

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: 11341019

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: 11341019

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/10/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1134

Subject No: 11341019

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	[11341019]
2.	Birth Date:	(b) (6)/1961
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

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/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1134

Subject No: 11341019

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
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Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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/10/2020
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: 11341019

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:	[Hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae300f\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: 11341019

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:	[Percutaneous Transluminal Coronary Angioplasty]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cardiac Stent Placement]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1134

Subject No: 11341019

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/10/2020
2.	Weight:	[219.6]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[30.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.8]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae300f\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: 11341019

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/10/2020
2.	Randomization Number:	[224721]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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/10/2020
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	[BP1KJR]
5.b	Sample ID	[BP1KJS]
5.c	Sample ID	[BP1KJT]
5.d	Sample ID	[BPHCC6]
5.e	Sample ID	[BPHCC7]

090177e196ae300f\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: 11341019

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/10/2020
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	[BP1KR5]
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090177e196ae300f\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: 11341019

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/10/2020 10:22
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

090177e196ae300f\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: 11341019

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

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/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1134

Subject No: 11341019

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:	Aug/31/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.9]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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/31/2020
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	[BP9L9V]
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090177e196ae300f\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: 11341019

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/31/2020 13:39
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

090177e196ae300f\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: 11341019

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/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

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: Sep/28/2020
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	[BM911B]
5.b	Sample ID	[BNVMH0]

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

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 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

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: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1134 **Site Name:** (1134) PMG Research of Winston-Salem

Subject No: 11341019 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

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 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

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: 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: 11341019

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: 11341019

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: 11341019

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 :	Sep/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1134

Subject No: 11341019

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: 11341019

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: 11341019

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: 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: 11341019

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	CHEST PAIN (CARDIC)	Feb/2/2021 UNK: UNK	YES	Repeating Pages

090177e196ae300f\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: 11341019

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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)	[CHEST PAIN (CARDIC)]
4.	Start Date Time:	Feb/2/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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: 11341019

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: 11341019

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	[]

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

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: 11341019

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: 11341019

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.	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: 11341019

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: 11341019

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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: 11341019

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: 11341019

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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: TRANSFUSIONS

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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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: 11341019

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: 11341019

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: 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: 11341019

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: 11341019

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: 11341019

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: 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: 11341019

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/1/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1134

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

Subject No: 11341019

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 per local/national recommendations and 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: 11341019

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/1/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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: 11341019

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: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/2/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, 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
----	--	----------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Feb/2/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/2/2021
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	[BR1BKX]
5.b	Sample ID	[BSMSGH]
5.c	Sample ID	[BSMSJP]

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Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/2/2021
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	[BRBC40]
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090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/2/2021 14:49
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
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	[BRBCB4]
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090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, 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

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

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 :	Feb/2/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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	FOLLOW-UP
2.	Subject Status Date	Sep/28/2020

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: 11341019

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: 11341019

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-04-2021 16:04:25 (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.

090177e196ae300f\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: 11341019

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-10-2020 12:08:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA _____ Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-04-2021 14:27:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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](#)

Item	Date	User	Comment
Form	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
Form	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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](#)

Item	Date	User	Comment
1	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
1	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
2	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
2	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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](#)

Item	Date	User	Comment
3	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
3	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
4	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
4	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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](#)

Item	Date	User	Comment
5	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
5	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
5	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
6	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
6	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
6	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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](#)

Item	Date	User	Comment
7	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
7	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
7	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
8	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
8	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
8	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
9	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
9	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
9	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
10	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
10	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
10	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - Comments

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](#)

Item	Date	User	Comment
11	Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject will not get the second vaccine due to an AE. <hr/> Not Done
11	Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
11	Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae300f\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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jonathan Wilson	Approved	Mar-04-2021 16:04:25 (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-03-2021 08:36:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Mar-01-2021 11:07:02 (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	Mar-01-2021 09:09:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae300f\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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Jonathan Wilson	Approved	Feb-25-2021 16:03:06 (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-23-2021 19:25:09 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Feb-05-2021 14:07:46 (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-04-2021 14:27:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Feb-03-2021 09:15:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae300f\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: 11341019

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	Feb-01-2021 15:40:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Sep-30-2020 09:47:22 (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	Sep-28-2020 17:54:09 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jonathan Wilson	Approved	Sep-11-2020 09:59:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae300f\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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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.

090177e196ae300f\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: 11341019

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-10-2020 12:07:16 (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-10-2020 12:07:16 (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: 11341019

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-10-2020 12:07:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1134

Subject No: 11341019

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-10-2020 12:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11341019	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-10-2020 12:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1961	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-10-2020 12:07:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-10-2020 12:07:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 12:07:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

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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I. Date of Visit

Date	Location	User	Value	Reason
Aug-10-2020 12:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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-10-2020 12:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-10-2020 12:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-10-2020 12:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae300f\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: 11341019

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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I.a

Date	Location	User	Value	Reason
Aug-10-2020 12:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T Hypertension erm: Start Date: UNK/UNK/2 015 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 12:10:03 (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-10-2020 12:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 12:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 12:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae300f\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: 11341019

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

Date	Location	User	Value	Reason
Aug-10-2020 12:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: Hypothyroidism Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 12:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroidism	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

090177e196ae300f\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: 11341019

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-10-2020 12:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History T Depression erm: Start Date: UNK/UNK/2 011 Ongoing: YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:27 (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-10-2020 12:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae300f\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: 11341019

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-10-2020 12:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 4 ber: Medical Histor Coronary Artery y Term: Disease Start Date: UNK/UNK/201 5 Ongoing: YES	Initial Entry
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 12:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Coronary Artery Disease	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 12:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-10-2020 15:07:14 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: Line/MH 5	Changed Information

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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

Time (US & Canada)		(b) (4)	Number: Medical History Term: Percutaneous Transluminal Coronary Angioplasty Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	
Aug-10-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/Member Number: 5 Medical History Term: Percutaneous Transluminal Coronary Angioplasty with Stent Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	Initial Entry

090177e196ae300f\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: 11341019

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.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 17:05:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Cl osed	Discrepancy has been closed.
Aug-10-2020 15:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Changed Information
Aug-10-2020 15:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Percutaneo us Translu minal Coro nary Angio plasty	Changed Information
Aug-10-2020 13:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: O pened	Multiple concepts. Split the term into PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY/ CORONARY STENT PLACEMENT.
Aug-10-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Percutaneo us Translu minal Coro nary Angio	Initial Entry

090177e196ae300f\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: 11341019

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

			plasty with Stent	
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I.e Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 12:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-10-2020 17:21:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 6 Medical History Term: Cardiac Stent Placement Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	New Information
Aug-10-2020 15:06:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Cardiac Stent Start Date: UNK/UNK/2015	Initial Entry

090177e196ae300f\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: 11341019

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	
				/2015	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 15:06:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 18:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clo sed	Discrepancy has been closed.
Aug-10-2020 17:21:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swered	New Information
Aug-10-2020 17:21:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cardiac Sten t Placement	New Information
Aug-10-2020 17:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Clarify CARDIAC STENT as follows...Is this referring to CARDIAC STENT PLACENMENT, CARDIAC STENT REMOVAL or other, if so edit as such. Otherwise clarify term further. Thank you.
Aug-10-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae300f\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: 11341019

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

15:06:52 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	Cardiac Sten t	
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1.f Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 15:06:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 15:06:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1134

Subject No: 11341019

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-10-2020 12:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-10-2020 12:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 219.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 12:14:45 (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-10-2020 12:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 71.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 12:14:45 (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-10-2020 12:14:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.6	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1134

Subject No: 11341019

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)				
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7.a

Date	Location	User	Value	Reason
Aug-10-2020 12:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.8 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-10-2020 12:14:45 (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-10-2020 12:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-10-2020 12:14:45 (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-10-2020 12:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae300f\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: 11341019

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-10-2020 12:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-10-2020 12:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 224721	Initial Entry

090177e196ae300f\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:** 11341019**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-10-2020 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-10-2020 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-10-2020 19:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-10-2020 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 19:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1KJR	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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 19:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1KJR	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-10-2020 19:23:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1KJS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 19:23:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1KJS	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-10-2020 19:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1KJT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 19:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1KJT	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-10-2020 19:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPHCC6	Initial Entry

090177e196ae300f\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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 19:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHCC6	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-10-2020 19:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHCC7	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 19:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHCC7	Initial Entry

090177e196ae300f\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: 11341019

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-10-2020 12:15:34 (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-10-2020 12:15:34 (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-10-2020 19:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 12:15:34 (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-10-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 19:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1KR5	Initial Entry

090177e196ae300f\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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 19:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1KR5	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341019

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-10-2020 12:16:10 (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-10-2020 12:16:10 (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-10-2020 12:16:10 (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-10-2020 12:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020 10:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-10-2020 12:16:10 (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-10-2020 12:16:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae300f\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: 11341019

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)		(b) (4)	
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7. Route:

Date	Location	User	Value	Reason
Aug-10-2020 12:16:10 (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-10-2020 12:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-10-2020 12:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae300f\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: 11341019

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-10-2020 12:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-D IARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

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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I. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 20:58:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemic N symptoms present on th O e last day the Subject Di ary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA	Initial Entry

090177e196ae300f\Final\On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

			TI GU E NO	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.b Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE MUSCL E PAIN Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed ?:	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUS CLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERED JOINT P AIN Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed? :	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 21:01:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction RE :: DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-31-2020 21:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1134

Subject No: 11341019

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
Aug-31-2020 21:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-31-2020 21:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 98.9 Temperature Uni F t: Temperature Loc FOREHE ation:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 21:01:47 (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
Aug-31-2020 21:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 21:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1134

Subject No: 11341019

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
Aug-31-2020 21:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1134**Subject No:** 11341019**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 16:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 16:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 16:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 16:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 16:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 16:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP9L9V	Initial Entry

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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP9L9V	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1134

Subject No: 11341019

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-31-2020 21:02:27 (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-31-2020 21:02:27 (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-31-2020 21:02:27 (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-31-2020 21:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020 13:39	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 21:02:27 (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-31-2020 21:02:27 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae300f\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: 11341019

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
Aug-31-2020 21:02:27 (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-31-2020 21:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-31-2020 21:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae300f\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: 11341019

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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I. Date of Visit

Date	Location	User	Value	Reason
Sep-28-2020 20:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/28/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA	Initial Entry

090177e196ae300f\Final\On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

			TI GU E NO	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.b Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry NO

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE MUSCL E PAIN Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed ?:	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUS CLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERED JOINT P AIN Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed? :	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOIN T PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction RE :: DN ES S Were injection site reac NO tions present on the las t day the Subject Diary was completed?:	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction SW :: ELL ING Were injection site rea NO ctions present on the l ast day the Subject Di ary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-28-2020 20:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae300f\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:** 11341019**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
Sep-28-2020 17:54:09 (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-28-2020 17:54:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-28-2020 17:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 17:54:09 (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-28-2020 17:54:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Sep/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 17:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BM911B	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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 17:54:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BM911B	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-28-2020 18:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BNVMH0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BNVMH0	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae300f\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: 11341019

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
Mar-01-2021 09:09:11 (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: 11341019

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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
Mar-01-2021 09:09:11 (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
Mar-01-2021 09:09:11 (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
Mar-04-2021 12:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 12:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST PAIN (CARDIC)	Transcription Error
Mar-03-2021 13:07:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please clarify in event term if this event was cardiac or non-cardiac in nature
Mar-01-2021 09:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST PAIN	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae300f\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

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Mar-03-2021 13:06:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-03-2021 08:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-03-2021 08:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021 UNK:UNK	Transcription Error
Mar-03-2021 08:14:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: This treatment RELATED event is reported to have started 01Feb21, whilst Vax3 is not reported until 02Feb21. Please review entries; else, clarify
Mar-01-2021 09:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 16:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 10:01:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Symptoms started 2 hours after injection and have continued daily intermittently.
Mar-10-2021 09:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Chest Pain (Cardiac), related to VAX 3, is still reported as ONGOING. Please review and confirm Ongoing, or enter

090177e196ae300f\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

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

				END DATE if known.
Mar-01-2021 09:09:11 (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
Mar-01-2021 09:09:11 (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
Mar-01-2021 09:09:11 (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
Mar-01-2021 09:09:11 (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
Mar-08-2021 15:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 15:04:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Query 1: Answered	Symptoms started 2 hours after injection

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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

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4)		and have continued daily intermittently which was not present prior to vaccination. And per investigator judgement it is related.
Mar-08-2021 13:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise as to why assessed as related in subject with known history of cardiac disease. Thanks.
Mar-01-2021 09:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-04-2021 13:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Mar-04-2021 13:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Mar-04-2021 12:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: This field is related to end of treatment (links to EOT2). Current entry reports treatment was discontinued in response to the event. If DRUG WITHDRAWN is correct, please update EOT2 page

090177e196ae300f\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

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

				to match
Mar-04-2021 12:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Mar-04-2021 12:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	subject was not discontinued- updated.
Mar-03-2021 08:29:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM RQ #1: Per response, however if action taken is drug withdrawal and outcome is not FETAL then reason for treatment discontinuation should be ADVERSE EVENT, however treatment form is missing. Please update else clarify.
Mar-03-2021 08:15:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Entry indicates treatment was discontinued in response to this event. If correct, please update the EOT2 page to reflect this information
Mar-02-2021 10:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per the AE source the outcome is not listed as FATAL
Mar-02-2021 10:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: "Latest action taken with study treatment" on AE form is DRUG WITHDRAWN and AE Outcome is not FATAL. Please update the outcome and EOT form accordingly. Thank

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

				you.
Mar-01-2021 09:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-01-2021 09:09:11 (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
Mar-01-2021 09:09:11 (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
Mar-01-2021 09:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 12:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:26:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 12:26:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Mar-03-2021 08:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Entry indicates subject discontinued

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

				participation in study due to this event. If correct, please update the FUP tab to indicate end of study
Mar-01-2021 09:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 15:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/1/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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-01-2021 15:41:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 15:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-01-2021 15:40:55 (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 per local/national recommendations and 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: 11341019

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-01-2021 15:41:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-01-2021 15:41:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 14:27:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION - 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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I. Consent Was:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: OBTAINED Date Written Consent Obtained Feb/2/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-02-2021 17:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/2/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-02-2021 17:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-02-2021 17:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**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:** 11341019**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-02-2021 17:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-02-2021 17:37:12 (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-02-2021 17:37:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 17:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-02-2021 17:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-02-2021 17:37:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR1BKX	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 17:37:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR1BKX	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-02-2021 17:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BSMSGH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 17:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BSMSGH	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-02-2021 17:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BSMSJP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 17:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BSMSJP	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

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: 11341019

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
Feb-02-2021 17:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-02-2021 17:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-05-2021 12:27:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-04-2021 14:28:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-04-2021 13:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Multiple pages remain BLANK for this visit dated 02 Feb 20. Please confirm subject received VAX 3 and update as applicable.
Feb-02-2021 17:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 17:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

				entered. Please review and correct as appropriate.
Feb-02-2021 17:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-02-2021 17:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRBC40	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 17:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BRBC40	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

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Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/2/2021 14:49	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4)	
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7. Route:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-24-2021 08:54:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/23/2021	Initial Entry

Header Text: c4591001**Visit:** V102_VAX4**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:** 11341019**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-23-2021 19:25:09 (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-23-2021 19:25:09 (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
Feb-23-2021 19:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 19:25:09 (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-23-2021 19:25:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 19:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRBCB4	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
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Form Status: Data Complete, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 19:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BRBCB4	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - 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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I. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not D one	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Mar-01-2021 16:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	new query issued
Mar-01-2021 09:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Subject will not get the second vaccine due to AE.
Mar-01-2021 06:40:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7478441;Temp Delay is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - 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

(US & Canada)			pplica ble	
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2. Treatment Name

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Not D one	Initial Entry
Mar-04-2021 12:36:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u>	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 10-Dec-2020 02:26**Site No:** 1134**Subject No:** 11341019**Generated By:** (b) (4)**Form:** VACCINATION - 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

(UTC-05:00) Eastern Time (US & Canada)			:	
Mar-01-2021 16:09:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Per site response.
Mar-01-2021 09:06:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Subject will not get the second vaccine due to an AE.
Mar-01-2021 06:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7478666;Dose Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - 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

Time (US & Canada)		(b) (4)	
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6. Body Side:

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1134

Subject No: 11341019

Generated By: (b) (4)

Form: VACCINATION - 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

9. Unit:

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-04-2021 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae300f\Final\On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-04-2021 12:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/2/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-04-2021 12:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-04-2021 12:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1134

Subject No: 11341019

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

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1. Subject Status

Date	Location	User	Value	Reason
Sep-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-10-2020 12:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-10-2020 12:09:18 (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
Sep-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/28/2020	Initial Entry
Aug-10-2020 12:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/10/2020	Initial Entry
Aug-10-2020 12:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/10/2020	Initial Entry

090177e196ae300f\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1134

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

Subject No: 11341019

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-10-2020 13:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry