

Annotated Study Book for Study Design: C4591001

Study Design Version: 14.0

Sponsor: Pfizer

Protocol: C4591001

Sponsor Drug Name: BLINDED THERAPY

C4591001 - COVID19

Generated by Central Designer TM

January 14, 2021 12:00PM

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Visits**SCR**

MAIN INFORMED CONSENT
 DEMOGRAPHY
 DATE OF VISIT
 INCLUSION/EXCLUSION CRITERIA (INC EXCS)
 INCLUSION/EXCLUSION CRITERIA (INC EXCS)
 INCLUSION/EXCLUSION CRITERIA (INC EXCS)
 INCLUSION/EXCLUSION CRITERIA (INC EXC)
 DISPOSITION - SCREENING
 GENERAL MEDICAL HISTORY
 CONCOMITANT MEDICATIONS - BASELINE
 PHYSICAL EXAMINATION
 VITAL SIGNS - BASELINE
 ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION
 MICROBIOLOGY SPECIMEN (COV19 SITE)
 CENTRAL LAB SAMPLE COLLECTION – BASELINE
 LAB URINALYSIS - PREGNANCY TEST

V1_DAY1_VAX1_S

DATE OF VISIT
 PHYSICAL EXAMINATION
 VITAL SIGNS
 LAB URINALYSIS - PREGNANCY TEST
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 MICROBIOLOGY SPECIMEN (SWAB SITE)
 RANDOMIZATION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 VACCINATION
 VACCINATION DIARY

V2_DAY2_POSTVAX1_S

DATE OF VISIT
 PHYSICAL EXAMINATION
 VITAL SIGNS
 CENTRAL LAB SAMPLE COLLECTION

V3_WEEK1_POSTVAX1_S

DATE OF VISIT
 PHYSICAL EXAMINATION
 VITAL SIGNS
 CENTRAL LAB SAMPLE COLLECTION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V4_WEEK3_VAX2_S

DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 PHYSICAL EXAMINATION
 VITAL SIGNS
 LAB URINALYSIS - PREGNANCY TEST
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB

MICROBIOLOGY SPECIMEN (SWAB SITE)
 CENTRAL LAB SAMPLE COLLECTION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 VACCINATION
 VACCINATION DIARY

V5_WEEK1_POSTVAX2_S
 DATE OF VISIT
 PHYSICAL EXAMINATION
 VITAL SIGNS
 CENTRAL LAB SAMPLE COLLECTION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V6_WEEK2_POSTVAX2_S
 DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 PHYSICAL EXAMINATION
 VITAL SIGNS
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 VACCINATION DIARY

V7_MONTH1_S
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V4_WEEK3_VAX2_S_R
 DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 PHYSICAL EXAMINATION
 VITAL SIGNS
 LAB URINALYSIS - PREGNANCY TEST
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 MICROBIOLOGY SPECIMEN (SWAB SITE)
 CENTRAL LAB SAMPLE COLLECTION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 VACCINATION
 VACCINATION DIARY

V5_WEEK1_POSTVAX2_S_R
 DATE OF VISIT
 PHYSICAL EXAMINATION
 VITAL SIGNS
 CENTRAL LAB SAMPLE COLLECTION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V6_WEEK2_POSTVAX2_S_R
 DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 PHYSICAL EXAMINATION
 VITAL SIGNS
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 VACCINATION DIARY

V7_MONTH1_S_R
 DATE OF VISIT

ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V8_MONTH6_S
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V9_MONTH12_S
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V10_MONTH24_S
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V1_DAY1_VAX1_NS
 DATE OF VISIT
 INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
 INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
 INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
 DISPOSITION - SCREENING
 GENERAL MEDICAL HISTORY
 PHYSICAL EXAMINATION
 VITAL SIGNS - BASELINE
 LAB URINALYSIS - PREGNANCY TEST
 RANDOMIZATION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 VACCINATION
 V2_VAX2_NS
 DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 VITAL SIGNS - TEMP
 LAB URINALYSIS - PREGNANCY TEST
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 VACCINATION
 V3_WEEK2_POSTVAX2_NS
 DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V4_MONTH1_NS
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V5_MONTH6_NS
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V6_MONTH12_NS
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 V7_MONTH24_NS
 DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V1_DAY1_VAX1_L

DATE OF VISIT
 INCLUSION/EXCLUSION CRITERIA (IN EX STG3)
 INCLUSION/EXCLUSION CRITERIA (IN EX STG3)
 INCLUSION/EXCLUSION CRITERIA (IN EX STG3)
 INCLUSION/EXCLUSION CRITERIA (IN EX STG3)
 DISPOSITION - SCREENING
 GENERAL MEDICAL HISTORY
 PHYSICAL EXAMINATION
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 VITAL SIGNS - BASELINE
 VITAL SIGNS - BASELINE
 LAB URINALYSIS - PREGNANCY TEST
 RANDOMIZATION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 VACCINATION
 VACCINATION DIARY

V2_VAX2_L

DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 VITAL SIGNS - TEMP
 LAB URINALYSIS - PREGNANCY TEST
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 VACCINATION
 VACCINATION DIARY

V3_MONTH1_POSTVAX2_L

DATE OF VISIT
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 VACCINATION DIARY

V4_MONTH6_L

DATE OF VISIT
 CONTACT OUTCOME
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

V5_MONTH12_L

DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY

V6_MONTH24_L

DATE OF VISIT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 POT_COVID_ILL
 DATE OF VISIT - ILLNESS
 CONTACT OUTCOME - MONTH 1
 SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
 SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
 MICROBIOLOGY SPECIMEN (COVID TEST)
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 HEALTH CARE UTILIZATION
 HOSPITALIZATION DETAILS
 RESPIRATORY TREATMENT
 RESPIRATORY TREATMENT
 ILLNESS DETAILS
 ILLNESS DETAILS - SEVERE
 ILLNESS DETAILS - SEVERE
 LOCAL LABORATORY DATA - REPEATING CHEMISTRY
 LOCAL LABORATORY DATA - REPEATING CHEMISTRY
 LOCAL LABORATORY DATA - REPEATING HEMATOLOGY
 VITAL SIGNS - COVID
 VITAL SIGNS - PULSE OX ROOM AIR
 OXYGENATION PARAMETERS
 CONCOMITANT MEDICATIONS - VASOPRESSORS
 IMAGING
 VACCINATION DIARY
 POT_COVID_CONVA
 DATE OF VISIT - ILLNESS CONVALESCENT
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 VACCINATION DIARY
 POT_COVID_REPEAT_SWAB
 DATE OF VISIT - REPEAT SWAB
 ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
 VACCINATION DIARY
 LOGS
 ADVERSE EVENT REPORT
 MEDICATION ERROR
 CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
 CONCOMITANT MEDICATIONS - PROHIBITED
 RADIATION TREATMENT
 TRANSFUSIONS
 UNPL
 DATE OF VISIT
 CONTACT OUTCOME - UNPLANNED
 VITAL SIGNS - TEMP
 UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT
 UNPLANNED_VACCINATION
 DATE OF VISIT

VITAL SIGNS - TEMP
 LAB URINALYSIS - PREGNANCY TEST
 VACCINATION
 CONTACT OUTCOME - MONTH 1
 CONTACT OUTCOME - MONTH 6
 V201_SURVEIL_CONSENT
 DATE OF VISIT
 INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 V202_SURVEIL_SWAB
 DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
 ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
 DISP
 TREATMENT UNBLINDED
 WITHDRAWAL OF CONSENT
 DEATH DETAILS CODED
 END_OF_TRT
 DISPOSITION – TREATMENT
 REVAX_CONTACT
 DATE OF VISIT
 V101_VAX3
 DATE OF VISIT
 INFORMED CONSENT - FURTHER VACCINATION
 INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)
 DISPOSITION - SCREENING FOR FURTHER VACCINATION
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 LAB URINALYSIS - PREGNANCY TEST
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 VACCINATION
 V102_VAX4
 DATE OF VISIT
 LAB URINALYSIS - PREGNANCY TEST
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 VACCINATION
 V103_MONTH1
 DATE OF VISIT
 CONTACT OUTCOME
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 V104_MONTH6
 DATE OF VISIT
 CONTACT OUTCOME
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 V105_MONTH18

DATE OF VISIT
 CONTACT OUTCOME
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 FURTHER_VACCINATION_EOT
 DISPOSITION - TREATMENT
 FOLLOW_UP
 DISPOSITION - FOLLOW-UP

Domains

AE=ADVERSE EVENTS

VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 ADVERSE EVENT REPORT
 MEDICATION ERROR

CE=CLINICAL EVENTS

VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
 SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
 ILLNESS DETAILS
 ILLNESS DETAILS - SEVERE
 ILLNESS DETAILS - SEVERE

CM=CONCOMITANT MEDICATIONS

CONCOMITANT MEDICATIONS - BASELINE
 CONCOMITANT MEDICATIONS - VASOPRESSORS
 CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
 CONCOMITANT MEDICATIONS - PROHIBITED

CO=COMMENTS

ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION
 MICROBIOLOGY SPECIMEN (COV19 SITE)
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 MICROBIOLOGY SPECIMEN (SWAB SITE)
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 MICROBIOLOGY SPECIMEN (COVID TEST)
 ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
 ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

DD=DEATH DETAILS

DEATH DETAILS CODED

DI=DEVICE IDENTIFIERS

MICROBIOLOGY SPECIMEN (COV19 SITE)
 MICROBIOLOGY SPECIMEN (SWAB SITE)
 MICROBIOLOGY SPECIMEN (COVID TEST)

DM=DEMOGRAPHICS

DEMOGRAPHY
 REACTOGENICITY DIARY

DS=DISPOSITION

MAIN INFORMED CONSENT
 DISPOSITION - SCREENING
 RANDOMIZATION

TREATMENT UNBLINDED
 WITHDRAWAL OF CONSENT
 DISPOSITION - TREATMENT
 DISPOSITION - FOLLOW-UP
 INFORMED CONSENT - FURTHER VACCINATION
 DISPOSITION - SCREENING FOR FURTHER VACCINATION
 INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
 EC=EXPOSURE AS COLLECTED
 VACCINATION
 VACCINATION
 EX=EXPOSURE
 VACCINATION
 VACCINATION
 FA=FINDINGS ABOUT EVENTS OR INTERVENTIONS
 VACCINATION DIARY
 VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
 SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
 SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
 HEALTH CARE UTILIZATION
 UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT
 HO=HEALTHCARE ENCOUNTERS
 HEALTH CARE UTILIZATION
 HOSPITALIZATION DETAILS
 IE=INCLUSION/EXCLUSION CRITERIA NOT MET
 INCLUSION/EXCLUSION CRITERIA (INC EXC S)
 INCLUSION/EXCLUSION CRITERIA (INC EXC S)
 INCLUSION/EXCLUSION CRITERIA (INC EXC S)
 INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
 INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
 INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
 INCLUSION/EXCLUSION CRITERIA (IN EX STG3)
 INCLUSION/EXCLUSION CRITERIA (IN EX STG3)
 INCLUSION/EXCLUSION CRITERIA (IN EX STG3)
 INCLUSION/EXCLUSION CRITERIA (INC EXC)
 INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)
 IS=IMMUNOGENICITY SPECIMEN ASSESSMENTS
 ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION
 ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
 LB=LABORATORY TEST RESULTS
 CENTRAL LAB SAMPLE COLLECTION - BASELINE
 LAB URINALYSIS - PREGNANCY TEST
 CENTRAL LAB SAMPLE COLLECTION
 LAB CHEMISTRY
 LABORATORY DATA - HEMATOLOGY
 LOCAL LABORATORY DATA - REPEATING CHEMISTRY
 LOCAL LABORATORY DATA - REPEATING CHEMISTRY
 LOCAL LABORATORY DATA - REPEATING HEMATOLOGY
 OXYGENATION PARAMETERS

MB=MICROBIOLOGY SPECIMEN

MICROBIOLOGY SPECIMEN (COV19 SITE)
CENTRAL LAB SAMPLE COLLECTION - BASELINE
ELECTRONIC SAMPLE TRACKING - NASAL SWAB
MICROBIOLOGY SPECIMEN (SWAB SITE)
CENTRAL LAB SAMPLE COLLECTION
MICROBIOLOGY SPECIMEN (COVID TEST)
ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

MH=MEDICAL HISTORY

GENERAL MEDICAL HISTORY

MO=MORPHOLOGY

IMAGING

PE=PHYSICAL EXAMINATION

PHYSICAL EXAMINATION

PR=PROCEDURES

RESPIRATORY TREATMENT
RESPIRATORY TREATMENT
RADIATION TREATMENT
TRANSFUSIONS

SV=SUBJECT VISITS

DATE OF VISIT
CONTACT OUTCOME
DATE OF VISIT - ILLNESS ONSET
CONTACT OUTCOME - MONTH 1
DATE OF VISIT - ILLNESS CONVALESCENT
DATE OF VISIT - REPEAT SWAB
CONTACT OUTCOME - UNPLANNED
CONTACT OUTCOME - MONTH 6
DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

VS=VITAL SIGNS

VITAL SIGNS - BASELINE
VITAL SIGNS
VACCINATION DIARY
VITAL SIGNS - BASELINE
VITAL SIGNS - TEMP
VITAL SIGNS - COVID
VITAL SIGNS - PULSE OX ROOM AIR

STUDYID

AE=Adverse Events

C4591001: ADVERSE EVENT REPORT (AE) - Repeating Form

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Toxicity Grade	Serious	Is AE a Result of a Medication Error	Relationship to Study Treatment	Action Taken with Study Treatment	Concomitant Medication Given	Non-Drug Treatment Given	Outcome	Caused Study Discontinuation	Serious Adverse Event Number
1															
Adverse Event Report															
1.	Category: [Category]	<input type="radio"/> ADVERSE EVENT AECAT													
2.	AE ID: [AE Identifier]	AESPID													
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms) [Adverse Event]	AETERM													
4.	Start Date Time: [Start Date]	<div> <div> <div>▼</div> <div>/</div> <div>▼</div> </div> <div> <div>▼</div> <div>/</div> <div>▼</div> </div> <div> <div>▼</div> <div>:</div> <div>▼</div> </div> <div>24-hour clock</div> </div> AESTDTC													
5.	Is the adverse event still ongoing? [Is the Adverse Event Still Ongoing]	<input type="radio"/> YES AEENRPT= ONGOING AEENTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date Time: <div> <div>▼</div> <div>/</div> <div>▼</div> </div> <div> <div>▼</div> <div>/</div> <div>▼</div> </div> <div> <div>▼</div> <div>:</div> <div>▼</div> </div> <div>24-hour clock</div> AEENDTC													
6.	Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 1 AETOXGR <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4													
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). [Serious]	<input type="radio"/> YES AESER Is this serious event associated with congenital anomaly or birth defect? <input type="radio"/> YES AESCONG <input type="radio"/> NO Did this serious event result in death? <input type="radio"/> YES AESDTH <input type="radio"/> NO Did this serious event require or prolong hospitalization? <input type="radio"/> YES AESHOSP <input type="radio"/> NO Did this serious event result in persistent or significant disability/incapacity? <input type="radio"/> YES AESDISAB <input type="radio"/> NO Is this serious event life threatening? <input type="radio"/> YES AESLIFE <input type="radio"/> NO Other medically important serious event <input type="radio"/> YES AESMIE <input type="radio"/> NO <input type="radio"/> 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. [Is AE a Result of a Medication Error]	<input type="radio"/> YES AEMERES in SUPPAE <input type="radio"/> NO													
9.	Is this event related to study treatment: [Relationship to Study Treatment]	<input type="radio"/> NOT RELATED AEREL If Not Related to study treatment(s), this event is due to: <input type="radio"/> CONCOMITANT DRUG TREATMENT AERELNST <input type="radio"/> CONCOMITANT NON-DRUG TREATMENT <input type="radio"/> OTHER If Other, specify: AERELTXT in SUPPAE <input type="radio"/> RELATED													
10.	Latest Action Taken with Study	<input type="radio"/> DRUG WITHDRAWN AEACN <input type="radio"/> NOT APPLICABLE													

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AE=Adverse Events

	Treatment: [Action Taken with Study Treatment]	<input type="radio"/>
11.	Was a Concomitant Medication given? [Concomitant Medication Given]	<input type="radio"/> YES AECONTRT AECMGIV in SUPPAE <input type="radio"/> NO
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	<input type="radio"/> YES AECONTRT AENDGIV in SUPPAE <input type="radio"/> NO
13.	What was the outcome of this adverse event?: [Outcome]	<input type="radio"/> FATAL <input type="radio"/> NOT RECOVERED/NOT RESOLVED AEOUT <input type="radio"/> RECOVERED/RESOLVED <input type="radio"/> RECOVERED/RESOLVED WITH SEQUELAE <input type="radio"/> RECOVERING/RESOLVING <input type="radio"/> UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuation]	<input type="radio"/> YES AESUBJDC in SUPPAE Linked to related DS record via RELREC <input type="radio"/> NO
15.	Serious Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]	AEREFID
16.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED
17.	Lowest Level Term [hidden] [Lowest Level Term]	AELLT
18.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	AELLTCD
19.	Dictionary-Derived Term [hidden] [Dictionary-Derived Term]	AEDECOD
20.	Preferred Term Code [hidden] [Preferred Term Code]	AEPTCD
21.	High Level Term [hidden] [High Level Term]	AEHLT
22.	High Level Term Code [hidden] [High Level Term Code]	AEHLTCD
23.	High Level Group Term [hidden] [High Level Group Term]	AEHLGT
24.	High Level Group Term Code [hidden] [High Level Group Term Code]	AEHLGTCD
25.	Primary System Organ Class [hidden] [Primary System Organ Class]	AEBODSYS AESOC
26.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	AEBDSYCD AESOCCD

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STUDYID**LB=Laboratory Test Results****C4591001: LABORATORY DATA - HEMATOLOGY (CD4)****Laboratory Data Hematology**

1. Lab Panel: [Category for Lab Test]	<input type="radio"/> HEMATOLOGY LBCAT
2. Laboratory Name and Address [Vendor Name (DERIVED)]	LBNAM
3. Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC
4. Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		CD4_PX4722			

Lab Result Entry

5.1 Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/> LBSPID
5.2 Test: [Test:]	<input type="radio"/> CD4_PX4722 LBTEST
5.3 Result: [Result:]	<input type="text"/> LBORRES
5.4 Not Done: <i>[hidden]</i> [Not Done:]	<input type="radio"/> NOT DONE LBSTAT
5.5 LNMT [Lab Normal Range]	Low <input type="text"/> LBORNRL0 High <input type="text"/> LBORNRI Unit <input type="radio"/> 10 ³ /mm ³ LBORRESU <input type="radio"/> /uL <input type="radio"/> %

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C4591001: COHORT SELECTION (COHORT SEL) NOT SUBMITTED	
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 [Trigger Response 1]	<input type="button" value="v"/>
2. Select appropriate response - What cohort does the subject belong to? [Trigger Response 10]	<input type="radio"/> STAGE 1 SENTINEL COHORTS <input type="radio"/> STAGE 1 NONSENTINEL COHORTS <input type="radio"/> STAGE 2 COHORTS <input type="radio"/> STAGE 3 COHORTS

STUDYID**CM=Concomitant Medications****C4591001: CONCOMITANT MEDICATIONS - BASELINE (CONMED BSL) - Repeating Form**

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date
1									
Concomitant Medications									
1.	What is the medication identifier? [Sponsor-Defined Identifier]	<input type="text" value="CMSPID"/>							
2.	Category: [Category for Medication]	<input type="radio"/> GENERAL CONCOMITANT MEDICATIONS <input type="text" value="CMCAT"/>							
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input type="radio"/> NO <input type="text" value="NOT SUBMITTED"/>							
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). [Name of Medication]	<input type="text" value="CMTRT"/>							
5.	Dose: [Dose Description]	<input type="text" value="CMDOSE"/> <input type="text" value="CMDOSTXT"/>							
6.	Dose Unit: [Dose Unit]	<input type="text" value="CMDOSU"/>							
7.	Dose Frequency: [Dose Frequency]	<input type="text" value="CMDOSFRQ"/>							
8.	Route: [Route]	<input type="text" value="CMROUTE"/>							
9.	Start Date: [Start Date]	<input type="text" value="CMSTDTC"/>							
10.	Comparison Term <i>[hidden]</i> [Comparison Term]	<input type="text" value="NOT SUBMITTED"/>							
11.	Standardized Medication Name - Dictionary derived. <i>[hidden]</i> [Standardized Medication Name]	<input type="text" value="CMDECOD"/>							
12.	Standardized Medication Code - Dictionary derived <i>[hidden]</i> [Standardized Medication Code]	<input type="text" value="CMCODE in SUPPCM"/>							

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STUDYID**CM=Concomitant Medications****C4591001: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS (CONMED VAX) - Repeating Form**

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date
1					
Concomitant Medications					
1.	What is the medication identifier? [Sponsor-Defined Identifier]	CMSPID			
2.	Category: [Category for Medication]	<input type="radio"/> VACCINATIONS CMCAT			
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input type="radio"/> NO NOT SUBMITTED			
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). [Name of Medication]	CMTRT			
5.	Date: [Start Date]	<input type="text"/> / <input type="text"/> / <input type="text"/> CMSTDTC			
6.	Comparison Term <i>[hidden]</i> [Comparison Term]	NOT SUBMITTED			
7.	Standardized Medication Name - Dictionary derived. <i>[hidden]</i> [Standardized Medication Name]	CMDECOD			
8.	Standardized Medication Code - Dictionary derived <i>[hidden]</i> [Standardized Medication Code]	<input type="text"/> CMCODE in SUPPCM			

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STUDYID		DS=Disposition	
C4591001: MAIN INFORMED CONSENT (CONSENT)		DSCAT=PROTOCOL MILESTONE	
Informed Consent			
1.	Consent Was: [Consent Was:]	<input type="radio"/> OBTAINED Date Written Consent Obtained <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/>	DSSTDTC when DSTERM/DSDECOD=INFORMED CONSENT OBTAINED

STUDYID**SV=Subject Visits****C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)****Contact Outcome**

1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME	NOT SUBMITTED
2.	Contact Type: [Type of Contact/Visit]	<input type="radio"/> CLINIC VISIT <input type="radio"/> TELEHEALTH VISIT	SVREFID
3.	Was contact made? [Was Contact Made]	<input type="radio"/> YES Date of Contact: <div> <div>▼</div> / <div>▼</div> / <div>▼</div> </div> <input type="radio"/> NO If No, why?	NOT SUBMITTED SVSTDTC SVENDTC when UNPLANNED VISITS NOT SUBMITTED
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED	

STUDYID		SV=Subject Visits	
C4591001: CONTACT OUTCOME - MONTH 6 (CONTACT 6M)			
Contact Outcome			
1. Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME NOT SUBMITTED		
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> CLINIC VISIT SVREFID <input type="radio"/> TELEHEALTH VISIT		
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES NOT SUBMITTED Date of Contact: <div> <div>▼</div> / <div>▼</div> / <div>▼</div> </div> SVSTDTC SVENDTC when UNPLANNED VISITS <input type="radio"/> NO If No, why? <div>NOT SUBMITTED</div>		
4. Comments: [Comments/Findings/Details]	<div>NOT SUBMITTED</div>		

STUDYID		SV=Subject Visits	
C4591001: CONTACT OUTCOME (CONTACT SV)			
Contact Outcome			
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME NOT SUBMITTED	
2.	Contact Type: [Type of Contact/Visit]	<input type="radio"/> TELEPHONE VISIT SVREFID	
3.	Was contact made? [Was Contact Made]	<input type="radio"/> YES NOT SUBMITTED Date of Contact: <input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/> SVSTDTC <input type="radio"/> NO If No, why? <div>NOT SUBMITTED</div>	
4.	Comments: [Comments/Findings/Details]	<div>NOT SUBMITTED</div>	

STUDYID**SV=Subject Visits****C4591001: CONTACT OUTCOME - UNPLANNED (CONTACT UV)****Contact Outcome**

1. Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME NOT SUBMITTED
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> TELEPHONE VISIT SVREFID
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES NOT SUBMITTED Date of Contact: <input type="text"/> / <input type="text"/> / <input type="text"/> SVSTDTC SVENDTC when UNPLANNED VISITS Contact Outcome: <input type="radio"/> VISIT ARRANGED NOT SUBMITTED <input type="radio"/> VISIT ARRANGED, BUT NOT ATTENDED <input type="radio"/> VISIT NOT ARRANGED, REACTION NO LONGER PRESENT <input type="radio"/> VISIT NOT ARRANGED, UNABLE TO ATTEND <input type="radio"/> VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY <input type="radio"/> VISIT NOT REQUIRED, INVESTIGATOR DECISION <input type="radio"/> NO If No, why? <div>NOT SUBMITTED</div>
4. Comments: [Comments/Findings/Details]	NOT SUBMITTED

STUDYID		MB=Microbiology Specimen		DI=Device Identifiers	CO=Comments
C4591001: MICROBIOLOGY SPECIMEN (COV19 SITE) - Repeating Form					
				MBCAT=CONFIRMATION OF INFECTION	
#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result
1					
Microbiology Specimen					
1.	Actual Date of Collection: [Date of Collection]	<input type="text"/> / <input type="text"/> / <input type="text"/>	MBDTC		
2.	Specimen Type: [Specimen Type]	<input type="radio"/> SERUM <input type="radio"/> BLOOD <input type="radio"/> PLASMA	MBSPEC		
3.	Assay Code and Description: [Assay Code and Description]	<input type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	MBTEST		
4.	Device Type: [Device Type]	<input type="radio"/> SARS-COV-2 DIAGNOSTIC TEST	DIVAL when DIPARMCD = DEVTYPE		
5.	Test Result: [Result]	<input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE <input type="radio"/> INDETERMINATE	MBORRES when MBTESTCD = SARSCOV2		
6.	Comments/Findings/Details: [Comments:]	COVAL when RDOMAIN = MB			

STUDYID		MB=Microbiology Specimen		DI=Device Identifiers		CO=Comments			
C4591001: MICROBIOLOGY SPECIMEN (COVID TEST) - Repeating Form								MBCAT=CONFIRMATION OF INFECTION	
#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:	Trade Name Other, Specify
1									
Microbiology Specimen									
1.	Actual Date of Collection: [Date of Collection]	<input type="text"/> / <input type="text"/> / <input type="text"/> MBDTC							
2.	Specimen Type: [Specimen Type]	<input type="radio"/> SWABBED MATERIAL MBSPEC <input type="radio"/> RESPIRATORY SECRETIONS							
3.	Specimen Collection Location: [Specimen Collection Location]	<input type="radio"/> NASOPHARYNX <input type="radio"/> LOWER RESPIRATORY SYSTEM MBLOC <input type="radio"/> THROAT							
4.	Assay Code and Description: [Assay Code and Description]	<input type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 MBTEST							
5.	Device Type: [Device Type]	<input type="radio"/> SARS-COV-2 DIAGNOSTIC TEST DIVAL when DIPARMCD = DEVTYPE							
6.	Trade Name: [Trade Name]	<input type="text"/> DIVAL when DIPARMCD = TRADENAM							
7.	Test Result: [Result]	<input type="radio"/> POSITIVE MBORRES when MBTESTCD = SARSCOV2 <input type="radio"/> NEGATIVE <input type="radio"/> INDETERMINATE							
8.	Comments/Findings/Details: [Comments:]	<div style="border: 1px solid black; padding: 5px;">COVAL when RDOMAIN = MB</div>							
9.	Trade Name Other, Specify: [Trade Name Other, Specify]	<div style="border: 1px solid black; padding: 5px;">SUPPMB in TRADEOTH</div>							

STUDYID**DD=Death Details****C4591001: DEATH DETAILS CODED (DEATH DTL) DDCAT = DEATH DETAILS CODED****Death Details**

1.	Date of Collection / Notification of Death: [Date of Collection / Notification of Death]	▼ /	▼ /	▼ DDDTTC
2.	Cause of Death Status	Cause of Death		

Cause of Death Entry

2.1	Cause of Death Status: [Cause of Death Status]	<input type="radio"/> PRIMARY CAUSE OF DEATH <input type="radio"/> SECONDARY CAUSE OF DEATH	DDTEST
2.2	Cause of Death: [Cause of Death]	DDORRES	
2.3	Comparison Term <i>[hidden]</i> [Comparison Term]	NOT SUBMITTED	
2.4	Lowest Level Term <i>[hidden]</i> [Lowest Level Term]	NOT SUBMITTED	
2.5	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	NOT SUBMITTED	
2.6	Dictionary-Derived Term <i>[hidden]</i> [Dictionary-Derived Term]	DDSTRESC	
2.7	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	NOT SUBMITTED	
2.8	High Level Term <i>[hidden]</i> [High Level Term]	NOT SUBMITTED	
2.9	High Level Term Code <i>[hidden]</i> [High Level Term Code]	NOT SUBMITTED	
2.10	High Level Group Term <i>[hidden]</i> [High Level Group Term]	NOT SUBMITTED	
2.11	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	NOT SUBMITTED	
2.12	Primary System Organ Class <i>[hidden]</i> [Primary System Organ Class]	NOT SUBMITTED	
2.13	Primary System Organ Class Code <i>[hidden]</i> [Primary System Organ Class Code]	NOT SUBMITTED	

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STUDYID**DM=Demographics****C4591001: DEMOGRAPHY (DEMOG)****Demography**

1. Subject ID [Subject ID]	<input type="text"/> SUBJID
2. Birth Date: [Birth Date]	<input type="text"/> / <input type="text"/> / <input type="text"/> BIRTHDTC
3. Sex: [Sex]	<input type="radio"/> FEMALE <input type="radio"/> MALE SEX
4. Ethnicity: [Ethnicity]	<input type="radio"/> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN <input type="radio"/> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN ETHNIC <input type="radio"/> NOT REPORTED
5. Race: (Check X all that apply): [Race Of Subject]	<input type="checkbox"/> BLACK OR AFRICAN AMERICAN <input type="checkbox"/> AMERICAN INDIAN OR ALASKA NATIVE <input type="checkbox"/> ASIAN <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> WHITE <input type="checkbox"/> NOT REPORTED <div style="border: 1px solid black; padding: 5px; color: red; font-weight: bold;"> RACE, when more than one selected, RACE=MULTIPLE and individual responses are RACE1, RACE2, etc. in SUPPDM </div>
6. Racial Designation: [Racial Designation]	<input type="radio"/> JAPANESE <input type="radio"/> OTHER RACIALD in SUPPDM

STUDYID		<i>Linked to related AE record via RELREC</i>		DS=Disposition	
C4591001: DISPOSITION - FOLLOW-UP (DISP FUP) DSCAT = DISPOSITION EVENT					
Disposition - Follow-Up					
1.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]		<input type="text"/> / <input type="text"/> / <input type="text"/>	DSSTDTC	
2.	Phase of Disposition: [Disposition Phase]	<input type="radio"/> FOLLOW-UP		DSPHASE in SUPPDS	
3.	Status: [Status]		<input type="text"/>	DSDECOD	
4.	Specify Status: [Specify Status]	DSTERM			

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STUDYID**Linked to related AE record via RELREC****DS=Disposition****C4591001: DISPOSITION - SCREENING FOR FURTHER VACCINATION (DISP RESCR) **DSCAT = DISPOSITION EVENT******Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	<div> <div></div> <div>/</div> <div></div> </div> <div> <div></div> <div>/</div> <div></div> </div> <div> <div></div> </div> <div>DSSTDTC</div>
2.	Phase of Disposition: [Disposition Phase]	<input type="radio"/> REPEAT SCREENING 1 <div>DSPHASE in SUPPDS</div>
3.	Status: [Status]	<div> <div></div> </div> <div>DSDECOD</div>
4.	Specify Status: [Specify Status]	<div>DSTERM</div>

STUDYID		Linked to related AE record via RELREC		DS=Disposition	
C4591001: DISPOSITION - SCREENING (DISP SCR) DSCAT = DISPOSITION EVENT					
Disposition - Screening					
1.	Date of Completion/Discontinuation/Death [Date of Completion/Discontinuation/Death]	<input type="text"/> / <input type="text"/> / <input type="text"/>	DSSTDTC		
2.	Phase of Disposition: [Disposition Phase]	<input checked="" type="radio"/> SCREENING	DSPHASE in SUPPDS		
3.	Status: [Status]	<input type="text"/>	DSDECOD		
4.	Specify Status: [Specify Status]	DSTERM			

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STUDYID**Linked to related AE record via RELREC****DS=Disposition****C4591001: DISPOSITION - TREATMENT (DISP TRT) DSCAT = DISPOSITION EVENT****Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	<input type="text"/> / <input type="text"/> / <input type="text"/> DSSTDTC
2.	Phase of Disposition: [Disposition Phase]	<input type="radio"/> VACCINATION DSPHASE in SUPPDS <input type="radio"/> OPEN LABEL TREATMENT
3.	Status: [Status]	<input type="text"/> DSDECOD
4.	Specify Status: [Specify Status]	DSTERM

STUDYID

SV=Subject Visits

C4591001: DATE OF VISIT (DOV)		
Date of Visit		
1.	Date of Visit [Date of Visit]	<input type="text"/> / <input type="text"/> / <input type="text"/> SVSTDTC SVENDTC when UNPLANNED VISITS
2.	Erroneous Visit [Visit Error]	<input type="radio"/> ERRONEOUS VISIT NOT SUBMITTED

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STUDYID**SV=Subject Visits****C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)****Date of Visit**

1.	Date of Visit [Date of Visit]	<input type="text"/> / <input type="text"/> / <input type="text"/>	SVSTDTC
2.	Erroneous Visit [Visit Error]	<input type="radio"/> ERRONEOUS VISIT	NOT SUBMITTED
COVID-19 Illness Visit			
3.	COVID-19 Illness Visit: [COVID-19 Illness Visit]	<input type="text"/>	VISIT

STUDYID**SV=Subject Visits****C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)****Date of Visit**

1.	Date of Visit [Date of Visit]	<input type="text"/> / <input type="text"/> / <input type="text"/>	SVSTDTC
2.	Erroneous Visit [Visit Error]	<input type="radio"/> ERRONEOUS VISIT	NOT SUBMITTED
COVID-19 Illness Visit			
3.	COVID-19 Illness Visit: [COVID-19 Illness Visit]	<input type="text"/>	VISIT

STUDYID**SV=Subject Visits****C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV)****Date of Visit**

1.	Date of Visit [Date of Visit]	<input type="text"/> / <input type="text"/> / <input type="text"/>	SVSTDTC SVENDTC when UNPLANNED VISITS
2.	Erroneous Visit [Visit Error]	<input type="radio"/> ERRONEOUS VISIT	NOT SUBMITTED
COVID-19 Surveillance Visit			
3.	COVID-19 Surveillance Visit: [COVID-19 Surveillance Visit]	<input type="text"/>	NOT SUBMITTED

STUDYID**SV=Subject Visits****C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)****Date of Visit**

1.	Date of Visit [Date of Visit]	<input type="text"/> / <input type="text"/> / <input type="text"/>	SVSTDTC
2.	Erroneous Visit [Visit Error]	<input type="radio"/> ERRONEOUS VISIT	NOT SUBMITTED
COVID-19 Repeat Swab			
3.	COVID-19 Repeat Swab: [COVID-19 Repeat Swab]	<input type="text"/>	VISIT

C4591001: INFORM ENROLLMENT (ENROLL) NOT SUBMITTED	
InForm Enrollment	
1. Subject ID [Subject ID]	<input type="text"/>

C4591001: HIV STATUS (HIV) NOT SUBMITTED	
HIV Status	
1. Select appropriate response - What is the subject HIV status? [Trigger Response 2]	<input type="radio"/> The subject is known to be HIV POSITIVE <input type="radio"/> The subject is NOT known to be HIV POSITIVE

STUDYID**LB=Laboratory Test Results****C4591001: LAB CHEMISTRY (HIV RNA)****Lab Chemistry Details**

1. Lab Panel: [Category for Lab Test]	<input type="radio"/> CLINICAL CHEMISTRY LBCAT
2. Laboratory Name and Address [Vendor Name]	LBNAM
3. Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC
4. Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		HIV RNA (Ultrasensitive)			

Lab Result Entry

5.1 Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/> LBSPID
5.2 Test: [Test:]	<input type="radio"/> HIV RNA (Ultrasensitive) LBTEST
5.3 Result: [Result:]	<input type="text"/> LBORRES
5.4 Not Done: <i>[hidden]</i> [Not Done:]	<input type="radio"/> NOT DONE LBSTAT
5.5 LNMT [Lab Normal Range]	Low <input type="text"/> LBORNRL0 High <input type="text"/> LBORNRI Unit <input type="radio"/> /mL LBORRESU

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STUDYID**HO=Healthcare Encounters****FA=Findings About Events or Interventions****C4591001: HEALTH CARE UTILIZATION (HLTHCARE)****HOCAT=HEALTHCARE
UTILIZATION ASSESSMENT****FACAT=HEALTHCARE
UTILIZATION****Health Care Utilization**

1.	Evaluation Interval: [hidden] [Evaluation Interval]	<input type="radio"/> SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE	HOEVINTX	FAEVINTX
2.	Disease Name: [hidden] [Disease Name]	<input type="radio"/> RESPIRATORY ILLNESS	HCUIDIS in SUPPHO	

Health Care Utilization

#	Pre-Specified	Type of Practitioner	Occurrence of Visits or Contacts
3.a	YES	SPECIALIST	
3.b	YES	EMERGENCY ROOM	
3.c	YES	PRIMARY CARE PHYSICIAN	
3.d	YES	URGENT CARE	
3.e	YES	TELEPHONE CONSULTATION	
3.f	YES	OTHER	

Health Care Utilization Entry

3.1	Pre-Specified: [hidden] [Pre-Specified]	<input type="radio"/> YES	HOPRESP
3.2	Physician or Healthcare Professional: [Type of Practitioner]	<input type="radio"/> SPECIALIST <input type="radio"/> EMERGENCY ROOM <input type="radio"/> PRIMARY CARE PHYSICIAN <input type="radio"/> URGENT CARE <input type="radio"/> TELEPHONE CONSULTATION <input type="radio"/> OTHER	HOTERM
3.3	Occurrence of Visits or Contacts: [Occurrence of Visits or Contacts]	<input type="radio"/> YES Number of Visits or Contacts: <input type="text"/>	HOCCUR FAORRES when FATESTCD=NUMBER
		<input type="radio"/> NO	

Health Care Utilization Other

4.	Other Type of Practitioner Specify: [Other Type of Practitioner Specify]	HOTERM
----	---	---------------

Health Care Utilization

5.	Has the subject been hospitalized due to potential COVID-19 illness? [Been Hospitalized]	<input type="radio"/> YES Has the subject been in intensive care due to potential COVID-19 illness? <input type="radio"/> YES <input type="radio"/> NO	HCUHSP in SUPPHO HCUICU in SUPPHO
		<input type="radio"/> NO	

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STUDYID**HO=Healthcare Encounters****C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form**

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing
1				
Hospitalization Details				
1.	Hospitalization Category: [Hospitalization Category]	<input type="radio"/> HOSPITALIZATION STATUS HOCAT		
2.	Hospitalization Term: [Hospitalization Term]	<input type="radio"/> ICU HOTERM <input type="radio"/> HOSPITAL		
3.	Admission Date: [Admission Date]	<div> <div>▼ /</div> <div>▼ /</div> <div>▼ HOSTDTC</div> </div>		
4.	Ongoing? [Ongoing]	<input type="radio"/> YES HOENRTPT= ONGOING HOENTPT= ONGOING AT CURRENT VISIT <input type="radio"/> NO Discharge Date: <div> <div>▼ /</div> <div>▼ /</div> <div>▼ HOENDTC</div> </div>		

STUDYID**CE=Clinical Events****C4591001: ILLNESS DETAILS (ILL POTEN) CECAT = EFFICACY****Illness Details**

1.	Category of Clinical Event: [Category of Clinical Event:]	<input type="radio"/> POTENTIAL COVID-19 ILLNESS NOT SUBMITTED
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	<input type="radio"/> YES Respiratory Illness Diagnosis: CETERM Date of Diagnosis: <input type="text"/> / <input type="text"/> / <input type="text"/> CEDTC <input type="radio"/> NO NOT SUBMITTED
3.	Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 0 <input type="radio"/> 1 CETOXGR <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
4.	Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED
5.	Lowest Level Term [hidden] [Lowest Level Term]	CELLT
6.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	CELLTCD
7.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	CEDECOD
8.	Preferred Term Code [hidden] [Preferred Term Code]	CEPTCD
9.	High Level Term [hidden] [High Level Term]	CEHLT
10.	High Level Term Code [hidden] [High Level Term Code]	CEHLTCD
11.	High Level Group Term [hidden] [High Level Group Term]	CEHLGT
12.	High Level Group Term Code [hidden] [High Level Group Term Code]	CEHLGTCD
13.	Primary System Organ Class [hidden] [Primary System Organ Class]	CEBODSYS CESOC
14.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	CEBDSYCD CESOCCD

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STUDYID**CE=Clinical Events****C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)****Illness Details**

1.	Category of Clinical Event: [Category of Clinical Event:]	<input type="radio"/> SEVERE COVID-19 ILLNESS CECAT
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	<input type="radio"/> SIGNIFICANT ACUTE RENAL DYSFUNCTION <input type="radio"/> SIGNIFICANT ACUTE HEPATIC DYSFUNCTION CESCAT <input type="radio"/> SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3.	Was a diagnosis obtained? [Diagnosis Obtained]	<input type="radio"/> YES Diagnosis: CETERM Start Date: / / CESTDTC Ongoing?: <input type="radio"/> YES CEENRTPT= ONGOING/BEFORE CEENTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: / / CEENDTC <input type="radio"/> NO NOT SUBMITTED
4.	Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 1 <input type="radio"/> 2 CETOXGR <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
5.	Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED
6.	Lowest Level Term [hidden] [Lowest Level Term]	CELLT
7.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	CELLTCD
8.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	CEDECOD
9.	Preferred Term Code [hidden] [Preferred Term Code]	CEPTCD
10.	High Level Term [hidden] [High Level Term]	CEHLT
11.	High Level Term Code [hidden] [High Level Term Code]	CEHLTCD
12.	High Level Group Term [hidden] [High Level Group Term]	CEHLGT
13.	High Level Group Term Code [hidden] [High Level Group Term Code]	CEHLGTCD
14.	Primary System Organ Class [hidden] [Primary System Organ Class]	CEBODSYS CESOC
15.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	CEBDSYCD CESOCCD

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STUDYID**CE=Clinical Events****C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE) - Repeating Form**

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade
1				
Illness Details				
1.	Category of Clinical Event: [Category of Clinical Event:]	<input type="radio"/> SEVERE COVID-19 ILLNESS CECAT		
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	<input type="radio"/> SIGNIFICANT ACUTE RENAL DYSFUNCTION <input type="radio"/> SIGNIFICANT ACUTE HEPATIC DYSFUNCTION CESCAT <input type="radio"/> SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION		
3.	Was a diagnosis obtained? [Diagnosis Obtained]	<input type="radio"/> YES Diagnosis: CETERM Start Date: / / CESTDTC Ongoing?: <input type="radio"/> YES CEENRTPT= ONGOING/BEFORE CEENTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: / / CEENDTC <input type="radio"/> NO NOT SUBMITTED		
4.	Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 1 <input type="radio"/> 2 CETOXGR <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5		
5.	Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED		
6.	Lowest Level Term [hidden] [Lowest Level Term]	CELLT		
7.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	CELLTCD		
8.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	CEDECOD		
9.	Preferred Term Code [hidden] [Preferred Term Code]	CEPTCD		
10.	High Level Term [hidden] [High Level Term]	CEHLT		
11.	High Level Term Code [hidden] [High Level Term Code]	CEHLTCD		
12.	High Level Group Term [hidden] [High Level Group Term]	CEHLGT		
13.	High Level Group Term Code [hidden] [High Level Group Term Code]	CEHLGTCD		
14.	Primary System Organ Class [hidden] [Primary System Organ Class]	CEBODSYS CESOC		
15.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	CEBDSYCD CESOCCD		

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STUDYID**MO=Morphology****C4591001: IMAGING (IMAGING) - Repeating Form** **MOCAT=CLINICAL ASSESSMENT OF RADIOGRAPHS - IMAGING**

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment
1				
Imaging				
1.	Date of Assessment: [Date of Assessment]	<input type="text"/> / <input type="text"/> / <input type="text"/> MODTC		
2.	Location of Assessment: [Location of Assessment]	<input type="radio"/> CHEST MOLOC <input type="radio"/> HEAD <input type="radio"/> OTHER If other, specify: LOCOTH in SUPPMO		
3.	Type of Imaging Exam: [Imaging Method]	<input type="radio"/> CT SCAN MOMETHOD <input type="radio"/> X-RAY <input type="radio"/> ULTRASOUND <input type="radio"/> MRI <input type="radio"/> OTHER If other, specify: METHOTH in SUPPMO		
4.	Assessment: MOTEST [Overall Assessment]	<input type="radio"/> ABNORMAL MOORRES If abnormal, specify findings: ASPECIFY IN SUPPMO <input type="radio"/> INDETERMINATE <input type="radio"/> NORMAL MOORRES <input type="radio"/> UNKNOWN <input type="radio"/> NOT EVALUABLE		

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)**

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input checked="" type="radio"/> 2 IESPID <input type="radio"/> 3 <input type="radio"/> 4
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IETEST
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES <input type="radio"/> NO Describe details if relevant <div>IEDESC in SUPPIE</div>
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input checked="" type="radio"/> IN02A00 IETESTCD <input type="radio"/> IN03A00 <input type="radio"/> IN04A00

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.k	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A00
2.l	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A00
2.m	16	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.n	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

Exclusion Criteria Entry **IECAT = EXCLUSION**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/> IESPID
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IETEST
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES <input type="radio"/> NO Describe details if relevant <div>IEDESC in SUPPIE</div>

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IE=Inclusion/Exclusion Criteria Not Met

		<input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="checkbox"/> IETESTCD

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)**

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#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4	IESPID
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IEATEST	
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant	IEORRES
		IEDESC in SUPPIE	
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00	IEATESTCD

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.g	11	Women who are pregnant or breastfeeding		EX11A00
2.h	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.i	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.j	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.k	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.l	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.m	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry **IECAT = EXCLUSION**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/> IESPID	
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IEATEST	
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant	IEORRES
		IEDESC in SUPPIE	
2.4	Criterion ID: (For Pfizer use only)	IEATESTCD	

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only)
[Criterion ID: (For Pfizer use
only)]



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STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)**

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Inclusion Criteria

#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input checked="" type="radio"/> 2 IESPID <input type="radio"/> 3 <input type="radio"/> 4
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> JETEST
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES <input type="radio"/> NO Describe details if relevant <div>IEDESC in SUPPIE</div>
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input checked="" type="radio"/> IN02A00 JETESTCD <input type="radio"/> IN03A00 <input type="radio"/> IN04A00

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.m	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry **IECAT = EXCLUSION**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/> IESPID
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> JETEST
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES Describe details if relevant <div>IEDESC in SUPPIE</div>

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IE=Inclusion/Exclusion Criteria Not Met

		<input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="v"/> IETESTCD

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STUDYID**IE=Inclusion/Exclusion Criteria Not Met**

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)	
Criterion Description	
1.	
Inclusion Criteria Not Met Entry	
1.1 Description of Inclusion Criterion Not Met [Criterion Description]	<input type="checkbox"/> IE TEST when IEORRES=N
Criterion Description	
2.	
Exclusion Criteria Met Entry	
2.1 Description of Exclusion Criterion Met [Criterion Description]	<input type="checkbox"/> IE TEST when IEORRES=Y

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)**

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input checked="" type="radio"/> 2 IESPID <input type="radio"/> 3 <input type="radio"/> 4
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IETEST
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES <input type="radio"/> NO Describe details if relevant <div>IEDESC in SUPPIE</div>
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input checked="" type="radio"/> IN02A00 IETESTCD <input type="radio"/> IN03A00 <input type="radio"/> IN04A00

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.m	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry **IECAT = EXCLUSION**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/> IESPID
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IETEST
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES Describe details if relevant <div>IEDESC in SUPPIE</div> <input type="radio"/> NO

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2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	 IE TESTCD
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STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)**

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Inclusion Criteria

#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4	IESPID
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IE TEST	
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant	IEORRES IEDESC in SUPPIE
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00	IE TEST CD

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
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2.j	12	Previous vaccination with any coronavirus vaccine		EX12A00
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Exclusion Criteria Entry **IECAT = EXCLUSION**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/> IESPID	
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IE TEST	
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant	IEORRES IEDESC in SUPPIE

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		<input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="v"/> IE TESTCD

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)**

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1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4	IESPID
1.2	Criterion Description: [Criterion Description]	<input checked="" type="radio"/> IE TEST	
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant	IEORRES IEDESC in SUPPIE
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00	IE TESTCD

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#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
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2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
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2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
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2.j	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
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2.m	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A00
2.n	16	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
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Exclusion Criteria Entry **IECAT = EXCLUSION**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="radio"/> IESPID	
2.2	Criterion Description: [Criterion Description]	<input checked="" type="radio"/> IE TEST	
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant	IEORRES IEDESC in SUPPIE

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IE=Inclusion/Exclusion Criteria Not Met

		<input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="v"/> IE TESTCD

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)**

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#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 IESPID <input type="radio"/> 3 <input type="radio"/> 4
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IETEST
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES <input type="radio"/> NO Describe details if relevant <div>IEDESC in SUPPIE</div>
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 IETESTCD <input type="radio"/> IN03A00 <input type="radio"/> IN04A00

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Sentinel participants in Stage 1 only: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A04
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.q	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.r	18	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen		EX19A01

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IE=Inclusion/Exclusion Criteria Not Met

		(HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit		
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A01
2.v	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

Exclusion Criteria Entry **IECAT = EXCLUSION**

2.1	Exclusion Number: [Exclusion Number]	<input type="text" value="IESPID"/>
2.2	Criterion Description: [Criterion Description]	<input type="text" value="IETEST"/>
2.3	Criterion met? [Criterion met?]	<input checked="" type="radio"/> YES IEORRES Describe details if relevant <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">IEDESC in SUPPIE</div> <input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="text" value="IETESTCD"/>

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)**

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input checked="" type="radio"/> 2 IESPID <input type="radio"/> 3 <input type="radio"/> 4
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IETEST
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">IEDESC in SUPPIE</div>
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 IETESTCD <input type="radio"/> IN03A00 <input type="radio"/> IN04A00

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19		EX06A00
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.m	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.n	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A00
2.o	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A00
2.p	16	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.q	17	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A00
2.r	18	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A00
2.s	19	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit		EX19A00

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2.t	20	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A00
2.u	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00
Exclusion Criteria Entry IECAT = EXCLUSION				
2.1	Exclusion Number: [Exclusion Number]	<input type="button" value="v"/> IESPID		
2.2	Criterion Description: [Criterion Description]	<input type="button" value="v"/> IETEST		
2.3	Criterion met? [Criterion met?]	<input checked="" type="radio"/> YES IEORRES Describe details if relevant <div style="border: 1px solid black; padding: 5px; margin: 5px 0;">IEDESC in SUPPIE</div> <input type="radio"/> NO		
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="v"/> IETESTCD		

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)**

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00
1.b	2	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures		IN02A00
1.c	3	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study		IN03A00
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol		IN04A00

Inclusion Criteria Entry **IECAT = INCLUSION**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 IESPID <input type="radio"/> 3 <input type="radio"/> 4
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/> IETEST
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES <input type="radio"/> NO Describe details if relevant <div>IEDESC in SUPPIE</div>
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 IETESTCD <input type="radio"/> IN03A00 <input type="radio"/> IN04A00

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.q	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.r	18	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen		EX19A01

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IE=Inclusion/Exclusion Criteria Not Met

		(HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit		
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A01
2.v	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01
Exclusion Criteria Entry IECAT = EXCLUSION				
2.1	Exclusion Number: [Exclusion Number]	<input type="button" value="v"/> IESPID		
2.2	Criterion Description: [Criterion Description]	<input type="button" value="v"/> IETEST		
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES IEORRES Describe details if relevant <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">IEDESC in SUPPIE</div> <input type="radio"/> NO		
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="v"/> IETESTCD		

C4591001: CASEBOOK SIGNATURE FORM (INVSIG) NOT SUBMITTED	
Casebook Signature Form	
1. Casebook Signature [Casebook Signature]	<input type="radio"/> Click Here to Enable

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STUDYID**LB=Laboratory Test Results****MB=Microbiology Specimen****C4591001: CENTRAL LAB SAMPLE COLLECTION (LAB)****Central Lab Sample Collection**

1.	Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC MBDTC
2.	Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD LBSPEC MBSPEC

Lab Test

#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected
3.a	CLINICAL CHEMISTRY	BLOOD CHEMISTRY	
3.b	HEMATOLOGY	DIFFERENTIAL	

Lab Test Entry

3.1	Lab Panel: [Category for Lab Test]	<input type="radio"/> HEMATOLOGY LBCAT MBCAT <input type="radio"/> CLINICAL CHEMISTRY
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	<input type="radio"/> DIFFERENTIAL <input type="radio"/> BLOOD CHEMISTRY NOT SUBMITTED
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	<input type="radio"/> YES LBSCATYN in SUPPLB MBSCATYN in SUPPMB <input type="radio"/> NO

STUDYID**LB=Laboratory Test Results****MB=Microbiology Specimen****C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)****Central Lab Sample Collection**

1.	Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC MBDTC
2.	Specimen Type: [Specimen Type]	<input checked="" type="radio"/> BLOOD LBSPEC MBSPEC

Lab Test

#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected
3.a	CLINICAL CHEMISTRY	BLOOD CHEMISTRY	
3.b	CLINICAL CHEMISTRY	VIROLOGY	
3.c	HEMATOLOGY	DIFFERENTIAL	

Lab Test Entry

3.1	Lab Panel: [Category for Lab Test]	<input type="radio"/> HEMATOLOGY <input type="radio"/> CLINICAL CHEMISTRY LBCAT MBCAT
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	<input type="radio"/> DIFFERENTIAL <input type="radio"/> BLOOD CHEMISTRY NOT SUBMITTED <input type="radio"/> VIROLOGY
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	<input type="radio"/> YES LBSCATYN in SUPPLB MBSCATYN in SUPPMB <input type="radio"/> NO

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STUDYID**LB=Laboratory Test Results****C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form**

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result
1					
Lab Chemistry Details					
1.	Lab Panel: [Category for Lab Test]	<input type="radio"/> CLINICAL CHEMISTRY LBCAT			
2.	Laboratory Name and Address [Vendor Name]	LBNAM			
3.	Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC			
4.	Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD LBSPEC			
Lab Result					
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		C Reactive Protein_PX329			
Lab Result Entry					
5.1	Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/> LBSPID			
5.2	Test: [Test:]	<input type="radio"/> C Reactive Protein_PX329 LBTEST			
5.3	Result: [Result:]	<input type="text"/> LBORRES			
5.4	Not Done: <i>[hidden]</i> [Not Done:]	<input type="radio"/> NOT DONE LBSTAT			
5.5	LNMT [Lab Normal Range]	Low <input type="text"/> LBORNRL0 High <input type="text"/> LBORNRI Unit <input type="text"/> LBORRESU			

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STUDYID**LB=Laboratory Test Results****C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form**

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result
1					

Lab Chemistry Details

1. Lab Panel: [Category for Lab Test]	<input type="radio"/> CLINICAL CHEMISTRY LBCAT
2. Laboratory Name and Address [Vendor Name]	LBNAM
3. Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC
4. Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		C Reactive Protein_PX329			
5.b		Alanine Aminotransferase_PX30			
5.c		Aspartate Aminotransferase_PX28			
5.d		Alkaline Phosphatase_PX35			
5.e		Bilirubin_PX21			
5.f		Blood Urea Nitrogen_PX47			
5.g		Creatinine_PX48			

Lab Result Entry

5.1 Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/> LBSPID
5.2 Test: [Test:]	<input type="text"/> LBTEST
5.3 Result: [Result:]	<input type="text"/> LBORRES
5.4 Not Done: [Not Done:]	<input type="radio"/> NOT DONE LBSTAT
5.5 LNMT [Lab Normal Range]	Low <input type="text"/> LBORNRL0 High <input type="text"/> LBORNRI Unit <input type="text"/> LBORRESU

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STUDYID**LB=Laboratory Test Results****C4591001: LOCAL LABORATORY DATA - REPEATING Hematology (LAB HEM) - Repeating Form**

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result
1					

Laboratory Data Hematology

1. Lab Panel: [Category for Lab Test]	<input type="radio"/> HEMATOLOGY LBCAT
2. Laboratory Name and Address [Vendor Name (DERIVED)]	LBNAM
3. Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC
4. Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		Hemoglobin_PX1			
5.b		Hematocrit_PX2			
5.c		Erythrocytes_PX3			
5.d		Platelets_PX5			
5.e		Leukocytes_PX7			
5.f		Neutrophils_PX608			
5.g		Eosinophils_PX609			
5.h		Monocytes_PX612			
5.i		Basophils_PX610			
5.j		Lymphocytes_PX611			

Lab Result Entry

5.1 Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/> LBSPID
5.2 Test: [Test:]	<input type="text"/> LBTEST
5.3 Result: [Result:]	<input type="text"/> LBORRES
5.4 Not Done: [Not Done:]	<input type="radio"/> NOT DONE LBSTAT
5.5 LNMT [Lab Normal Range]	Low <input type="text"/> LBORNRL0 High <input type="text"/> LBORNRFI Unit <input type="text"/> LBORRESU

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STUDYID**LB=Laboratory Test Results****C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)****Lab Urinalysis**

1. Lab Panel: [Category for Lab Test]	<input type="radio"/> URINALYSIS LBCAT
2. Lab Sub-Panel: [Subcategory for Lab Test]	<input type="radio"/> PREGNANCY LBSCAT
3. Collection Date: [Collection Date:]	<input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/> LBDTC
4. Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]	LBNAM
5. Specimen Type: [Specimen Type]	<input type="radio"/> URINE LBSPEC

Lab Result

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:
6.a		Choriogonadotropin Beta_PX113		

Lab Result Entry

6.1 Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/> LBSPID
6.2 Test: [Test:]	<input type="radio"/> Choriogonadotropin Beta_PX113 LBTEST
6.3 Result: [Result:]	<input type="radio"/> NEGATIVE LBORRES <input type="radio"/> POSITIVE
6.4 Not Done: [Not Done:]	<input type="radio"/> NOT DONE LBSTAT

STUDYID										AE=Adverse Events
C4591001: MEDICATION ERROR (MED ERROR) - Repeating Form										
#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	Serious Adverse Event Number
1										
Medication Error										
1.	Category:	<input type="radio"/> MEDICATION ERROR AECAT								
2.	Medication Error (Type of Medication Error):	AETERM								
3.	If this is a dispensing error, record the incorrect container number that was dispensed/administered to the subject: [hidden]	<input type="text"/> AEIPKGID in SUPPAE								
4.	Start Date:	<input type="text"/> / <input type="text"/> / <input type="text"/> AESTDTC								
5.	Is the medication error still ongoing?	<input type="radio"/> YES AEENRTPT= ONGOING AEENTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/> AEENDTC								
6.	Latest Action Taken with Study Treatment:	<input type="radio"/> NO ACTION TAKEN <input type="radio"/> PERMANENTLY DISCONTINUED AEACN								
7.	Was a Concomitant Medication given?	<input type="radio"/> YES <input type="radio"/> NO AECONTRT AECMGIV in SUPPAE								
8.	Was a Non-Drug Treatment given?	<input type="radio"/> YES <input type="radio"/> NO AECONTRT AENDGIV in SUPPAE								
9.	Did the Medication Error cause the subject to be discontinued from the study?	<input type="radio"/> YES <input type="radio"/> NO AESUBJDC in SUPPAE Linked to related DS record via RELREC								
10.	Was this medication error associated with any adverse events?	<input type="radio"/> YES AE ID: AEMEFL in SUPPAE <input type="text"/> AEAENO in SUPPAE AE ID: <input type="text"/> AEAENO in SUPPAE AE ID: <input type="text"/> AEAENO in SUPPAE AE ID: <input type="text"/> AEAENO in SUPPAE AE ID: <input type="text"/> AEAENO in SUPPAE AE ID: <input type="text"/> AEAENO in SUPPAE <input type="radio"/> NO								
11.	Serious Adverse Event Number: For Pfizer Use Only	AEREFID								
12.	Comparison Term	NOT SUBMITTED								
13.	Lowest Level Term	AELLT								
14.	Lowest Level Term Code	AELLTCD								
15.	Dictionary-Derived Term	AEDECOD								

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AE=Adverse Events

16.	Preferred Term Code [hidden] [Preferred Term Code]	<input type="text"/> AEPTCD
17.	High Level Term [hidden] [High Level Term]	<input type="text"/> AEHLT
18.	High Level Term Code [hidden] [High Level Term Code]	<input type="text"/> AEHLTCD
19.	High Level Group Term [hidden] [High Level Group Term]	<input type="text"/> AEHLGT
20.	High Level Group Term Code [hidden] [High Level Group Term Code]	<input type="text"/> AEHLGTCD
21.	Primary System Organ Class [hidden] [Primary System Organ Class]	<input type="text"/> AEBODSYS AESOC
22.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	<input type="text"/> AEBDSYCD AESOCCD

STUDYID**MH=Medical History****C4591001: GENERAL MEDICAL HISTORY (MEDHX) MHCAT=GENERAL MEDICAL HISTORY**

1.	Line/MH Number	Medical History Term	Start Date	Ongoing
Medical History Details Entry				
1.1	Line/MH Number: [Line/MH Number]	<input type="text"/> MHSPID		
1.2	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies: [Medical History Term]	<input type="text"/> MHTERM		
1.3	Start Date: [Start Date]	<input type="text"/> / <input type="text"/> / <input type="text"/> MHSTDTC		
1.4	Ongoing: [Ongoing]	<input type="radio"/> YES MHENRTPT= ONGOING/BEFORE MHENTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/> MHENDTC		
1.5	Comparison Term [hidden] [Comparison Term]	<input type="text"/> NOT SUBMITTED		
1.6	Lowest Level Term [hidden] [Lowest Level Term]	<input type="text"/> MHLLT		
1.7	Lowest Level Term Code [hidden] [Lowest Level Term Code]	<input type="text"/> MHLLTCD		
1.8	Dictionary Derived Term [hidden] [Dictionary Derived Term]	<input type="text"/> MHDECOD		
1.9	Preferred Term Code [hidden] [Preferred Term Code]	<input type="text"/> MHPTCD		
1.10	High Level Term [hidden] [High Level Term]	<input type="text"/> MHHLT		
1.11	High Level Term Code [hidden] [High Level Term Code]	<input type="text"/> MHHLTCD		
1.12	High Level Group Term [hidden] [High Level Group Term]	<input type="text"/> MHHLGT		
1.13	High Level Group Term Code [hidden] [High Level Group Term Code]	<input type="text"/> MHHLGTCD		
1.14	Primary System Organ Class [hidden] [Primary System Organ Class]	<input type="text"/> MHBODSYS MHSOC		
1.15	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	<input type="text"/> MHBDSYCD MHSOCCD		

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STUDYID**LB=Laboratory Test Results**

C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form			LBCAT= OXYGENATION PARAMETERS	
#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	
1			LBSCAT= BLOOD CHEMISTRY	
Oxygenation Parameters				
1.	Date Time of Assessment: [Date Time of Assessment]	<div> <div>▼</div> / <div>▼</div> / <div>▼</div> </div> <div> <div>▼</div> : <div>▼</div> 24-hour clock </div>	LBDTC	
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	<input type="text"/>	LBORRES when LBTESTCD = PO2	
3.	FiO2 (Fraction of Inhaled Oxygen): [FiO2 (Fraction of Inhaled Oxygen)]	<input type="text"/>	LBORRES when LBTESTCD = FIO2	

STUDYID**PE=Physical Examination****C4591001: PHYSICAL EXAMINATION (PHYS EXAM) ~~PECAT=PHYSICAL EXAMINATION~~****Physical Examination**

1. Exam Date: / / **PEDTC**

Physical Examination Result

#	Body System Examined	Result
2.a	GENERAL APPEARANCE	
2.b	SKIN	
2.c	HEAD	
2.d	EYES	
2.e	EARS	
2.f	NOSE	
2.g	THROAT	
2.h	HEART	
2.i	LUNGS	
2.j	ABDOMEN	
2.k	MUSCULOSKELETAL	
2.l	EXTREMITIES	
2.m	NEUROLOGICAL	
2.n	LYMPH NODES	

Physical Examination Result Entry

2.1	Body System Examined: [Body System Examined]	<input type="text"/> PETEST
2.2	Result: [Result]	<p><input type="radio"/> NORMAL PEORRES</p> <p><input type="radio"/> ABNORMAL PEORRES</p> <p>If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as appropriate).</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>Are there clinically significant findings?</p> <p><input type="radio"/> YES PECLSIG in SUPPE</p> <p><input type="radio"/> NO</p> <p><input type="radio"/> NOT DONE PESTAT</p>

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STUDYID**IS=Immunogenicity Specimen Assessment****CO=Comments****C4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19)****ISCAT=SEROLOGY****Electronic Sample Tracking**

1.	Data Origin [Data Origin]	<input type="radio"/> SITE	ETRKDOR in SUPPIS
2.	Sample Type [Sample Type]	<input type="radio"/> SERUM	ISSPEC
3.	Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES Date of Collection:	COVAL when COREF=SAMPLE COLLECTED <input type="text"/> / <input type="text"/> / <input type="text"/> ISDTC CODTC
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = IS	

Sample ID

5.

Aliquot Entry

Please enter barcode for each aliquot.

5.1	Sample ID [Sample ID]	NOT SUBMITTED
-----	--------------------------	----------------------

STUDYID**CM=Concomitant Medications****C4591001: CONCOMITANT MEDICATIONS - PROHIBITED (PROHIB CM) - Repeating Form**

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing
1										
Concomitant Medications										
1.	What is the medication identifier? [Sponsor-Defined Identifier]		CMSPID							
2.	Category: [Category for Medication]		<input type="radio"/> CONCOMITANT IMMUNOSUPPRESSIVE THERAPY <input type="radio"/> CORTICOSTEROIDS CMCAT <input type="radio"/> IMMUNOGLOBULINS							
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]		<input type="radio"/> NO NOT SUBMITTED							
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). [Name of Medication]		CMTRT							
5.	Dose: [Dose Description]		CMDOSE CMDOSTXT							
6.	Dose Unit: [Dose Unit]		<input type="button" value="v"/> CMDOSU							
7.	Dose Frequency: [Dose Frequency]		<input type="button" value="v"/> CMDOSFRQ							
8.	Route: [Route]		<input type="button" value="v"/> CMROUTE							
9.	Start Date: [Start Date]		<input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/> CMSTDTC							
10.	Ongoing? [Ongoing]		<input type="radio"/> YES CMENRTPT= ONGOING CMENPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: <input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/> CMENDTC							
11.	Comparison Term <i>[hidden]</i> [Comparison Term]		NOT SUBMITTED							
12.	Standardized Medication Name - Dictionary derived. <i>[hidden]</i> [Standardized Medication Name]		CMDECOD							
13.	Standardized Medication Code - Dictionary derived <i>[hidden]</i> [Standardized Medication Code]		<input type="text"/> CMCODE in SUPPCM							

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STUDYID**PR=Procedures****C4591001: RADIATION TREATMENT (PROHIB ND) - Repeating Form**

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?
1						
Radiation Treatment						
1.	Category: [Category]	<input type="radio"/> RADIATION THERAPY PRCAT				
2.	What is the treatment Identifier? [Treatment Identifier]	PRSPID				
3.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES PRPRES				
4.	Treatment: [Treatment]	PRTRT				
5.	Start Date: [Start Date]	<div> <div>▼</div> / <div>▼</div> / <div>▼</div> PRSTDTC </div>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES PRENRTPT= ONGOING PRENTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: <div> <div>▼</div> / <div>▼</div> / <div>▼</div> PRENDTC </div>				
7.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED				
8.	Lowest Level Term [hidden] [Lowest Level Term]	PRLLT in SUPPPR				
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	PRLTCD in SUPPPR				
10.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	PRDECOD				
11.	Preferred Term Code [hidden] [Preferred Term Code]	PRPTCD in SUPPPR				
12.	High Level Term [hidden] [High Level Term]	PRHLT in SUPPPR				
13.	High Level Term Code [hidden] [High Level Term Code]	PRHLTCD in SUPPPR				
14.	High Level Group Term [hidden] [High Level Group Term]	PRHLGT in SUPPPR				
15.	High Level Group Term Code [hidden] [High Level Group Term Code]	PRHLGTCD in SUPPPR				
16.	Primary System Organ Class [hidden] [Primary System Organ Class]	PRBODSYS in SUPPPR PRSOC in SUPPPR				
17.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	PRBDSYCD in SUPPPR PRSOCOD in SUPPPR				

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STUDYID**VS=Vital Signs****C4591001: VITAL SIGNS - PULSE OX ROOM AIR (PULSE OX) - Repeating Form** **VSCAT=GENERAL VITAL SIGNS**

#	Date:	Vital Signs Details	
1			
Vital Signs			
1.	Date: [Date:]	<input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/> VSDTC	
Vital Signs Details			
#	Record Identifier:	Oxygen Saturation	
✓			
2.a	1		
Vital Signs Details Entry			
2.1	Record Identifier: [Record Identifier:]	<input type="radio"/> 1 VSSPID	
2.2	SPO2 Pulse Oximetry % [Oxygen Saturation]	<input type="text"/> VSORRES when VSTESTCD = OXYSAT	

STUDYID		DS=Disposition	
C4591001: RANDOMIZATION (RAND) DSCAT=PROTOCOL MILESTONE			
Disposition			
1.	Randomization Date : [Randomization Date :]	<input type="text"/> / <input type="text"/> / <input type="text"/>	DSSTDTC when DSTERM/DSDECOD=RANDOMIZED
2.	Randomization Number: [Randomization Number]	DSREFID	
3.	Randomization Group: [Randomization Group]	DSRANGRP in SUPPDS	

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STUDYID

DM=Demographics

C4591001: REACTOGENICITY DIARY (REAC DIARY)

Reactogenicity Diary

- | | | |
|----|--|---|
| 1. | Select appropriate response -
Reactogenicity diary collection
[Trigger Response 9] | <input type="radio"/> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
<input type="radio"/> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT |
|----|--|---|

**REACTOFL='Y' in SUPPDM when non-missing
of vaccination start date**

REACTOFL='N' in SUPPDM

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STUDYID**FA=Findings About Events or Interventions****C4591001: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT (REACTION)****Unplanned Assessment Of Local Reaction** **FACAT=REACTOGENICITY -UNPLANNED ASSESSMENT**

1. CISR Category [hidden] [CISR Category]	<input type="radio"/> UNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT NOT SUBMITTED
2. Date of Assessment: [Date of Assessment]	<input type="text"/> / <input type="text"/> / <input type="text"/> FADTC
3. Injection Site Location [Injection Site Location]	<input type="radio"/> DELTOID MUSCLE FALOC
4. Injection Site Body Side: [Injection Site Body Side]	<input type="radio"/> LEFT FALAT <input type="radio"/> RIGHT

Reaction

#	Reaction:	Reaction Present:
5.a	REDNESS	
5.b	SWELLING	

Reaction Entry

5.1 Reaction: [Reaction:]	<input type="radio"/> REDNESS FAOBJ <input type="radio"/> SWELLING
5.2 Reaction Present: [Reaction Present:]	<input type="radio"/> YES FAORRES when FATESTCD=OCCUR Maximum Diameter (cm): <input type="text"/> FAORRES when FATESTCD=MAXDIAM Minimum Diameter (cm): <input type="text"/> FAORRES when FATESTCD=MINDIAM Meets Grade 4 Reaction Criteria: <input type="radio"/> YES FAORRES when FATESTCD=G4CRIMET <input type="radio"/> NO <input type="radio"/> NO

Symptom

#	Symptom:	Symptom Present:
6.a	PAIN AT INJECTION SITE	
6.b	FATIGUE/TIREDNESS	
6.c	HEADACHE	
6.d	VOMITING	
6.e	DIARRHEA	
6.f	NEW OR WORSENERED MUSCLE PAIN	
6.g	NEW OR WORSENERED JOINT PAIN	
6.h	CHILLS	

Symptom Entry

6.1 Symptom: [Symptom:]	<input type="text"/> FAOBJ
6.2 Symptom Present: [Symptom Present:]	<input type="radio"/> YES FAORRES when FATESTCD=OCCUR Symptom Grade: <input type="radio"/> 1 FAORRES when FATESTCD=SEV <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 Event related to Study Treatment? <input type="radio"/> YES FAORRES when FATESTCD=REL <input type="radio"/> NO <input type="radio"/> NO

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STUDYID**PR=Procedures****C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form** **PRCAT=GENERAL NON-DRUG TREATMENT**

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?
1						
Respiratory Treatment						
1.	What is the treatment Identifier? [Treatment Identifier]	PRSPID				
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES PRPRES				
3.	Treatment: [Treatment]	<input type="radio"/> NON-INVASIVE POSITIVE PRESSURE VENTILATION <input type="radio"/> CPAP <input type="radio"/> MECHANICAL VENTILATION PRTRT <input type="radio"/> EXTRACORPOREAL MEMBRANE OXYGENATION <input type="radio"/> HIGH FLOW OXYGEN THERAPY				
4.	Treatment: [Treatment]	PRTRT				
5.	Start Date: [Start Date]	<div> <div>▼</div> / <div>▼</div> / <div>▼</div> PRSTDTC </div>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES PRENRTPT= ONGOING PRENRTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: <div> <div>▼</div> / <div>▼</div> / <div>▼</div> PRENDTC </div>				
7.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED				
8.	Lowest Level Term [hidden] [Lowest Level Term]	PRLLT in SUPPPR				
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	PRLTCD in SUPPPR				
10.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	PRDECOD				
11.	Preferred Term Code [hidden] [Preferred Term Code]	PRPTCD in SUPPPR				
12.	High Level Term [hidden] [High Level Term]	PRHLT in SUPPPR				
13.	High Level Term Code [hidden] [High Level Term Code]	PRHLTCD in SUPPPR				
14.	High Level Group Term [hidden] [High Level Group Term]	PRHLGT in SUPPPR				
15.	High Level Group Term Code [hidden] [High Level Group Term Code]	PRHLGTCD in SUPPPR				
16.	Primary System Organ Class [hidden] [Primary System Organ Class]	PRBODSYS in SUPPPR PRSOC in SUPPPR				
17.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	PRBDSYCD in SUPPPR PRSOCCD in SUPPPR				

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STUDYID**PR=Procedures****C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form** **PRCAT=GENERAL NON-DRUG TREATMENT**



#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?
1						
Respiratory Treatment						
1.	What is the treatment Identifier? [Treatment Identifier]	PRSPID				
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES PRPRESP				
3.	Treatment: [Treatment]	<input type="radio"/> INTUBATION <input type="radio"/> NON-INVASIVE POSITIVE PRESSURE VENTILATION PRTRT <input type="radio"/> CPAP <input type="radio"/> OXYGEN THERAPY				
4.	Treatment: [Treatment]	PRTRT				
5.	Start Date: [Start Date]	<div> <div>▼</div> / <div>▼</div> / <div>▼</div> PRSTDTC </div>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES PRENRTPT= ONGOING PRENTPT= LAST SUBJECT ENCOUNTER <input type="radio"/> NO End Date: <div> <div>▼</div> / <div>▼</div> / <div>▼</div> PRENDTC </div>				
7.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED				
8.	Lowest Level Term [hidden] [Lowest Level Term]	PRLLT in SUPPPR				
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	PRLTCD in SUPPPR				
10.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	PRDECOD				
11.	Preferred Term Code [hidden] [Preferred Term Code]	PRPTCD in SUPPPR				
12.	High Level Term [hidden] [High Level Term]	PRHLT in SUPPPR				
13.	High Level Term Code [hidden] [High Level Term Code]	PRHLTCD in SUPPPR				
14.	High Level Group Term [hidden] [High Level Group Term]	PRHLGT in SUPPPR				
15.	High Level Group Term Code [hidden] [High Level Group Term Code]	PRHLGTCD in SUPPPR				
16.	Primary System Organ Class [hidden] [Primary System Organ Class]	PRBODSYS in SUPPPR PRSOC in SUPPPR				
17.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	PRBDSYCD in SUPPPR PRSOCCD in SUPPPR				

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C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF) NOT SUBMITTED	
Further Vaccination Confirmation	
1. Select appropriate response - Is participant willing to return for Vaccination 3? [Trigger Response 1]	<input type="radio"/> Participant is willing to return for Vaccination 3 Participant is: <input type="radio"/> eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 <input type="radio"/> eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 <input type="radio"/> eligible and NOT confirmed to have received only placebo at Vaccination 1/2 <input type="radio"/> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible

STUDYID		DS=Disposition	
C4591001: INFORMED CONSENT - FURTHER VACCINATION (REVAX CONS)		DSCAT=PROTOCOL MILESTONE	
Informed Consent - Further Vaccination			
1.	Consent Was: [Consent Was:]	<input type="radio"/> OBTAINED Date Written Consent Obtained <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/>	DSSTDTC when DSTERM/DSDECOD=INFORMED CONSENT OBTAINED

STUDYID**IE=Inclusion/Exclusion Criteria Not Met****C4591001: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)**

1.		Criterion Description
Inclusion Criteria Not Met Entry		
1.1	Description of Inclusion Criterion Not Met [Criterion Description]	 IE TEST when I EORRES=N
2.		Criterion Description
Exclusion Criteria Met Entry		
2.1	Description of Exclusion Criterion Met [Criterion Description]	 IE TEST when I EORRES=Y

STUDYID		MB=Microbiology Specimen	CO=Comments
C4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB) MBCAT=VIROLOGY			
Electronic Sample Tracking			
1. Data Origin [Data Origin]	<input type="radio"/> SITE ETRKDOR in SUPPMB		
2. Sample Type [Sample Type]	<input type="radio"/> NASAL_SWAB MBSPEC <input type="radio"/> NASAL_SWAB_SELF		
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO NOT SUBMITTED <input type="radio"/> YES Date of Collection: <input type="text"/> / <input type="text"/> / <input type="text"/> MBDTC		
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = MB		
Sample ID			
5.			
Aliquot Entry			
Please enter barcode for each aliquot.			
5.1 Sample ID [Sample ID]	NOT SUBMITTED		

STUDYID		IS=Immunogenicity Specimen Assessment		CO=Comments
C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK) ISCAT=SEROLOGY				
Electronic Sample Tracking				
1.	Data Origin [Data Origin]	<input type="radio"/> SITE	ETRKDOR in SUPPIS	
2.	Sample Type [Sample Type]	<input type="radio"/> SERUM	ISSPEC	
3.	Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES	COVAL when COREF=SAMPLE COLLECTED Date of Collection: <input type="text"/> / <input type="text"/> / <input type="text"/> ISDTC CODTC	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = IS		
Sample ID				
5.				
Aliquot Entry				
Please enter barcode for each aliquot.				
5.1	Sample ID [Sample ID]	NOT SUBMITTED		

C4591001: INFORM SCREENING (SCREEN) NOT SUBMITTED	
InForm Screening	
1. InForm Initials <i>[hidden]</i> [InForm Initials]	<input type="text"/>
2. Birth Date: [Birth Year]	<input type="text"/> / <input type="text"/> / <input type="text"/>

STUDYID		MB=Microbiology Specimen	CO=Comments
C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB) MBCAT=VIROLOGY			
Electronic Sample Tracking			
1. Data Origin [Data Origin]	<input type="radio"/> SITE ETRKDOR in SUPPMB		
2. Sample Type [Sample Type]	<input type="radio"/> NASAL_SWAB_SELF MBSPEC		
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO NOT SUBMITTED <input type="radio"/> YES Date of Collection: <div> <input type="text"/> / <input type="text"/> / <input type="text"/> MBDTC </div>		
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<div>COVAL when RDOMAIN = MB</div>		
Sample ID			
5.			
Aliquot Entry			
Please enter barcode for each aliquot.			
5.1 Sample ID [Sample ID]	NOT SUBMITTED		

STUDYIDOriginal version: VERSION 1: USED PRIOR TO JULY 6, 2020
New version: VERSION 2: USED AFTER JULY 6, 2020**FA=Findings About
Events or Interventions****CE=Clinical Events****C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)****FACAT=EFFICACY****CECAT=EFFICACY****Signs and Symptoms****FASCAT=RESPIRATORY ILLNESS****CESCAT=SIGNS AND SYMPTOMS OF DISEASE**

1. Date of Assessment: [Date of assessment]	<input type="text"/> / <input type="text"/> / <input type="text"/>	FADTC	CEDTC
2. Date of First Symptom Started: [First Symptom Started Date]	<input type="text"/> / <input type="text"/> / <input type="text"/>	FAORRES when FATESTCD=FSYMDATE	
3. Symptoms Ongoing? [Symptoms Ongoing]	<input type="radio"/> YES FAORRES when FATESTCD=SYMONGO CEENRPT= ONGOING CEENTPT= ONGOING AT CURRENT VISIT <input type="radio"/> NO Date of Last Symptom Resolved: <input type="text"/> / <input type="text"/> / <input type="text"/> FAORRES when FATESTCD=LSYMDATE CEENDTC		

Symptoms

#	Event Pre-specified	Symptoms	Symptom Present
4.a	YES	FEVER	
4.b	YES	NEW OR INCREASED COUGH	
4.c	YES	NEW OR INCREASED SHORTNESS OF BREATH	
4.d	YES	CHILLS	
4.e	YES	NEW OR INCREASED MUSCLE PAIN	
4.f	YES	NEW LOSS OF TASTE OR SMELL	
4.g	YES	NEW OR INCREASED SORE THROAT	
4.h	YES	DIARRHEA	
4.i	YES	VOMITING	

Symptoms Entry

4.1 Event Pre-specified: [hidden] [Event Pre-specified]	<input type="radio"/> YES NOT SUBMITTED
4.2 Symptoms: [Symptoms]	<input type="text"/> FAOBJ CETERM
4.3 Was symptom present? [Symptom Present]	<input type="radio"/> YES FAORRES when FATESTCD=OCCUR <input type="radio"/> NO
Symptoms - Other	
5. <input type="text"/>	

Symptoms - Other Entry

5.1 Symptoms - Other Text: [Symptoms - Other]	NOT SUBMITTED
5.2 Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED
5.3 Lowest Level Term [hidden] [Lowest Level Term]	NOT SUBMITTED
5.4 Lowest Level Term Code [hidden] [Lowest Level Term Code]	NOT SUBMITTED
5.5 Dictionary Derived Term [hidden] [Dictionary Derived Term]	FAOBJ
5.6 Preferred Term Code [hidden] [Preferred Term Code]	NOT SUBMITTED
5.7 High Level Term [hidden] [High Level Term]	NOT SUBMITTED
5.8 High Level Term Code [hidden] [High Level Term Code]	NOT SUBMITTED
5.9 High Level Group Term [hidden] [High Level Group Term]	NOT SUBMITTED
5.10 High Level Group Term Code [hidden] [High Level Group Term Code]	NOT SUBMITTED
5.11 Primary System Organ Class [hidden] [Primary System Organ Class]	NOT SUBMITTED
5.12 Primary System Organ Class Code [hidden] [Primary System Organ Class]	NOT SUBMITTED

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STUDYID **Original version: VERSION 1: USED PRIOR TO JULY 6, 2020** **FA=Findings About Events or Interventions** **CE=Clinical Events**
New version: VERSION 2: USED AFTER JULY 6, 2020

C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD) **FACAT=EFFICACY** **CECAT=EFFICACY**

Signs and Symptoms **FASCAT=RESPIRATORY ILLNESS** **CESCAT=SIGNS AND SYMPTOMS OF DISEASE**

1. Date of Assessment: [Date of assessment]	<input type="text"/> / <input type="text"/> / <input type="text"/>	FADTC CEDTC
2. Date of First Symptom Started: [First Symptom Started Date]	<input type="text"/> / <input type="text"/> / <input type="text"/>	FAORRES when FATESTCD=FSYMDATE CESTDTC
3. Symptoms Ongoing? [Symptoms Ongoing]	<input type="radio"/> YES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOING CEENTPT= ONGOING AT CURRENT VISIT <input type="radio"/> NO Date of Last Symptom Resolved: <input type="text"/> / <input type="text"/> / <input type="text"/> FAORRES when FATESTCD=LSYMDATE CEENDTC	

Symptoms			
#	Event Pre-specified	Symptoms	Symptom Present
4.a	YES	FEVER	
4.b	YES	LOSS OF TASTE/SMELL	
4.c	YES	NEW OR INCREASED COUGH	
4.d	YES	NEW OR INCREASED NASAL CONGESTION	
4.e	YES	NEW OR INCREASED NASAL DISCHARGE	
4.f	YES	NEW OR INCREASED SHORTNESS OF BREATH	
4.g	YES	NEW OR INCREASED SORE THROAT	
4.h	YES	NEW OR INCREASED SPUTUM PRODUCTION	
4.i	YES	NEW OR INCREASED WHEEZING	

Symptoms Entry

4.1 Event Pre-specified: [hidden] [Event Pre-specified]	<input type="radio"/> YES NOT SUBMITTED
4.2 Symptoms: [Symptoms]	<input type="text"/> FAOBJ CETERM
4.3 Was symptom present? [Symptom Present]	<input type="radio"/> YES <input type="radio"/> NO FAORRES when FATESTCD=OCCUR

Symptoms - Other

5. <input type="text"/>

Symptoms - Other Entry

5.1 Symptoms - Other Text: [Symptoms - Other]	NOT SUBMITTED
5.2 Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED
5.3 Lowest Level Term [hidden] [Lowest Level Term]	NOT SUBMITTED
5.4 Lowest Level Term Code [hidden] [Lowest Level Term Code]	<input type="text"/> NOT SUBMITTED
5.5 Dictionary Derived Term [hidden] [Dictionary Derived Term]	FAOBJ
5.6 Preferred Term Code [hidden] [Preferred Term Code]	<input type="text"/> NOT SUBMITTED
5.7 High Level Term [hidden] [High Level Term]	NOT SUBMITTED
5.8 High Level Term Code [hidden] [High Level Term Code]	<input type="text"/> NOT SUBMITTED
5.9 High Level Group Term [hidden] [High Level Group Term]	NOT SUBMITTED
5.10 High Level Group Term Code [hidden] [High Level Group Term Code]	<input type="text"/> NOT SUBMITTED
5.11 Primary System Organ Class [hidden] [Primary System Organ Class]	NOT SUBMITTED
5.12 Primary System Organ Class Code [hidden] [Primary System Organ Class]	<input type="text"/> NOT SUBMITTED

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C4591001: STRATIFICATION (STRAT) **NOT SUBMITTED****Stratification**

1.	Select appropriate response - Randomization Stage [Trigger Response 3]	<input type="radio"/> Non-Sentinel Stage 1
2.	Select appropriate response - Randomization Age Group [Trigger Response 4]	<input type="radio"/> Age 18 to 55 <input type="radio"/> Age 65 to 85
3.	Select appropriate response - Randomization Dose [Trigger Response 5]	<input type="radio"/> 10 mcg <input type="radio"/> 20 mcg <input type="radio"/> 30 mcg
4.	Select appropriate response - Randomization Dose Group [Trigger Response 8]	<input type="radio"/> 21 Day <input type="radio"/> 60 Day
5.	Select appropriate response - BNT Number [Trigger Response 7]	<input type="radio"/> (BNT162b1 or PBO) <input type="radio"/> (BNT162b2 or PBO) <input type="radio"/> (BNT162b3 or PBO)

C4591001: STRATIFICATION (STRAT) NOT SUBMITTED	
Stratification	
1. Select appropriate response - Randomization Stage [Trigger Response 3]	<input type="radio"/> Stage 2
2. Select appropriate response - Randomization Age Group [Trigger Response 4]	<input type="radio"/> Age 18 to 55 <input type="radio"/> Age 56 to 85
3. Select appropriate response - Randomization Dose [Trigger Response 5]	<input type="radio"/> 10 mcg <input type="radio"/> 20 mcg <input type="radio"/> 30 mcg
4. Select appropriate response - BNT Number [Trigger Response 7]	<input type="radio"/> (BNT162b1 or PBO) <input type="radio"/> (BNT162b2 or PBO) <input type="radio"/> (BNT162b3 or PBO)

C4591001: STRATIFICATION (STRAT) NOT SUBMITTED**Stratification**

1. Select appropriate response - Randomization Stage [Trigger Response 3]	<input type="radio"/> Stage 1 <input type="radio"/> Stage 2
2. Select appropriate response - Randomization Age Group [Trigger Response 4]	<input type="radio"/> Age 18 to 55 <input type="radio"/> Age 56 to 85 <input type="radio"/> Age 65 to 85
3. Select appropriate response - Randomization Dose [Trigger Response 5]	<input type="radio"/> Low dose level (3mcg) <input type="radio"/> Medium dose level (10mcg) <input type="radio"/> High dose level (30mcg) <input type="radio"/> Low dose level (10mcg) <input type="radio"/> Medium dose level (30mcg) <input type="radio"/> High dose level (100mcg) <input type="radio"/> Low dose level (0.1mcg) <input type="radio"/> Medium dose level (0.3mcg) <input type="radio"/> High dose level (1mcg) <input type="radio"/> Mid-High dose level (50mcg) <input type="radio"/> Low-Mid dose level (20mcg)
4. Select appropriate response - Randomization Dose Group [hidden] [Trigger Response 6]	<input type="radio"/> 21 Day 2-dose group <input type="radio"/> 60 Day 2-dose group <input type="radio"/> 1-dose group
5. Select appropriate response - Randomization Dose Group [Trigger Response 8]	<input type="radio"/> 21 Day <input type="radio"/> 60 Day
6. Select appropriate response - BNT Number [Trigger Response 7]	<input type="radio"/> (BNT162a1 or PBO) <input type="radio"/> (BNT162b1 or PBO) <input type="radio"/> (BNT162b2 or PBO) <input type="radio"/> (BNT162c2 or PBO) <input type="radio"/> (BNT162b3 or PBO)

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C4591001: SUBJECT STATUS (SUB STATU) NOT SUBMITTED	
Subject Status	
1. Subject Status [Subject Status]	<input type="button" value="v"/>
2. Subject Status Date [Status Date]	<input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/>

STUDYID**DS=Disposition****C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS)** **DSCAT=PROTOCOL MILESTONE****Informed Consent - Asymptomatic Surveillance**

1.	Consent Was: [Consent Was:]	<input type="radio"/> OBTAINED Date Written Consent Obtained <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/>	DSSTDTC when DSTERM/DSDECOD=INFORMED CONSENT OBTAINED
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STUDYID		MB=Microbiology Specimen	CO=Comments
C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE) MBCAT=VIROLOGY			
Electronic Sample Tracking			
1. Data Origin [Data Origin]	<input type="radio"/> SITE ETRKDOR in SUPPMB		
2. Sample Type [Sample Type]	<input type="radio"/> NASAL_SWAB MBSPEC		
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO NOT SUBMITTED <input type="radio"/> YES Date of Collection: <div> <input type="text"/> / <input type="text"/> / <input type="text"/> MBDTC </div>		
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<div>COVAL when RDOMAIN = MB</div>		
Sample ID			
5.			
Aliquot Entry			
Please enter barcode for each aliquot.			
5.1 Sample ID [Sample ID]	NOT SUBMITTED		

STUDYID		MB=Microbiology Specimen		DI=Device Identifiers		CO=Comments		
C4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form								MBCAT=CONFIRMATION OF INFECTION
#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:
1								
Microbiology Specimen								
1.	Actual Date of Collection: [Date of Collection]	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> MBDTC						
2.	Specimen Type: [Specimen Type]	<input type="radio"/> SWABBED MATERIAL <input type="text"/> MBSPEC						
3.	Specimen Collection Location: [Specimen Collection Location]	<input type="radio"/> NASAL CAVITY <input type="text"/> MBLOC						
4.	Assay Code and Description: [Assay Code and Description]	<input type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 <input type="text"/> MBTEST						
5.	Device Type: [Device Type]	<input type="radio"/> SARS-COV-2 DIAGNOSTIC TEST <input type="text"/> DIVAL when DIPARMCD = DEVTYPE						
6.	Trade Name: [Trade Name]	<input type="radio"/> CEPHEID XPRT XPRESS SARS-COV-2 TEST <input type="text"/> DIVAL when DIPARMCD = TRADENAM						
7.	Test Result: [Result]	<input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE <input type="radio"/> INDETERMINATE <input type="text"/> MBORRES when MBTESTCD = SARSCOV2						
8.	Comments/Findings/Details: [Comments:]	<input type="text"/> COVAL when RDOMAIN = MB						

STUDYID**CE=Clinical Events****FA=Findings About Events or Interventions****AE=Adverse Events****C4591001: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE)****CECAT=REACTOGENICITY****Vaccination Symptoms Diary - Symptom Resolved Dates****FACAT=REACTOGENICITY****AECAT=REACTOGENICITY**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed? [Fever/Pain Medication on Last Diary Day]	<input type="radio"/> YES <input type="radio"/> Ongoing? FAORRES <input type="radio"/> YES FAENRTPT= ONGOING FAENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD <input type="radio"/> NO Stop Date: <input type="text"/> / <input type="text"/> / <input type="text"/> FAORRES when FATESTCD =STPDMDP <input type="radio"/> NO
#	Symptom:	Were fever or systemic symptoms present on the last day the Subject Diary was completed?
2.a	FEVER	CESCAT=SYSTEMIC FASCAT=SYSTEMIC AESCAT=SYSTEMIC
2.b	FATIGUE	
2.c	HEADACHE	
2.d	CHILLS	
2.e	VOMITING	
2.f	DIARRHEA	
2.g	NEW OR WORSENERED MUSCLE PAIN	
2.h	NEW OR WORSENERED JOINT PAIN	
2.1	Symptom: [Symptom:]	<input type="text"/> CETERM FAOBJ AETERM
2.2	Were fever or systemic symptoms present on the last day the Subject Diary was completed? [Were fever or systemic symptoms present on the last day the Subject Diary was completed?]	<input type="radio"/> YES NOT SUBMITTED <input type="radio"/> Ongoing? CEENRTPT= ONGOING CEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD ONGNXVIS in SUPPCE AEENRTPT = ONGOING AEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD <input type="radio"/> NO Stop Date: <input type="text"/> / <input type="text"/> / <input type="text"/> RCENDTC in SUPPCE <input type="radio"/> NO
3.	Injection Site Location: [Injection Site Location:]	<input type="radio"/> DELTOID MUSCLE CELOC AELOC
4.	Injection Site Body Side: [Injection Site Body Side:]	<input type="radio"/> LEFT CELAT AEAT <input type="radio"/> RIGHT
#	Injection Site Reaction:	Were injection site reactions present on the last day the Subject Diary was completed?
5.a	REDNESS	CESCAT=ADMINISTRATION SITE FASCAT=ADMINISTRATION SITE
5.b	SWELLING	AESCAT=ADMINISTRATION SITE
5.c	PAIN AT INJECTION SITE	
5.1	Injection Site Reaction: [Injection Site Reaction:]	<input type="radio"/> REDNESS CETERM FAOBJ AETERM <input type="radio"/> SWELLING <input type="radio"/> PAIN AT INJECTION SITE
5.2	Were injection site reactions present on the last day the Subject Diary was completed? [Were injection site reactions present on the last day the Subject Diary was completed?]	<input type="radio"/> YES NOT SUBMITTED <input type="radio"/> Ongoing? CEENRTPT= ONGOING CEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD ONGNXVIS in SUPPCE AEENRTPT = ONGOING AEENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD <input type="radio"/> NO Stop Date: <input type="text"/> / <input type="text"/> / <input type="text"/> RCENDTC in SUPPCE <input type="radio"/> NO

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STUDYID**PR=Procedures****C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form****PRCAT=TRANSFUSION DETAILS**

#	Transfusion Type	Date of Transfusion
1		
1.	Transfusion Type: [Transfusion Type] <div> <input type="radio"/> PACKED RBC <input type="radio"/> PLATELETS <input type="radio"/> WHOLE BLOOD <input type="radio"/> PLASMA <input type="radio"/> OTHER Specify: <input type="text"/> </div>	<div> <input type="text"/> / <input type="text"/> / <input type="text"/> </div>
2.	Date of Transfusion: [Date of Transfusion]	<div> <input type="text"/> / <input type="text"/> / <input type="text"/> </div>

STUDYID		DS=Disposition	
C4591001: TREATMENT UNBLINDED (TRN UNBLN) DSCAT=OTHER EVENT			
Treatment Unblinded			
1.	Date Treatment Unblinded : [Date Treatment Unblinded :]	<input type="text"/> / <input type="text"/> / <input type="text"/>	DSSTDTC
2.	Primary Reason for Unblinding: [Primary Reason for Unblinding]	<input type="radio"/> SUBJECT SAFETY CONCERN DSTERM <input type="radio"/> OTHER If other, specify: <input type="text"/> <input type="radio"/> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	

C4591001: UNPLANNED VISIT (UNPL) NOT SUBMITTED	
Unplanned Assessments	
1. Assessments [Assessments]	<input type="checkbox"/> CONTACT OUTCOME

STUDYID**EX=Exposure EC=Exposure as Collected****C4591001: VACCINATION (VACIN TRT)****EXCAT=INVESTIGATIONAL****ECCAT=INVESTIGATIONAL****ECSCAT=VACCINATION****Vaccination****EXSCAT=VACCINATION****PRODUCT****PRODUCT**

1.	Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	<input type="radio"/> YES EXTDV in SUPPEX ECTDV in SUPPEC Date of First Delay: <input type="text"/> / <input type="text"/> / <input type="text"/> FDDTC in SUPPEX FDDTC in SUPPEC Reason(s) for Temporary Delay of Vaccination <input type="checkbox"/> FEVER OR ACUTE ILLNESS <input type="checkbox"/> RECENT SYSTEMIC CORTICOSTEROID TREATMENT <input type="checkbox"/> RECENT NON-STUDY VACCINATION <input type="checkbox"/> ANTICIPATED NON-STUDY VACCINATION <input type="radio"/> NO	EXADJ when more than one selected, EXADJ=MULTIPLE and individual responses are EXADJ1, EXADJ2, etc. in SUPPEX ECADJ when more than one selected, ECADJ=MULTIPLE and individual responses are ECADJ1, ECADJ2, etc. in SUPPEC
2.	Treatment Name [Treatment Name]	EXTRT ECTRT	
3.	Formulation: [Formulation:]	<input type="radio"/> INJECTION EXDOSFRM ECDOSFRM	
4.	Dose Date Time: [Dose Date Time:]	<input type="text"/> / <input type="text"/> / <input type="text"/> EXSTDTC EXENDTC ECSTDTC ECENDTC <input type="text"/> : <input type="text"/> 24-hour clock	
5.	Anatomical Location: [Anatomical Location:]	<input type="radio"/> DELTOID MUSCLE EXLOC ECLOC	
6.	Body Side: [Body Side:]	<input type="radio"/> LEFT EXLAT ECLAT <input type="radio"/> RIGHT	
7.	Route: [Route:]	<input type="radio"/> INTRAMUSCULAR EXROUTE ECROUTE	
8.	Planned Dose: [Planned Dose:]	<input type="text"/> ECDOSE	
9.	Planned Dose Unit: [Planned Dose Unit]	<input type="radio"/> ug ECDOSU	
10.	Actual Dose: [Actual Dose:]	<input type="text"/> EXDOSE ECDOSE	
11.	Unit: [Unit:]	<input type="radio"/> ug EXDOSU ECDOSU	
12.	Was the Actual Dose adjusted from planned? [Dose Adjusted From Planned]	<input type="radio"/> YES EXDOSADJ in SUPPEX ECDOSADJ in SUPPEC What was the reason the dose was adjusted? <input type="radio"/> ADVERSE EVENT(S) <input type="radio"/> INSUFFICIENT CLINICAL RESPONSE <input type="radio"/> OTHER SPECIFY If other, specify: <input type="text"/> EXDOSAJ0 in SUPPEX ECDOSAJ0 in SUPPEC <input type="radio"/> NO	
13.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	<input type="radio"/> THE PROTOCOL SPECIFIED OBSERVATION PERIOD EXOBSVT in SUPPEX ECOBSVT in SUPPEC	
14.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	<input type="radio"/> YES EXOBSV in SUPPEX ECOBSV in SUPPEC <input type="radio"/> NO If No, specify reason: <input type="text"/> EXOBSVD in SUPPEX ECOBSVD in SUPPEC	
15.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED	
16.	Standardized Medication Name -	EXDECOD in SUPPEX ECDECOD in SUPPEC	

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EX=Exposure **EC=Exposure as Collected**

	Dictionary Derived. <i>[hidden]</i> [Standardized Medication Name]	
17.	Standardized Medication Code - Dictionary Derived <i>[hidden]</i> [Standardized Medication Code]	<div></div> <div>EXCD in SUPPEX ECCD in SUPPEC</div>

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STUDYID		EX=Exposure	EC=Exposure as Collected
C4591001: VACCINATION (VACIN TRT)		EXCAT=INVESTIGATIONAL PRODUCT	ECCAT=INVESTIGATIONAL PRODUCT
Vaccination		EXSCAT=VACCINATION	ECSCAT=VACCINATION
1. Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	<input type="radio"/> YES EXTDV in SUPPEX ECTDV in SUPPEC Date of First Delay: <input type="text"/> / <input type="text"/> / <input type="text"/> FDDTC in SUPPEX FDDTC in SUPPEC Reason(s) for Temporary Delay of Vaccination <input type="checkbox"/> FEVER OR ACUTE ILLNESS <input type="checkbox"/> RECENT SYSTEMIC CORTICOSTEROID TREATMENT <input type="checkbox"/> RECENT NON-STUDY VACCINATION <input type="checkbox"/> ANTICIPATED NON-STUDY VACCINATION <input type="radio"/> NO <div> EXADJ when more than one selected, EXADJ=MULTIPLE and individual responses are EXADJ1, EXADJ2, etc. in SUPPEX ECADJ when more than one selected, ECADJ=MULTIPLE and individual responses are ECADJ1, ECADJ2, etc. in SUPPEC </div>		
2. Treatment Name [Treatment Name]	EXTRT ECTRT		
3. Formulation: [Formulation:]	<input type="radio"/> INJECTION EXDOSFRM ECDOSFRM		
4. Dose Date Time: [Dose Date Time:]	<input type="text"/> / <input type="text"/> / <input type="text"/> EXSTDTC EXENDTC ECSTDTC ECENDTC <input type="text"/> : <input type="text"/> 24-hour clock		
5. Anatomical Location: [Anatomical Location:]	<input type="radio"/> DELTOID MUSCLE EXLOC ECLOC		
6. Body Side: [Body Side:]	<input type="radio"/> LEFT <input type="radio"/> RIGHT EXLAT ECLAT		
7. Route: [Route:]	<input type="radio"/> INTRAMUSCULAR EXROUTE ECROUTE		
8. Container Number: [hidden] [PAC / Kit Number:]	NOT SUBMITTED		
9. Actual Dose: [Actual Dose:]	<input type="text"/> EXDOSE ECDOSE		
10. Unit: [Unit:]	<input type="radio"/> mL <input type="radio"/> ug EXDOSU ECDOSU		
11. Timeframe Subject Was Observed [Timeframe Subject Was Observed]	<input type="radio"/> THE PROTOCOL SPECIFIED OBSERVATION PERIOD <input type="radio"/> EXOBSVT in SUPPEX ECOBSVT in SUPPEC		
12. Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	<input type="radio"/> YES EXOBSV in SUPPEX ECOBSV in SUPPEC <input type="radio"/> NO If No, specify reason: EXOBSVD in SUPPEX ECOBSVD in SUPPEC		
13. Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED		
14. Standardized Medication Name - Dictionary Derived. [hidden] [Standardized Medication Name]	EXDECOD in SUPPEX ECDECOD in SUPPEC		
15. Standardized Medication Code - Dictionary Derived [hidden]	<input type="text"/> EXCD in SUPPEX ECDD in SUPPEC		

EX=Exposure **EC=Exposure as Collected**

[Standardized Medication Code]	
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STUDYID**CM=Concomitant Medications****C4591001: CONCOMITANT MEDICATIONS - VASOPRESSORS (VASOPRESS) - Repeating Form**

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Ongoing
1						
Concomitant Medications <div style="float: right; border: 1px solid black; padding: 2px;">CMSCAT=VASOPRESSORS AGENTS</div>						
1.	What is the medication identifier? [Sponsor-Defined Identifier]	<div style="border: 1px solid black; padding: 2px;">CMSPID</div>				
2.	Category: [Category for Medication]	<input type="radio"/> GENERAL CONCOMITANT MEDICATIONS <div style="border: 1px solid black; padding: 2px;">CMCAT</div>				
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input type="radio"/> NO <div style="border: 1px solid black; padding: 2px;">NOT SUBMITTED</div>				
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). [Name of Medication]	<div style="border: 1px solid black; padding: 2px;">CMTRT</div>				
5.	Start Date: [Start Date]	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">▼</div> / <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">▼</div> / <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">▼</div> <div style="border: 1px solid black; padding: 2px;">CMSTDTC</div> </div>				
6.	Ongoing? [Ongoing]	<input type="radio"/> YES <div style="border: 1px solid black; padding: 2px;">CMENRTPT= ONGOING</div> <input type="radio"/> NO <div style="border: 1px solid black; padding: 2px;">CMENPT= LAST SUBJECT ENCOUNTER</div> <div style="margin-top: 5px;"> End Date: <div style="display: flex; align-items: center; margin-left: 10px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">▼</div> / <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">▼</div> / <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">▼</div> <div style="border: 1px solid black; padding: 2px;">CMENDTC</div> </div> </div>				
7.	Comparison Term <i>[hidden]</i> [Comparison Term]	<div style="border: 1px solid black; padding: 2px;">NOT SUBMITTED</div>				
8.	Standardized Medication Name - Dictionary derived. <i>[hidden]</i> [Standardized Medication Name]	<div style="border: 1px solid black; padding: 2px;">CMDECOD</div>				
9.	Standardized Medication Code - Dictionary derived <i>[hidden]</i> [Standardized Medication Code]	<div style="border: 1px solid black; padding: 2px; width: 100px;"></div> <div style="border: 1px solid black; padding: 2px;">CMCODE in SUPPCM</div>				

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STUDYID**VS=Vital Signs****C4591001: VITAL SIGNS - TEMP (VITAL TEMP)** **VSCAT=REACTOGENICITY - UNPLANNED TEMPERATURE****Vital Signs****VSSCAT=SYSTEMIC**1. Date: [Date:] / / **VSDTC****Vital Signs Details**

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:
2.a	1			

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	<input type="radio"/> 1 VSSPID
2.2	Temperature: [Temperature]	<input type="text"/> VSORRES when VSTESTCD = TEMP
2.3	Unit: [Temperature Unit]	<input type="radio"/> F <input type="radio"/> C VSORRESU when VSTESTCD = TEMP
2.4	Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD VSLOC when VSTESTCD = TEMP

STUDYID**VS=Vital Signs****C4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS****Vital Signs**

1.	Date: [Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> VSDTC
2.	Weight: [Weight]	<input type="text"/> VSORRES when VSTESTCD = WEIGHT
3.	Unit: [Weight Unit]	<input type="radio"/> kg VSORRESU when VSTESTCD = WEIGHT <input type="radio"/> LB
4.	Height: [Height]	<input type="text"/> VSORRES when VSTESTCD = HEIGHT
5.	Unit: [Height Unit]	<input type="radio"/> cm VSORRESU when VSTESTCD = HEIGHT <input type="radio"/> in
6.	Body Mass Index: [Body Mass Index]	<input type="text"/> VSORRES when VSTESTCD = BMI

Vital Signs Details

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:
7.a	1			

Vital Signs Details Entry

7.1	Record Identifier: [Record Identifier:]	<input type="radio"/> 1 VSSPID
7.2	Temperature: [Temperature]	<input type="text"/> VSORRES when VSTESTCD = TEMP
7.3	Unit: [Temperature Unit]	<input type="radio"/> C VSORRESU when VSTESTCD = TEMP <input type="radio"/> F
7.4	Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR VSLOC when VSTESTCD = TEMP <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD

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STUDYID**VS=Vital Signs****C4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS****Vital Signs**

1. Date: [Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/> VSDTC
2. Weight: [Weight]	<input type="text"/> VSORRES when VSTESTCD = WEIGHT
3. Unit: [Weight Unit]	<input type="radio"/> kg VSORRESU when VSTESTCD = WEIGHT <input type="radio"/> LB
4. Height: [Height]	<input type="text"/> VSORRES when VSTESTCD = HEIGHT
5. Unit: [Height Unit]	<input type="radio"/> cm VSORRESU when VSTESTCD = HEIGHT <input type="radio"/> in
6. Body Mass Index: [Body Mass Index]	<input type="text"/> VSORRES when VSTESTCD = BMI

Vital Signs Details

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:
7.a	1						SITTING	

Vital Signs Details Entry

7.1 Record Identifier: [Record Identifier:]	<input type="radio"/> 1 VSSPID
7.2 Temperature: [Temperature]	<input type="text"/> VSORRES when VSTESTCD = TEMP
7.3 Unit: [Temperature Unit]	<input type="radio"/> C VSORRESU when VSTESTCD = TEMP <input type="radio"/> F
7.4 Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR VSLOC when VSTESTCD = TEMP <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD
7.5 Systolic: [Systolic:]	<input type="text"/> VSORRES when VSTESTCD = SYSBP
7.6 Diastolic: [Diastolic:]	<input type="text"/> VSORRES when VSTESTCD = DIABP
7.7 BP Position: [BP Position]	<input type="radio"/> SITTING VSPOS when VSTESTCD = DIABP, SYSBP
7.8 Pulse: [Pulse:]	<input type="text"/> VSORRES when VSTESTCD = PULSE

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STUDYID**VS=Vital Signs****C4591001: VITAL SIGNS - COVID (VITALS COV) - Repeating Form** **VSCAT=GENERAL VITAL SIGNS**

#	Date:	Vital Signs Details
1		

Vital Signs

1. Date: [Date:]	<input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/> VSDTC
---------------------	---

Vital Signs Details

#	Record Identifier:	Systolic:	Diastolic:	Respiratory Rate in respirations/minute	Heart Rate in beats/minute
2.a	1				

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	<input type="radio"/> 1 VSSPID
2.2	Systolic: [Systolic:]	<input type="text"/> VSORRES when VSTESTCD = SYSBP
2.3	Diastolic: [Diastolic:]	<input type="text"/> VSORRES when VSTESTCD = DIABP
2.4	Respiratory Rate in respirations/minute: [Respiratory Rate in respirations/minute]	<input type="text"/> VSORRES when VSTESTCD = RESP
2.5	Heart Rate in beats/minute: [Heart Rate in beats/minute]	<input type="text"/> VSORRES when VSTESTCD = HR

STUDYID**VS=Vital Signs****C4591001: VITAL SIGNS (VITALS FUP)** **VSCAT=GENERAL VITAL SIGNS****Vital Signs**1. Date: [Date:] / / **VSDTC****Vital Signs Details**

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:
2.a	1						SITTING	

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	<input type="radio"/> 1 VSSPID
2.2	Temperature: [Temperature]	<input type="text"/> VSORRES when VSTESTCD = TEMP
2.3	Unit: [Temperature Unit]	<input type="radio"/> F VSORRESU when VSTESTCD = TEMP <input type="radio"/> C
2.4	Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY VSLOC when VSTESTCD = TEMP <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD
2.5	Systolic: [Systolic:]	<input type="text"/> VSORRES when VSTESTCD = SYSBP
2.6	Diastolic: [Diastolic:]	<input type="text"/> VSORRES when VSTESTCD = DIABP
2.7	BP Position: [BP Position]	<input type="radio"/> SITTING VSPOS when VSTESTCD = DIABP, SYSBP
2.8	Pulse: [Pulse:]	<input type="text"/> VSORRES when VSTESTCD = PULSE

STUDYID		DS=Disposition	
C4591001: WITHDRAWAL OF CONSENT (WOC)		DSCAT=OTHER EVENT	
Withdrawal Of Consent			
1.	Withdrawal of Consent Date : [Withdrawal of Consent Date :]	<input type="text"/> / <input type="text"/> / <input type="text"/>	DSSTDTC when DSTERM/DSDECOD=WITHDRAWAL OF CONSENT

STUDYID

VSCAT=REACTOGENICITY

VSSCAT=SYSTEMIC

3 Form: Vaccination Diary

Vaccination Diary	
[Computed]	
< Exit	Next >

Screen 1

Confirm	
Do you really want to exit without saving?	
No	Yes

Message 1

[Computed] Text will display "Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on {1}. You will answer these questions for {2} day(s)."

{1} Will display a date

{2} Will display a number of days.

Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 day(s).

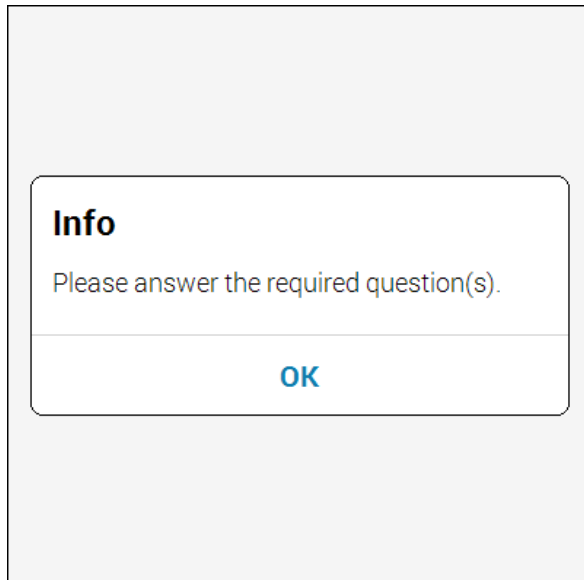
VSORRESU when VSTESTCD = TEMP

Vaccination Diary													
Please record your highest temperature today in degrees Fahrenheit.													
<table border="1"> <tbody> <tr> <td>9</td> <td>9</td> <td>9</td> <td>9</td> </tr> <tr> <td>0</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>1</td> <td>1</td> <td>1</td> <td>1</td> </tr> </tbody> </table>		9	9	9	9	0	0	0	0	1	1	1	1
9	9	9	9										
0	0	0	0										
1	1	1	1										
< Back	Next >												

Screen 3

VSORRES when VSTESTCD = TEMP

MAXIMUM in SUPPV5

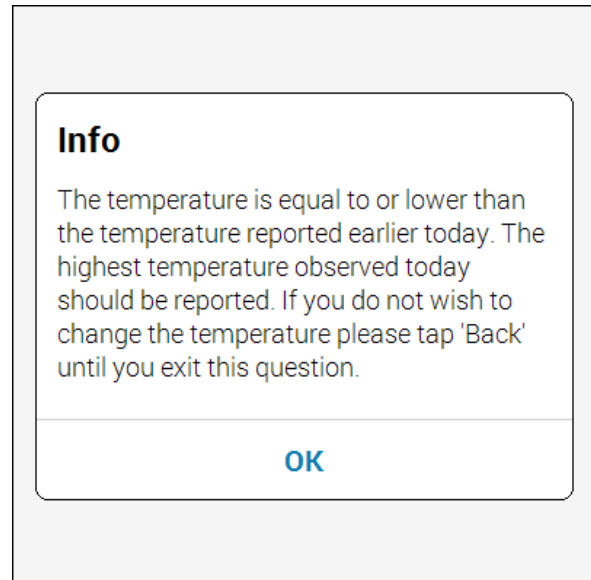


Info

Please answer the required question(s).

OK

Message 1



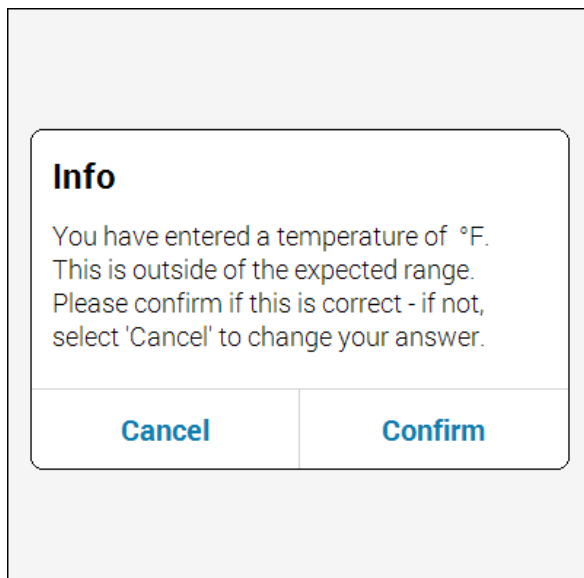
Info

The temperature is equal to or lower than the temperature reported earlier today. The highest temperature observed today should be reported. If you do not wish to change the temperature please tap 'Back' until you exit this question.

OK

Message 2

VSORRESU when VSTESTCD = TEMP

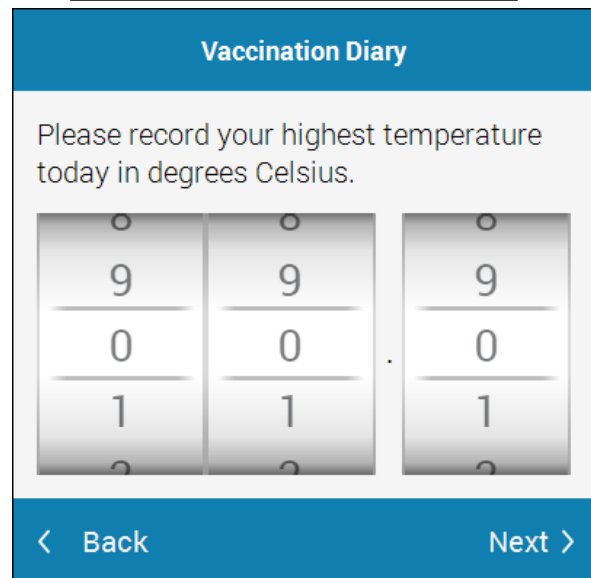


Info

You have entered a temperature of °F. This is outside of the expected range. Please confirm if this is correct - if not, select 'Cancel' to change your answer.

Cancel **Confirm**

Message 3



Vaccination Diary

Please record your highest temperature today in degrees Celsius.

0 9 0 9 0 9
0 0 0 0 0 0
1 1 1 1 1 1
2 2 2 2 2 2

< Back Next >

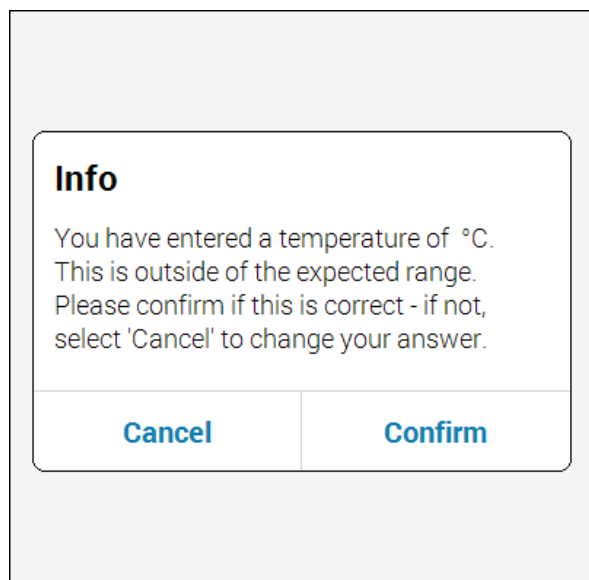
Screen 4

VSORRES when VSTESTCD = TEMP

MAXIMUM in SUPPVS

STUDYID

FACAT=REACTOGENICITY

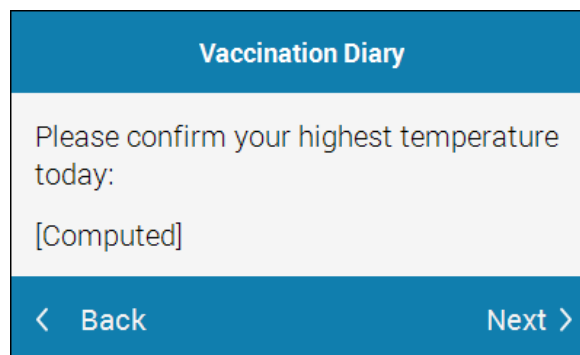


Info

You have entered a temperature of °C.
This is outside of the expected range.
Please confirm if this is correct - if not,
select 'Cancel' to change your answer.

Cancel **Confirm**

Message 3



Vaccination Diary

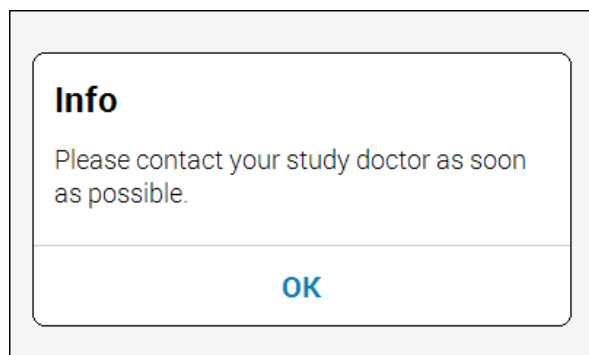
Please confirm your highest temperature today:

[Computed]

< Back **Next >**

Screen 5

[Computed] will display the temperature
selected on Screen 3 or Screen 4

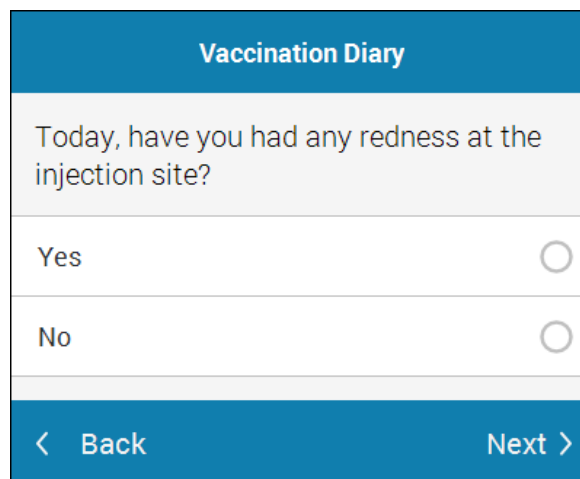


Info

Please contact your study doctor as soon
as possible.

OK

Message 1



Vaccination Diary

Today, have you had any redness at the
injection site?

Yes ☐

No ☐

< Back **Next >**

Screen 6

FAORRES when FATESTCD = OCCUR and FAOBJ = REDNESS

FASCAT = ADMINISTRATION SITE

FASCAT = ADMINISTRATION SITE**FAORRES when FATESTCD = DIAMETER and FAOBJ = REDNESS**

Info


The value you reported is the same as previously reported. If you do not wish to change the response please tap 'Back' until you exit this question.

OK

Message 2

Vaccination Diary

Please tap on the number from the measuring device for redness.



If your redness was greater than 21, please select 21.

< Back **Next >**

Screen 7

Info

The measurement is equal to or lower than that reported earlier today. The highest measurement observed today should be reported. If you do not wish to change the measurement please tap 'Back' until you exit this question.

OK

Message 2

Vaccination Diary

Please confirm the number from the measuring device for redness:

[Computed]

< Back **Next >**

Screen 8

[Computed] will display the number selected on Screen 7.

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C4591001-Post-12-July-2020

App Subject Facing Screen Report
English (USA) enUS

22-JUN-2020
Version 2

FASCAT = ADMINISTRATION SITE


FASCAT = ADMINISTRATION SITE

FAORRES when FATESTCD = OCCUR and
FAOBJ = SWELLING

FAORRES when FATESTCD = DIAMETER and
FAOBJ = SWELLING

Vaccination Diary	
Today, have you had any swelling at the injection site?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 9

Vaccination Diary	
Please select the number from the measuring device for swelling.	
	
If your swelling was greater than 21, please select 21.	
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 10

Vaccination Diary	
Please confirm the number from the measuring device for swelling:	
[Computed]	
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 11

[Computed] will display the number selected on Screen 10.

Vaccination Diary	
Today, have you had any pain at the injection site?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 12

FAORRES when FATESTCD = OCCUR and
FAOBJ = PAIN AT INJECTION SITE

FASCAT = ADMINISTRATION SITE

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FASCAT = ADMINISTRATION SITE

**FAORRES when FATESTCD = SEV and
FAOBJ = PAIN AT INJECTION SITE**

Vaccination Diary	
Pain at the injection site definitions:	
Mild = Does not interfere with activity	
Moderate = Interferes with activity	
Severe = Prevents daily activity	
< Back	Next >

Screen 13

Vaccination Diary	
Please indicate whether the pain at the injection site was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back	Next >

Screen 14

Info Severe = Prevents daily activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.	
No	Yes

Message 2

Info The severity is equal to or lower than the severity reported earlier today. The most severe symptom observed today should be reported. If you do not wish to change the severity please tap 'Back' until you exit this question.
OK

Message 4

FASCAT = ADMINISTRATION SITE**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR INJECTION SITE
PAIN****FASCAT = SYSTEMIC****FAORRES when FATESTCD = OCCUR and
FAOBJ = FATIGUE**

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 15

Vaccination Diary	
Today, have you experienced fatigue (tiredness)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 16

FASCAT = SYSTEMIC**FAORRES when FATESTCD = SEV and
FAOBJ = FATIGUE**

Vaccination Diary	
Fatigue (tiredness) definitions: Mild = Does not interfere with activity Moderate = Some interference with activity Severe = Prevents daily routine activity	
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 17

Vaccination Diary	
Please indicate whether the fatigue (tiredness) was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<div> <div>< Back</div> <div>Next ></div> </div>	

Screen 18

FASCAT = SYSTEMIC**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR TIREDNESS
(FATIGUE)**

Info

Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No **Yes**

Message 2

Vaccination Diary

Did you go to the ER or were you hospitalized for this reaction?

Yes ☐

No ☐

< Back **Next >**

Screen 19

**FAORRES when FATESTCD = OCCUR and
FAOBJ = HEADACHE****FASCAT = SYSTEMIC**

Vaccination Diary

Today, have you experienced headache?

Yes ☐

No ☐

< Back **Next >**

Screen 20

Vaccination Diary

Headache definitions:

Mild = Does not interfere with activity

Moderate = Some interference with activity

Severe = Prevents daily routine activity

< Back **Next >**

Screen 21

FASCAT = SYSTEMIC**FAORRES when FATESTCD = SEV and
FAOBJ = HEADACHE**

Vaccination Diary	
Please indicate whether the headache was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<div> < Back Next > </div>	

Screen 22

FASCAT = SYSTEMIC**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR HEADACHE**

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> < Back Next > </div>	

Screen 23

**FAORRES when FATESTCD = OCCUR and
FAOBJ = VOMITING**

Vaccination Diary	
Today, have you experienced vomiting?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> < Back Next > </div>	

Screen 24

FASCAT = SYSTEMIC

Vaccination Diary	
Vomiting definitions:	
Mild = 1 to 2 times in 24 hours	
Moderate = More than twice in 24 hours	
Severe = Requires intravenous hydration	
<div> < Back Next > </div>	

Screen 25

**FAORRES when FATESTCD = SEV and
FAOBJ = VOMITING****FASCAT = SYSTEMIC**

Vaccination Diary	
Please indicate whether the vomiting was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 26

Info	
Severe = Requires intravenous hydration. If this is correct tap 'Yes' to go forward or 'No' to change your answer.	
No	Yes

Message 2

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 27

**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR VOMITING****FASCAT = SYSTEMIC**

Vaccination Diary	
Today, have you experienced diarrhea?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 28

**FAORRES when FATESTCD = OCCUR and
FAOBJ = DIARRHEA****FASCAT = SYSTEMIC**

FASCAT = SYSTEMIC

**FAORRES when FATESTCD = SEV and
FAOBJ = DIARRHEA**

Vaccination Diary	
Diarrhea definitions:	
Mild = 2 to 3 loose stools in 24 hours	
Moderate = 4 to 5 loose stools in 24 hours	
Severe = 6 or more loose stools in 24 hours	
< Back	Next >

Screen 29

Vaccination Diary	
Please indicate whether the diarrhea was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back	Next >

Screen 30

FASCAT = SYSTEMIC

**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR DIARRHEA**

<p>Info</p> <p>Severe = 6 or more loose stools in 24 hours. If this is correct tap 'Yes' to go forward or 'No' to change your answer.</p>	
No	Yes

Message 2

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back	Next >

Screen 31

**FAORRES when FATESTCD = OCCUR and
FAOBJ = CHILLS**

Vaccination Diary	
Today, have you experienced chills?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 32

FASCAT = SYSTEMIC

Vaccination Diary	
Chills definitions:	
Mild = Does not interfere with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 33

FASCAT = SYSTEMIC**FAORRES when FATESTCD = SEV and
FAOBJ = CHILLS**

Vaccination Diary	
Please indicate whether the chills were:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 34

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 35

**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR CHILLS****FASCAT = SYSTEMIC**

**FAORRES when FATESTCD = OCCUR and
FAOBJ = MUSCLE PAIN****FASCAT = SYSTEMIC**

Vaccination Diary	
Today, have you had new or worsened muscle pain (other than at the injection site)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 36

Vaccination Diary	
Muscle pain definitions:	
Mild = No interference with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back Next >	

Screen 37

FASCAT = SYSTEMIC**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR MUSCLE PAIN**

Vaccination Diary	
Please indicate whether the new or worsened muscle pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 38

**FAORRES when FATESTCD = SEV and
FAOBJ = MUSCLE PAIN****FASCAT = SYSTEMIC**

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 39

**FAORRES when FATESTCD = OCCUR and
FAOBJ = JOINT PAIN****FASCAT = SYSTEMIC**

Vaccination Diary	
Today, have you had any new or worsened joint pain?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> < Back Next > </div>	

Screen 40

Vaccination Diary	
Joint pain definitions:	
Mild = No interference with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
<div> < Back Next > </div>	

Screen 41

Vaccination Diary	
Please indicate whether the new or worsened joint pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<div> < Back Next > </div>	

Screen 42

**FAORRES when FATESTCD = SEV and
FAOBJ = JOINT PAIN****FASCAT = SYSTEMIC**

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<div> < Back Next > </div>	

Screen 43

**FAORRES when FATESTCD = OCCUR and
FAOBJ = HOSPITALIZED FOR JOINT PAIN****FASCAT = SYSTEMIC**

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FAORRES when FATESTCD = MEDTFVPN and
FAOBJ = MEDICATIONS

FASCAT = MEDICATIONS GIVEN

Vaccination Diary

Today, have you taken any medication to treat fever or pain?

Yes ☐

No ☐

< Back Next >

Screen 44

Info

You have reported taking medication to treat fever or pain. Is your answer correct?

No Yes

Message 2

Vaccination Diary

Thank you! You have now completed the diary for today. Please save your answers by selecting 'Save'. If you wish to change your answers, select 'Back'.

If your symptoms worsen today, please select 'Update Symptoms' from the main menu to update your symptoms.

[Computed]

Save

< Back

Screen 45

[Computed] will display "Please continue to fill out your diary for the next {1} day(s)."

Where {1} = a number of days

Example: Please continue to fill out your diary for the next 4 day(s).

Vaccination Diary

Thank you! You have now updated the diary for today. Please save your answers by selecting 'Save'. If you wish to change your answers, select 'Back'.

If your symptoms worsen again today, please select 'Update Symptoms' from the main menu to update your symptoms.

[Computed]

Save

< Back

Screen 46

[Computed] will display "Please continue to fill out your diary for the next {1} day(s)."

Where {1} = a number of days

Example: Please continue to fill out your diary for the next 4 day(s).