurrence of NO Visits or Contacts:	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/12/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-19-2021 21:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_HOHCUC002_03
Jan-19-2021 13:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Jan-19-2021 09:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6881679;"Other Type of Practitioner Specify" is not null, but Occurrence of Visits or Contacts for "Other" is NO. Please review and update as appropriate.
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Jan-19-2021 13:54:20 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/12/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)				
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: urgent care	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 01:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Jan/12/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-19-2021 01:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-19-2021 01:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/09/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-09-2021 16:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/9/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-09-2021 16:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COVID_A1	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/09/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-09-2021 16:40:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-09-2021 16:40:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-09-2021 16:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-09-2021 16:40:17 (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.
Feb-09-2021 16:40:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-09-2021 16:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRBC5M	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/09/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 16:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BRBC5M	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-09-2021 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BSMSHG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BSMSHG	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-09-2021 16:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BSMSKN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 16:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BSMSKN	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 15-Sep-2020 21:55**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-11-2020 15:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 12:56:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Nov-11-2020 12:56:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	updated
Nov-10-2020 22:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The discontinuation date of 20OCT2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 25AUG2020 and end 21SEP2020 (date should not be after the AE ended). Please adjust Discontinuation date.
Oct-22-2020 16:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	New Information
Sep-21-2020 16:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-21-2020 16:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 16:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-27-2020 12:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	updated
Oct-27-2020 11:09:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closing as 2nd of vaccination not done due to AE's
Oct-27-2020 10:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM: AE loglines 1-3 are unfrozen. Please update and confirm. Thanks
Oct-26-2020 14:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Please unfreeze AE logs 1,2 and 3 so we can update.
Oct-26-2020 14:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-26-2020 14:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-26-2020 14:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Transcription Error
Oct-26-2020 06:27:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	DM: Per completion guidelines, 'If the Participant receives all vaccinations as

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Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1134**Site Name:** (1134) PMG Research of Winston-Salem**Subject No:** 11341153**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

				per protocol and completes follow-up visit procedures within 1-month post vaccination period, report status as COMPLETED'. Kindly review and update CRF as needed. Else clarify
Oct-23-2020 15:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-22-2020 16:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-22-2020 14:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Per guidelines, the DOV for EOT is to be the same as V3. Please review and update.
Oct-22-2020 08:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-22-2020 08:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Transcription Error
Oct-22-2020 03:31:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per query response at Visit 3, the subject has agreed to stay in the study. Therefore, please update the EOT disposition as appropriate.
Oct-21-2020 15:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Per query response at Visit 3, the subject has agreed to stay in the study. Therefore, please update the EOT

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

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Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

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				disposition as appropriate.
Sep-21-2020 16:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-21-2020 16:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REFUSED FURTHER STUDY PROCEDURES	Changed Information
Sep-21-2020 16:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Sep-21-2020 16:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 15:28:19 (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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 16:01:38 (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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 16:03:11 (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: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-04-2020 23:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Clos ed	Response satisfies query
Sep-30-2020 17:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	Inadvertently entered as not related. PI has deemed this as related per the source. Please unfreeze this so the data can be updated.
Sep-30-2020 01:38:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reiss ued:Op ened	Clin: Since it is not considered related to the study vaccine, please review if it should be please document ed ONLY on the COVID Illness CRF SOD form and a Nasal

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

				Swab will not be collected. A protocol deviation will be documented
Sep-24-2020 17:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	no swab was required per PI since this was within 7 days of the vaccine
Sep-24-2020 10:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Since HEADEACHE is one of the CDC-defined symptoms of COVID-19 (see protocol section 8.1), please consider whether this symptom could have been due to COVID-19 and should have triggered a potential illness visit
Sep-23-2020 04:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 11:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	These are not duplicate AEs
Sep-22-2020 06:59:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4767538;This AE appears to be a duplicate with overlapping dates with another AE recorded on line

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

				<03>. Please review if any updates are needed. If no updates are required, please clarify.
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Site added another line for AE.
Oct-08-2020 12:31:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, subject called site on 8/31/2020 to report symptoms. Subject reported headache onset date as 8/25/20 and still ongoing at the time site spoke with subject on 8/31/20. Please reconcile.
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/25/2020 UNK:UNK	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-11-2020 20:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 16:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-05-2020 16:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Changed Information
Oct-05-2020 01:04:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	Clin Per site response to query:

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Time (US & Canada)		(b) (4)		Inadvertently entered as not related. PI has deemed this as related per the source. Please unfreeze this so the data can be updated.
Oct-04-2020 23:48:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Candidate	Clin Per site response to query: Inadvertently entered as not related. PI has deemed this as related per the source. Please unfreeze this so the data can be updated.
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> N/A	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 18:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Nov-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closing as query text matches a candidate query and is not clear for the site to take action. Will send for CRA assistance.

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 17:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 09:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-27-2020 12:52:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Subject No: 11341153

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 15:26:30 (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
Sep-21-2020 15:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site Name: (1134) PMG Research of Winston-Salem

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-21-2020 15:28:19 (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
Oct-04-2020 23:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Sep-30-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Inadvertently entered as not related. PI has deemed this as related per the source. Please unfreeze this so the data can be updated.
Sep-30-2020 01:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Since it is not considered related to the study vaccine it should be please documented ONLY on the COVID Illness CRF SOD form and a Nasal Swab will not be collected. A

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

				protocol deviation will be documented
Sep-24-2020 17:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no swab was required per PI since this was within 7 days of the vaccine
Sep-24-2020 14:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Per protocol COVID-19 listed symptoms DIARRHEA (1D POST Vax1) if not considered related to the study vaccine should be please documented ONLY on the COVID Illness CRF SOD form and a Nasal Swab will not be collected.
Sep-24-2020 10:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Candidate	Clin: Per protocol COVID-19 listed symptoms DIARRHEA (1D POST Vax1) if not considered related to the study vaccine should be please documented ONLY on the COVID Illness CRF SOD form and a Nasal Swab will not be collected.
Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

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Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 15:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/25/2020 UNK:UNK	Transcription Error
Sep-21-2020 15:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/25/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-21-2020 15:28:19 (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.

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Generated By: (b) (4)

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Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 08:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Oct-12-2020 10:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-12-2020 10:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Transcription Error
Oct-12-2020 01:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Kindly update as appropriate. Thanks
Oct-11-2020 20:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Oct-11-2020 20:47:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Candidate	Clin: Please unfreeze this so the data can be updated.
Oct-05-2020 16:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unable to change the response
Oct-05-2020 01:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin Per site response to query: Inadvertently entered as not related. PI has deemed this as related per the source. Please unfreeze this so the

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Header Text: c4591001

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Subject No: 11341153

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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				data can be updated.
Oct-04-2020 23:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Candidate	Clin Per site response to query: Inadvertently entered as not related. PI has deemed this as related per the source. Please unfreeze this so the data can be updated.
Sep-21-2020 15:28:19 (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> N/A	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 18:44:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Nov-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closing as query text matches a candidate query and is not clear for the site to take action. Will send for CRA assistance.
Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 17:05:28	ACV0PFEINFP6000	(b) (6)	Query 1: Reissued:Candidate	DM: Do not issue

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)		query. Sending to Triad team for CRA assistance.
Nov-11-2020 09:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-27-2020 12:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Sep-21-2020 15:28:19 (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
Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 15:28:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)

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

Date	Location	User	Value	Reason
Sep-21-2020 15:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-21-2020 15:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE diarrhea: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Sep-21-2020 15:28:19 (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
Sep-21-2020 15:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (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
Sep-21-2020 15:34:14 (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
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-08-2020 16:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-08-2020 16:37:28	ACV0PFEINFP6000	(b) (6)	Data Entry:	New Information

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	NO End Date Time: Aug/25/2020 UNK:UNK	
Oct-08-2020 14:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please confirm Headache is still Ongoing since 23 Sep 20. Update with END date if available.
Sep-24-2020 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 12:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per source document headache is still ongoing
Sep-23-2020 12:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if Headache is truly ongoing, then update the END DATE and OUTCOME as appropriate.
Sep-21-2020 15:34:14 (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
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.****Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may**

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require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 18:45:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Transcription Error
Nov-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as query text matches a candidate query and is not clear for the site to take action. Will send for CRA assistance.
Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 17:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA

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Subject No: 11341153

Generated By: (b) (4)

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				assistance.
Nov-11-2020 09:27:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:38:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-27-2020 12:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Oct-07-2020 12:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 11:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no vaccination given during V2
Oct-02-2020 03:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source 2nd vaccination was not given, please verify
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 16:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 16:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	New Information
Oct-08-2020 16:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE headache: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVI NG	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (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
Sep-21-2020 15:36:02 (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
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right eye pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/21/2020 UNK:UNK	Transcription Error
Oct-09-2020 12:43:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Oct-08-2020 16:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	we have left messages for the pt on 9/1/20 and 10/8/20 to verify status
Oct-08-2020 14:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please confirm RIGHT EYE PAIN is still Ongoing since 23 Sep 20 query. Update with END date if available.
Sep-24-2020 15:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 12:10:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	according to source document, right eye pain is ongoing
Sep-23-2020 12:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if Right Eye Pain is truly ongoing, then update the END DATE and OUTCOME as appropriate.
Sep-21-2020 15:36:02 (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
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as query text matches a candidate query and is not clear for the site to take action. Will send for CRA assistance.
Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 17:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.

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Subject No: 11341153

Generated By: (b) (4)

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Nov-11-2020 09:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 14:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Oct-07-2020 12:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 11:40:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no vaccination given during V2
Oct-02-2020 03:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source 2nd vaccination was not given, please verify
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	NO	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 13:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 13:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Oct-26-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE right eye pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-21-2020 15:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 15:36:02 (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
Sep-21-2020 15:56:41 (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
Sep-21-2020 15:56:41 (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
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: muscle weakness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 13:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/21/2020 UNK:UNK	Transcription Error
Oct-09-2020 12:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Update when known

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Oct-08-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	we have left messages for the pt on 9/1/20 and 10/8/20 to verify status
Oct-08-2020 14:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY - Please confirm MUSCLE WEAKNESS is still Ongoing since 23 Sep 20. Update with END date if available.
Oct-08-2020 14:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Created in error
Oct-08-2020 14:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please confirm Headache is still Ongoing since 23 Sep 20. Update with END date if available.
Sep-24-2020 15:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 12:10:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	according to source document, muscle weakness is ongoing
Sep-23-2020 12:03:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if Muscle Weakness is truly ongoing, then update the END DATE and OUTCOME as appropriate.
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Generated By: (b) (4)

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Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 18:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Transcription Error
Nov-14-2020 09:35:04 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as query text matches a

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Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)				candidate query and is not clear for the site to take action. Will send for CRA assistance.
Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 17:06:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Oct-07-2020 12:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 11:40:17 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no vaccination given during V2

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Header Text: c4591001

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Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Time (US & Canada)				
Oct-02-2020 03:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source 2nd vaccination was not given, please verify
Sep-21-2020 15:56:41 (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
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 13:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 13:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Oct-26-2020 13:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE muscle weakness: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.

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Subject No: 11341153

Generated By: (b) (4)

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Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVI NG	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-21-2020 15:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (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
Sep-21-2020 15:59:29 (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
Sep-21-2020 16:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fatigue	Transcription Error
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fatigur	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 13:36:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/21/2020 UNK:UNK	Transcription Error

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Header Text: c4591001

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Oct-09-2020 12:43:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	update when known
Oct-08-2020 16:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	we have left messages for the pt on 9/1/20 and 10/8/20 to verify status
Oct-08-2020 14:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please confirm FATIGUE is still Ongoing since 23 Sep 20 query. Update with END date if available.
Sep-24-2020 15:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 12:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	according to source document, fatigue is ongoing
Sep-23-2020 12:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if Fatigue is truly ongoing, then update the END DATE and OUTCOME as appropriate.
Sep-21-2020 15:59:29 (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
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

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If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 18:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Transcription Error
Nov-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as query text matches a candidate query and is not clear for the site to take action. Will send for CRA assistance.
Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA

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				assistance.
Nov-11-2020 17:06:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 09:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 14:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Oct-07-2020 12:46:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 11:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no vaccination given during V2
Oct-02-2020 03:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source 2nd vaccination was not given, please verify
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 13:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 13:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Oct-26-2020 13:36:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE fatigue: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-21-2020 15:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVI NG	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 15:59:29 (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
Sep-21-2020 16:01:38 (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
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: upset stomach	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/21/2020 UNK:UNK	Transcription Error
Oct-09-2020 12:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Oct-08-2020 16:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	we have left messages for the pt on 9/1/20 and 10/8/20 to verify status
Oct-08-2020 14:32:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please confirm UPSET STOMACH is still Ongoing since 23 Sep 20 query. Update with END date if available.
Sep-24-2020 15:49:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 12:11:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	according to source document, upset stomach is ongoing
Sep-23-2020 12:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if Upset Stomach is truly ongoing, then update the END DATE and OUTCOME as appropriate.
Sep-21-2020 16:01:38 (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
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-21-2020 16:01:38 (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
Sep-21-2020 16:01:38 (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
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 18:47:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Nov-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as query text matches a candidate query and is not clear for the site to take action. Will send for CRA assistance.
Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA assistance.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1134**Subject No:** 11341153**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1134) PMG Research of Winston-Salem**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Nov-11-2020 17:06:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 09:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 14:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Oct-07-2020 12:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 11:40:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no vaccination given during V2
Oct-02-2020 03:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source 2nd vaccination was not given, please verify
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-21-2020 16:01:38 (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
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 13:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 13:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Oct-26-2020 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE upset stomach: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVI NG	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae300d\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 16:03:11 (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
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-25-2020 09:13:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-24-2020 17:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	entry is correct per PI, the severity decreased
Sep-23-2020 12:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY- Loose stools reported, overlaps with entry Diarrhea. Please review dates, severity, relationship to study treatment and update the CRF as appropriate.
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: loose stools	Initial Entry

4. Start Date Time:

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Site No: 1134

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 13:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/21/2020 UNK:UNK	Transcription Error
Oct-09-2020 12:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Update when known
Oct-08-2020 16:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	we have left messages for the pt on 9/1/20 and 10/8/20 to verify status
Oct-08-2020 14:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please confirm LOOSE STOOLS is still Ongoing since 23 Sep 20 query. Update with END date if available.
Sep-24-2020 15:49:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 12:12:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	according to source document, upset stomach is ongoing
Sep-23-2020 12:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if Upset Stomach is truly ongoing, then update the END DATE and

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Site Name: (1134) PMG Research of Winston-Salem

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				OUTCOME as appropriate.
Sep-21-2020 16:03:11 (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
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-21-2020 16:03:11 (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
Sep-21-2020 16:03:11 (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
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Nov-17-2020 18:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Nov-14-2020 09:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as query text matches a candidate query and is not clear for the site to take action. Will send for CRA assistance.
Nov-14-2020 08:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 17:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 09:28:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per the source all of these AEs are what led to the drug to be withdrawn. Data correct per source.
Nov-10-2020 22:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 14:16:25 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error

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Header Text: c4591001

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Subject No: 11341153

Generated By: (b) (4)

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Site Name: (1134) PMG Research of Winston-Salem

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Time (US & Canada)				
Oct-07-2020 12:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 11:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no vaccination given during V2
Oct-02-2020 03:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source 2nd vaccination was not given, please verify
Sep-21-2020 16:03:11 (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
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 13:39:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 13:39:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Oct-26-2020 13:39:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE loose stools: Response to "What

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)				was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-21-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:03:11 (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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 13:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/15/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Feb-17-2021 13:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-17-2021 13:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-17-2021 13:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

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1. Subject Status

Date	Location	User	Value	Reason
Oct-26-2020 14:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Transcription Error
Oct-22-2020 08:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Transcription Error
Sep-21-2020 16:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Sep-21-2020 16:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Aug-24-2020 19:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-24-2020 19:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-11-2020 12:56:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	updated
Oct-26-2020 14:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Transcription Error
Oct-22-2020 16:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	New Information
Oct-22-2020 08:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Transcription Error

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341153

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1134) PMG Research of Winston-Salem

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Sep-21-2020 16:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Changed Information
Sep-21-2020 16:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry
Aug-24-2020 19:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry
Aug-24-2020 19:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

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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: 1134

Site Name: (1134) PMG Research of Winston-Salem

Subject No: 11341153

Subject Initials: ---

Generated By: (b) (4)

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 11:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry