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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MAIN INFORMED CONSENT DEMOGRAPHY DATE OF VISIT INCLUSION/EXCLUSION CRITERIA (INCEXCS) INCLUSION/EXCLUSION CRITERIA (INCEXCS) INCLUSION/EXCLUSION CRITERIA (INCEXCS) INCLUSION/EXCLUSION CRITERIA (INCEXC) **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	
PHYSICALEXAMINATION	
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	
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	
VITALSIGNS	
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 (INCEXCNS) 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 (INCEXC) **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_C	OVID_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_C	OVID_CONVA
	DATE OF VISIT - ILLNESS CONVALESCENT
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
	VACCINATION DIARY
POT_C	OVID_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
	RADIATIONTREATMENT
	TRANSFUSIONS
UNPL	
	DATEOFVISIT
	CONTACT OUTCOME - UNPLANNED
	VITAL SIGNS - TEMP
	UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT
UNPLA	NNED_VACCINATION
	DATE OF VISIT

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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(REVAXIE)
        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
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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) ELECTRONICSAMPLE TRACKING - IMMUNOGENICITY MICROBIOLOGY SPECIMEN (COVID TEST) ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF ELECTRONIC SAMPLE TRACKING - REPEAT SWAB DD=DEATH DETAILS DEATH DETAILS CODED**

DATE OF VISIT

DI=DEVICE IDENTIFIERS

MICROBIOLOGY SPECIMEN (COV19 SITE) MICROBIOLOGY SPECIMEN (SWAB SITE)

MICROBIOLOGY SPECIMEN (COVID TEST)

DM=DEMOGRAPHICS

DEMOGRAPHY

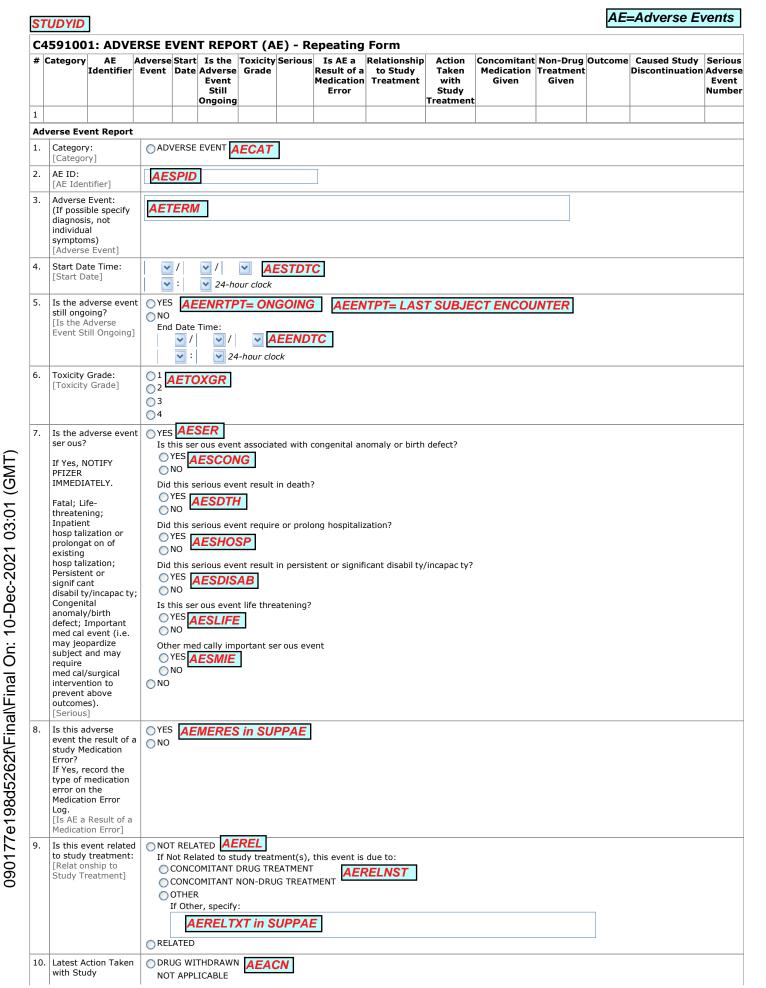
REACTOGENICITY DIARY

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 DAT	ES
SIGNS AND SYMPTOMS OF POTENTIAL COVID-19	
SIGNS AND SYMPTOMS OF POTENTIAL COVID-19	
HEALTH CARE UTILIZATION	
UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMICE	/ENT
HO=HEALTHCARE ENCOUNTERS	
HEALTH CARE UTILIZATION	
HOSPITALIZATION DETAILS	
IE=INCLUSION/EXCLUSION CRITERIA NOT MET	
INCLUSION/EXCLUSION CRITERIA (INCEXCS)	
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 (R	EVAX 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**



	Treatment: [Act on Taken with Study Treatment]	0
11.	Was a Concomitant Medication given? [Concom tant Med cat on Given]	O YES AECONTRT O NO AECMGIV in SUPPAE
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	O YES AECONTRT AENDGIV in SUPPAE
13.	What was the outcome of this adverse event?: [Outcome]	 FATAL NOT RECOVERED/NOT RESOLVED RECOVERED/RESOLVED RECOVERED/RESOLVED WITH SEQUELAE RECOVERING/RESOLVING UNKNOWN
14.	D d the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	O YES AESUBJDC in SUPPAE Linked to related DS record via RELREC NO NO
15.	Ser ous 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.	D ctionary-Derived Term [hidden] [D ctionary-Derived Term]	AEDECOD
20.	Preferred Term Code [hidden] [Preferred Term Code]	AEPTCD
21.	High Level Term <i>[hidden]</i> [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

AE=Adverse Events

LB=Laboratory Test Results

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La	boratory Data Hematology							
1.	Lab Panel: [Category for Lab Test]	b Test]						
2.	Laboratory Name and Address [Vendor Name (DERIVED)]	LBNAI	И					
3.	Collection Date: [Collect on Date:]	/						
4.	Specimen Type: [Specimen Type]	OBLOOD	LBSPEC					
Lal	o Result							
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:	Lab Normal Range		
5.a			CD4_PX4722					
La	b Result Entry							
5.1	Sponsor ID: [Sponsor-Defined Identifier]		LBSPID					
5.2	Test: [Test:]	OCD4_I	CD4_PX4722 LBTEST					
5.3	Result: [Result:]	LBO	LBORRES					
5.4	Not Done: [hidden] [Not Done:]		NOT DONE LBSTAT					
5.5	LNMT [Lab Normal Range]	High Un t	BORNRLO BORNRHI /mm3 LBORRESU					

C	4591001: COHORT SEL	591001: COHORT SELECTION (COHORT SEL) NOT SUBMITTED					
Co	hort Selection						
DC	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]						
2.	Select appropriate response - What cohort does the subject belong to? [Trigger Response 10]	 STAGE 1 SENTINEL COHORTS STAGE 1 NONSENTINEL COHORTS STAGE 2 COHORTS STAGE 3 COHORTS 					

ST	UDYID				C	M=Con	comitant N	/ledica	tions
C4	591001: CONCO	MITANT MEDICA	TIONS - BASELINE (CON	1ED BSL) - R	epeating For	m			
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre- specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date
1									
Con	comitant Medications								
1.	What is the medication [Sponsor-Defined Identi		CMSPID						
2.	Category: [Category for Medication	n]	GENERAL CONCOMITANT MEDI	CATIONS CMCA	Τ				
3.	Concomitant Medication [Concom tant Medication		○ NO NOT SUBMITTED						
4.	Med cation:		CMTRT						
		ere applicable). Where vn, enter the full trade o de clarifying information e.g., Ingredient(s),							
5.	Dose: [Dose Description]		CMDOSE CMDOSTXT						
6.	Dose Unit: [Dose Unit]								
7.	Dose Frequency: [Dose Frequency]								
8.	Route: [Route]								
9.	Start Date: [Start Date]			DTC					
10.	Comparison Term [hidd [Comparison Term]	en]	NOT SUBMITTED						
11.	Standardized Med cat or derived. [hidden] [Standardized Med cat o	,	CMDECOD						
12.	Standardized Med cat or derived [hidden] [Standardized Med cat o	,	CMCOL	E in SUPPCM	1				

CM=Concomitant Medications

S	TUDYID				CM=Concomitant Me	dications
C	4591001: CONCOMITANT	MEDICATI	ONS - NON S	TUDY VACCINATIONS (CONMED	VAX) - Repeating Form	n
#	Sponsor-Defined Identifier	Category fo	or Medication	Concomitant Medications Pre-specified	d Name of Medication	Start Date
1						
Co	ncomitant Medications					
1.	What is the medication identifier? [Sponsor-Defined Identifier]		CMSPID			
2.	Category: [Category for Med cat on]	0		CMCAT		
3.	Concomitant Medications Pre-specific [Concomitant Medications Pre-specific		NO NOT SUB	MITTED		
4.	Medication: Provide the complete gener c drug na (including salt form, where applicabl generic name is unknown, enter the or proprietary name. Include clarifyin information in the Med cat on text (e Ingredient(s), route, use, formulation [Name of Medication]	ame e). Where full trade ng .g.,	CMTRT]
5.	Date: [Start Date]		✓ /	CMSTDTC		
6.	Comparison Term [hidden] [Comparison Term]		NOT SUBMIT	TED		
7.	Standardized Medicat on Name - Dict derived. [hidden] [Standardized Med cat on Name]	t onary	MDECOD			
8.	Standardized Med cat on Code - Dicti derived [hidden] [Standardized Med cat on Code]	ionary		CMCODE in SUPPCM		



C4591001: MAIN INFORMED CONSENT (CONSENT) DSCAT=PROTOCOL MILESTONE

Informed Consent						
	Consent Was:	OBTAINED	DSSTDTC when			
	[Consent Was:]	Date Written Consent Obtained	DSTERM/DSDECOD=INFORMED CONSENT			
			OBTAINED			

DS=Disposition

			,			
C	C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)					
Co	ntact Outcome					
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	○ CONTACT OUTCOME NOT SUBMITTED				
2.	Contact Type: [Type of Contact/Visit]	O CLINIC VISIT SVREFID				
3.	Was contact made? [Was Contact Made]	YES NOT SUBMITTED Date of Contact: ✓ / ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓				
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED				

C	C4591001: CONTACT OUTCOME - MONTH 6 (CONTACT 6M)					
Co	ontact Outcome					
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	CONTACT OUTCOME NOT SUBMITTED				
2.	Contact Type: [Type of Contact/Visit]	CLINIC VISIT				
3.	Was contact made? [Was Contact Made]	YES NOT SUBMITTED Date of Contact: SVSTDTC SVSTDTC SVENDTC when UNPLANNED VISITS NO If No, why? NOT SUBMITTED				
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED				

S	TUDYID	SV=Subject Visits
С	4591001: CONTACT OU	ITCOME (CONTACT SV)
C	ontact Outcome	
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	CONTACT OUTCOME NOT SUBMITTED
2.	Contact Type: [Type of Contact/Visit]	TELEPHONE VISIT SVREFID
3.	Was contact made? [Was Contact Made]	YES NOT SUBMITTED Date of Contact: SVSTDTC NO If No, why? NOT SUBMITTED
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED

C	4591001: CONTACT OU	TCOME - UNPLANNED (CONTACT UV)
Co	ontact Outcome	
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	○ CONTACT OUTCOME NOT SUBMITTED
2.	Contact Type: [Type of Contact/Visit]	TELEPHONE VISIT SVREFID
3.	Was contact made? [Was Contact Made]	YES NOT SUBMITTED Date of Contact: SVSTDTC SVSTDTC SVENDTC when UNPLANNED VISITS Contact Outcome: VISIT ARRANGED VISIT ARRANGED, BUT NOT ATTENDED NOT SUBMITTED VISIT NOT ARRANGED, REACTION NO LONGER PRESENT VISIT NOT ARRANGED, UNABLE TO ATTEND VISIT NOT ARRANGED, UNABLE TO ATTEND VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY VISIT NOT REQUIRED, INVESTIGATOR DECISION NO If No, why? NOT SUBMITTED
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED

S 1	TUDYID MB=Microbiology Specimen DI=Device Identifiers CO=Comments							
C	C4591001: MICROBIOLOGY SPECIMEN (COV19 SITE) - Repeating Form <u>MBCAT=CONFIRMATION OF INFECTION</u>							
#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	Comments:		
1								
Mi	crobiology Specimen							
1.	Actual Date of Collection: [Date of Collection]		MBDTC					
2.	Specimen Type: [Specimen Type]	O SERUM BLOOD PLASMA	OBLOOD MBSPEC					
3.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP S	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 MBTEST					
4.	Device Type: [Device Type]	SARS-COV-2 DIAGNOS	SARS-COV-2 DIAGNOSTIC TEST DIVAL when DIPARMCD = DEVTYPE					
5.	Test Result: [Result]	OPOSITIVE NEGATIVE INDETERMINATE	ES when MBTESTCD = SARSCOV2					
6.	Comments/Findings/Details: [Comments:]	COVAL when RDO	MAIN = MB					

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S	TUDYID			MB=Microbiology Sp	ecimen	DI=Dev	vice la	lentifiers	CO=Comments
C	24591001: 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	1	Comments:	Trade Name Other, Specify
1									
м	icrobiology Speci	men							
1.	Actual Date of Col [Date of Collection			IBDTC					
2.	Specimen Type: [Specimen Type]		OSWABBED MATERIAL RESPIRATORY SECRETIO	MBSPEC					
3.	Specimen Collecti [Specimen Collect		NASOPHARYNX LOWER RESPIRATORY SYSTEM MBLOC THROAT						
4.	Assay Code and D [Assay Code and I		SEVERE ACUTE RESP SYN	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 MBTEST					
5.	Device Type: [Device Type]		◯ SARS-COV-2 DIAGNOSTI	C TEST DIVAL when DIP	A rmcd =	DEVTYP	PE		
6.	Trade Name: [Trade Name]		DIVAL when I	DIPARMCD = TRADENA	AM				
7.	Test Result: POSITIVE O POSITIVE O NEGATIVE O NEGATIVE O INDETERMINATE O INDETERMINATE O								
8.	Comments/Findin [Comments:]	gs/Details:	COVAL when RD	OMAIN = MB					
9.	Trade Name Othe		SUPPMB in TRADE	ОТН					

Annc	otated Study Book - C4591001			
รтเ	IDYID			DD=Death Details
		LS CODED (DEATH DTL)	TAILS CODED	
	th Details			
0 []	ate of Collect on / Notification f Death: Date of Collect on / Notif cat on f Death]			
	,	Cause of Death Status	Cause of D	eath
2.				
	se of Death Entry			
2.1	Cause of Death Status: [Cause of Death Status]	OPRIMARY CAUSE OF DEATH OSECONDARY CAUSE OF DEATH		
2.2	Cause of Death: [Cause of Death]	DDORRES		
2.3	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED		
2.4	Lowest Level Term [hidden] [Lowest Level Term]	NOT SUBMITTED		
2.5	Lowest Level Term Code [hidden] [Lowest Level Term Code]	NOT SUBMITTED		
2.6	Dict onary-Derived Term [hidden] [Dictionary-Derived Term]	DDSTRESC		
2.7	Preferred Term Code [hidden] [Preferred Term Code]	NOT SUBMITTED		
.8	High Level Term [hidden] [High Level Term]	NOT SUBMITTED		
2.9	High Level Term Code [hidden] [High Level Term Code]	NOT SUBMITTED		
2.10	High Level Group Term [hidden] [High Level Group Term]	NOT SUBMITTED		
2.11	High Level Group Term Code [hidden] [High Level Group Term Code]	NOT SUBMITTED		
2.12	Primary System Organ Class [hidden] [Primary System Organ Class]	NOT SUBMITTED		

2.13 Primary System Organ Class Code [hidden] [Primary System Organ Class Code]

VOT SUBMITTED

C4591001: DEMOGRAPHY (DEMOG)

D	lemography					
1.	Subject ID [Subject ID]	SUBJID				
2.	Birth Date: [Birth Date]					
3.	Sex: [Sex]	O FEMALE SEX				
4.	Ethnicity: [Ethnicity]	 HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT REPORTED 				
5.	Race: (Check X all that apply): [Race Of Subject]	BLACK OR AFRICAN AMERICAN AMERICAN INDIAN OR ALASKA NATIVE ASIAN NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WHITE NOT REPORTED				
6.	Racial Designation: [Racial Designat on]	O JAPANESE O OTHER RACIALD in SUPPDM				

S	TUDYID	nked to related AE record via RELREC DS=Disposition
С	4591001: DISPOSITION - FOLLOW-UP (DIS	P FUP) DSCAT = DISPOSITION EVENT
Di	sposition - Follow-Up	
1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	
2.	Phase of Disposition: [Disposition Phase]	OFOLLOW-UP DSPHASE in SUPPDS
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	DSTERM

Linked to related AE record via RELREC

DS=Disposition

C	C4591001: DISPOSITION - SCREENING FOR FURTHER VACCINATION (DISP RESCR) DSCAT = DISPOSITION EVENT					
Di	Disposition - Screening for Further Vaccination					
1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]					
2.	Phase of Disposition: [Disposition Phase]	© REPEAT SCREENING 1 DSPHASE in SUPPDS				
3.	Status: [Status]					
4.	Specify Status: [Specify Status]	DSTERM				

S	TUDYID	inked to related AE record via RELREC DS=Disposition
С	4591001: DISPOSITION - SCREENING (DIS	SP SCR) DSCAT = DISPOSITION EVENT
D	sposition - Screening	
1.	Date of Complet on/Discontinuation/Death [Date of Completion/Discontinuation/Death]	
2.	Phase of Disposition: [Disposition Phase]	OSCREENING DSPHASE in SUPPDS
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	DSTERM

S	TUDYID	Linked to related AE record via RELREC	DS=Disposition
С	4591001: DISPOSITION - TREATMENT	(DISP TRT) DSCAT = DISPOSITION EVENT	
Di	isposition - Treatment		
1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]		
2.	Phase of Disposition: [Disposition Phase]	OVACCINATION DSPHASE in SUPPDS OPEN LABEL TREATMENT	
3.	Status: [Status]		
4.	Specify Status: [Specify Status]	DSTERM	

S	TUDYID		SV=Subject Visits	
С	C4591001: DATE OF VISIT (DOV)			
D	Date of Visit			
1.	Date of Visit [Date of Visit]	✓ / ✓ SVSTDTC SVENDTC when UNPLANNED VISITS		
2.	Erroneous Visit [Visit Error]	O ERRONEOUS VISIT NOT SUBMITTED		

C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV) Date of Visit 1. Date of Visit [Date of Visit] Image: Conversion of Visit 2. Erroneous Visit [Visit Error] COVID-19 Illness Visit: [COVID-19 Illness Visit: [COVID-19 Illness Visit]

S	STUDYID					SV=Subject Visits
C	C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)					
Date of Visit						
1.	Date of Visit [Date of Visit]	v /	v /	SVSTDTC		

2.	Erroneous Visit [Visit Error]	OERRONEOUS VISIT NOT SUBMITTED
СС	VID-19 Illness Visit	
	COVID-19 Illness Visit: [COVID-19 Illness Vist]	

SV=Subject Visits STUDYID C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV) Date of Visit 1. Date of Visit **v** / **~** / SVSTDTC SVENDTC when UNPLANNED VISITS [Date of Visit] ○ ERRONEOUS VISIT NOT SUBMITTED 2. Erroneous Visit [Visit Error] **COVID-19 Surveillance Visit** 3. COVID-19 Surveillance Vist: [COVID-19 Surveillance Visit]

NOT SUBMITTED

S	TUDYID		SV=Subject Visits		
С	C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)				
Da	Date of Visit				
1.	Date of Visit [Date of Visit]				
2.	Erroneous Visit [Visit Error]	© ERRONEOUS VISIT NOT SUBMITTED			
С	COVID-19 Repeat Swab				
3.	COVID-19 Repeat Swab: [COVID-19 Repeat Swab]				

C4591001: INFORM ENROLLMENT (ENROLL) NOT SUBMITTED			
InForm Enrollment			
1.	Subject ID [Subject ID]		

C	C4591001: HIV STATUS (HIV) NOT SUBMITTED		
HI	HIV Status		
1.	Select appropriate response - What is the subject HIV status? [Trigger Response 2]	The subject is known to be HIV POSITIVE The subject is NOT known to be HIV POSITIVE	

LB=Laborator	y Test Results
--------------	----------------

C2	C4591001: LAB CHEMISTRY (HIV RNA)						
La	Lab Chemistry Details						
1.	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY					
2.	Laboratory Name and Address [Vendor Name]	LBNAM					
3.	Collection Date: [Collect on Date:]						
4.	Specimen Type: [Specimen Type]	BLOOD LBSPEC					
La	Lab Result						
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Norma	Range	
5.a	a	HIV RNA (Ultrasensitive)					
La	b Result Entry						
5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSPID					
5.2	2 Test: [Test:]	○ HIV RNA (Ultrasens tive) LBTEST					
5.3	B Result: [Result:]	LBORRES					
5.4	Not Done: [hidden] [Not Done:]	ONOT DONE					
5.5	5 [LAMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t _/mL LBORRESU					

Annotated Study Book - C4591001

		HO-Healthcare Encour	tors	EA-Eindii	ngs About Events or Interventions
	UDYID				
		ARE UTILIZATION (HLTHCARE)HOCAT=HE	ALTHO	CARE SESSMENT	FACAT=HEALTHCARE UTILIZATION
Hea	alth Care Utilization				
	Evaluation Interval: [hidden] [Evaluation Interval]	Ŭ		IOEVINTX	FAEVINTX
	Disease Name: <i>[hidden]</i> [Disease Name]	© RESPIRATORY ILLNESS HCUIDIS in SUPPHO			
Hea	alth Care Utilization				
# ✔	Pre-Specified	Type of Practitioner		0	ccurrence 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			
Hea	alth Care Utilization Entry				
3.1	Pre-Specified: [hidden] [Pre-Specified]	O YES HOPRESP			
3.2	Physician or Healthcare Professional: [Type of Practitioner]	 SPECIALIST EMERGENCY ROOM PRIMARY CARE PHYSICIAN URGENT CARE TELEPHONE CONSULTATION OTHER 			
3.3	Occurrence of Visits or Contacts: [Occurrence of Vis ts or Contacts]	VES HOOCCUR Number of Vis ts or Contacts:	MBER]	
Hea	alth Care Utilization Other				
;	Other Type of Pract tioner Specify: [Other Type of Pract t oner Specify]	HOTERM			
Hea	alth Care Utilization	· · · · · · · · · · · · · · · · · · ·			
	Has the subject been hospitalized due to potential COVID-19 illness? [Been Hospitalized]	VES HCUHSP in SUPPHO Has the subject been in intensive care due to potent VES HCUICU in SUPPHO NO	al COVID)-19 illness?	

HO=Healthcare Encounters

C	4591001: HOSPITALIZ	ATION DETAILS (HOSP) - Repeating	Form		
#	Hospitalization Category		Hospitalizatio	on Term	Admission Date	Ongoing
1						
H	ospitalization Details					
1.	Hosp talization Category: [Hospitalization Category]	OHOSPITALIZATION S	TATUS HOCAT			
2.	Hosp talization Term: [Hospitalization Term]	OICU HOTER HOSPITAL	2M			
3.	Admission Date: [Admission Date]					
4.	Ongoing? [Ongoing]	YES HOENRTP NO Discharge Date: V ✓ / /	T= ONGOING HOEN	NTPT= ONGOIN(G AT CURRENT VISIT	

ST	UDYID	CE=Clinical Event
C4	591001: ILLNESS DET	AILS (ILL POTEN) CECAT = EFFICACY
	ess Details	
1.	Category of Clinical Event: [Category of Clin cal Event:]	OPOTENTIAL COVID-19 ILLNESS NOT SUBMITTED
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	YES Respiratory Illness Diagnosis: CETERM Date of Diagnosis:
3.	Toxicity Grade: [Toxicity Grade]	O CETOXGR 01 CETOXGR 02 03 04 05
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.	D ctionary Derived Term [hidden] [D ctionary 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

C4	C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)					
Illn	ess Details					
1.	Category of Clinical Event: [Category of Clin cal Event:]	SEVERE COVID-19 ILLNESS				
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	 SIGNIFICANT ACUTE RENAL DYSFUNCTION SIGNIFICANT ACUTE HEPATIC DYSFUNCTION SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION 				
3.	Was a diagnosis obtained? [Diagnosis Obtained]	YES Diagnosis: CETERM Start Date: YES Ongoing?: YES CEENRTPT= ONGOING/BEFORE End Date: YES Date: YES NO CEENDTC NO Date: YES NO NO				
4.	Toxicity Grade: [Toxicity Grade]	01 2 3 CETOXGR 4 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.	D ctionary Derived Term [hidden] [D ctionary 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	CEBDSYCD CESOCCD				

CE=Clinical Events

ST	UDYID				CE=Clinical Eve
C4	591001: ILLNESS DET	AILS - SEV	ERE (ILL SEVERE) - Repeating Fo	orm	
#	Category of Clinical E	vent:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grac
1					
Illn	less Details				
1.	Category of Clinical Event: [Category of Clin cal Event:]	SEVERE CO	VID-19 ILLNESS CECAT		
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	SIGNIFICAN	IT ACUTE RENAL DYSFUNCTION IT ACUTE HEPATIC DYSFUNCTION CESCAT IT ACUTE NEUROLOGIC DYSFUNCTION]	
3.	Was a diagnosis obtained? [Diagnosis Obtained]	YES Diagnosis: CETEF Start Date: VES VES NO End Date VES Ongoing?: YES ONO End Date VES ONO	✓/ ✓ CESTDTC EENRTPT= ONGOING/BEFORE	CEENTPT= LAST SUBJECT E	NCOUNTER

4.	Toxicity Grade: [Toxicity Grade]	01 02 03 CETOXGR 04 05
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.	D ctionary Derived Term [hidden] [D ctionary 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

MO=Morphology

C	4591001: IMAGING (IMAG)	(NG) - Repeating Form MOCAT=CLI	NICAL ASSESSMENT OF	RADIOGRAPHS - IMAGING
#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment
1				
In	naging			
1.	Date of Assessment: [Date of Assessment]			
2.	[Location of Assessment]	HEST EAD THER Tother, specify: LOCOTH in SUPPMO		
3.	[İmaging Method] OX OV OV II	T SCAN -RAY HTRASOUND IRI THER Tother, specify: METHOTH in SUPPMO		
4.	[Overall Assessment] II	BNORMAL MOORRES abnormal, specify findings: ASPECIFY IN SUPPMO NDETERMINATE ORMAL MOORRES NKNOWN OT EVALUABLE		

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION	CRITERIA (IN EX STG3)
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Study eligibility requires subjects to meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).

Inc	lusion Criteria						
#	Inclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)				
1.a	1	Male or female part cipants 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	articipants who are willing and able to comply with all scheduled visits, vaccination plan, boratory tests, lifestyle considerations, and other study procedures					
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 restr ctions listed in the ICD and in this protocol					
Inc	Inclusion Criteria Entry IECAT = INCLUSION						
1.1	Inclusion Number: [Inclusion Number]						

		○3 ○4
1.2	Cr terion Description: [Criter on Descript on]	✓ IETEST
1.3	Cr terion met? [Criter on met?]	VES IEORRES NO Describe details if relevant IEDESC in SUPPIE
	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	 IN01A00 IN02A00 IETESTCD IN03A00

O IN04A00

#	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 deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19	EX04A00
2.e	8	Immunocompromised indiv duals with known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal 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 w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00
2.h	11	Women who are pregnant or breastfeeding	EX11A00
2.i	12	Previous vaccinat on with any coronavirus vaccine	EX12A00
2.j	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted	EX13A00
2.k	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A00
2.1	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A00
2.m	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A00
2.n	21	Investigator s te 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
Exc	lusion Criteria Entr	V IECAT = EXCLUSION	
	Exclusion Number: [Exclusion Number]		
2.2	Cr terion Description [Criter on Descript o		
2.3 Cr terion met? [Criter on met?] VESIEORRES Describe details if relevant			

	IE=Inclusion/Exclusion Criteria Not Met
	[⊙] NO
2.4 Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	✓ IETESTCD

Π.

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

Inc	Inclusion Criteria					
# Inclusion Number		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)		
1.a	1	Male or female part cipants 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		
		Participants who are willing and able to comply w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, 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		
		Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol		IN04A00		
Inclusion Criteria Entry		V IECAT = INCLUSION				

1					
1.1	Inclusion Number: [Inclusion Number]	0 1 2 IESPID 3 0 4			
1.2	Cr terion Description: [Criter on Descript on]	▼ IETEST			
1.3	Cr terion met? [Criter on met?]	 YES IEORRES NO Describe details if relevant IEDESC in SUPPLE 			
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IN01A00 IN02A00 IN03A00 IN04A00			

Excl	usion 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 deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19	EX04A00
2.e	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination	EX08A00
2.f	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00
2.g	11	Women who are pregnant or breastfeeding	EX11A00
2.h	12	Previous vaccinat on with any coronavirus vaccine	EX12A00
2.i	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids	EX13A01
2.j	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A01
2.k	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A01
2.1	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A01
2.m	22	Investigator s te 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
Exc	usion Criteria Entry	, IECAT = EXCLUSION	
2.1	Exclusion Number: [Exclusion Number]		
2.2	Cr terion Description [Criter on Descript or		
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPLE NO	
2.4	Cr terion ID: (For Pfi	zer use IETESTCD	

only) [Criter on ID: (For Pfizer use only)]

IE=Inclusion/Exclusion Criteria Not Met

C4591001 · TNCI USTON	/EXCLUSION CRITERIA	(IN FX STG3)
CHURCHONT: THEFORE	/ LACEOSION CRITERIA	

Inc	inclusion Criteria					
# Inclusion Number		Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)			
1.a	1	Male or female part cipants 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 w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, 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 restr ctions listed in the ICD and in this protocol	IN04A00			
Inc	Inclusion Criteria Entry IECAT = INCLUSION					

1.1	Inclusion Number: [Inclusion Number]	0 1 2 IESPID 0 3 0 4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES IEORRES NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IN01A00 IN02A00 IETESTCD IN03A00 IN04A00

EXC	cclusion 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 deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00			
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19	EX04A00			
2.e	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal 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 w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00			
2.h	11	Women who are pregnant or breastfeeding	EX11A00			
2.i	12	Previous vaccinat on with any coronavirus vaccine	EX12A00			
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids	EX13A01			
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A01			
2.1	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A01			
2.m	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A01			
2.n	22	Investigator s te 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			
Exc	lusion Criteria Entry	IECAT = EXCLUSION				
2.1	Exclusion Number: [Exclusion Number]					
2.2	Cr terion Description [Criter on Descript or					
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant				
		IEDESC in SUPPLE				

		IE=Inclusion/Exclusion Criteria Not Met
		○ NO
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	✓ IETESTCD

2.1 Description of Exclusion Cr terion Met [Criter on Descript on]

STL

ST	STUDYID		IE=Inclusion/Exclusion Criteria Not Met			
C4	591001: INCLUSION/E	EXCLUSION CRITERIA (INC EXC)				
		Criterion Description				
1.						
Inc	lusion Criteria Not Met Entry					
1.1	1.1 Description of Inclusion Cr terion Not Met [Criter on Descript on] IFTEST when IEORRES=N					
		Criterion Description				
2.						
Exc	Exclusion Criteria Met Entry					

✓ IETEST when IEORRES=Y

Cuitoula

STUDYID

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

Incl	nclusion Criteria					
#	Inclusion Number		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)	
1.a	1		ale part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 sive, or 18 and 85 years, inclusive, at randomization (dependent upon study		IN01A00	
			who are willing and able to comply w th all scheduled vis ts, vaccination plan, ests, lifestyle cons derat ons, and other study procedures		IN02A00	
1.c	.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		Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol			IN04A00	
Inc	Inclusion Criteria Entry IECAT = INCLUSION					
1.1 Inclusion Number:						

	[Inclusion Number]	0 2 IESPID 0 3 0 4
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	VES IEORRES NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	 IN01A00 IN02A00 <i>IETESTCD</i> IN03A00 IN04A00

EXCI	usion 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 deation/behavior/lab abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.g	10	Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A01
2.1	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A01
2.m	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A01
2.n	22	Investigator s te 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
Exc	usion Criteria Entr	, IECAT = EXCLUSION		
2.1	Exclusion Number: [Exclusion Number]			
2.2	Cr terion Description [Criter on Descript or	ı]		
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPIE		





IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)	C4591001	: INCLUSION	/EXCLUSION	CRITERIA	(INC EXC NS)
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Incl	nclusion Criteria					
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)		
1.a	1	Male or female part cipants 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 w th all scheduled vis ts, vaccination plan, laboratory tests, lifestyle cons derat ons, 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		Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol		IN04A00		
Inc	Inclusion Criteria Entry IECAT = INCLUSION					

1.1	Inclusion Number: [Inclusion Number]	0 1 0 2 0 3 0 4
1.2	Cr terion Description: [Criter on Descript on]	IETEST
1.3	Cr terion met? [Criter on met?]	VES IEORRES NO Describe details if relevant IEDESC in SUPPLE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	 IN01A00 IN02A00 <i>JETESTCD</i> IN03A00 IN04A00

Exc	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 deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00			
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19	EX04A00			
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19	EX05A00			
2.f	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal 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 w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00			
2.i	11	Women who are pregnant or breastfeeding	EX11A00			
2.j	12	Previous vaccinat on with any coronavirus vaccine	EX12A00			
2.k	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids	EX13A01			
2.1	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A01			
2.m	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A01			
2.n	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A01			
2.0	22	Investigator s te 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			
Exc	lusion Criteria Entr	IECAT = EXCLUSION	· · · · · · · · · · · · · · · · · · ·			
2.1	Exclusion Number: [Exclusion Number]					
2.2	Cr terion Description [Criter on Descript or					
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant				

			IE=Inclusion/Exclusion Criteria Not Met
		[◯] NO	
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD	

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)					
Stud	dy eligibility requires	subjects to	meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).			
Inc	lusion Criteria					
#	Inclusion Number		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)	
1.a	1		ale part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 sive, or 18 and 85 years, inclusive, at randomization (dependent upon study		IN01A00	
1.b	2		who are willing and able to comply w th all scheduled vis ts, vaccination plan, tests, lifestyle cons derat ons, and other study procedures		IN02A00	
1.c	3		ticipants who are determined by medical history, physical examination, and ment of the investigator to be eligible for inclusion in the study		IN03A00	
1.d		requiremen	giving personal signed informed consent, which includes compliance with the ts and restr ctions listed in the ICD and in this protocol		IN04A00	
Inc	lusion Criteria Entr	y IECAT :	= INCLUSION			
1.1	Inclusion Number: [Inclusion Number]		0 1 0 2 1 1 1 1 1 1 1 1 1 1 1 1 1			
1.2	Cr terion Description [Criter on Descript o		✓ IETEST			
1.3	Cr terion met? [Criter on met?]		VES IEORRES NO Describe details if relevant IEDESC in SUPPIE			
	Cr terion ID: (For Pf only) [Criter on ID: (For P only)]		 IN01A00 IN02A00 <i>JETESTCD</i> IN03A00 IN04A00 			
Eve						

Exc	cclusion 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 deation/behavior/lab abnormal ty that may increase the risk of study participation					
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19		EX04A00			
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00			
2.f	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal 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 w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00			
2.i	11	Women who are pregnant or breastfeeding		EX11A00			
2.j	12	Previous vaccinat on with any coronavirus vaccine		EX12A00			
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted		EX13A00			
2.1	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A00			
2.m	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A00			
2.n	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A00			
2.0	21	Investigator s te 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			
Exc	xclusion Criteria Entry IECAT = EXCLUSION						
2.1	Exclusion Number: [Exclusion Number]						
2.2	Cr terion Description [Criter on Descript or						
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant					

			IE=Inclusion/Exclusion Criteria Not Met
		[◯] NO	
2.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	IETESTCD	

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

Inc	nclusion Criteria					
#	Inclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)			
1.a	1	Male or female part cipants 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		IN03A00				
1.d4Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocolIN04A00		IN04A00				
Inc	Inclusion Criteria Entry IECAT = INCLUSION					

1.1	Inclusion Number: [Inclusion Number]	0 1 2 IESPID 0 3 0 4
1.2	Cr terion Description: [Criter on Descript on]	✓ IETEST
1.3	Cr terion met? [Criter on met?]	VES IEORRES NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	 IN01A00 IN02A00 IN03A00 IN04A00

#	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 deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19	EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal 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 indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on	EX08A00
2.i	9	Sentinel participants in Stage 1 only: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention	EX09A04
2.j	10	Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00
2.k	11	Women who are pregnant or breastfeeding	EX11A00
2.1	12	Previous vaccinat on with any coronavirus vaccine	EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids	EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids	EX22A01
2.0	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A01
2.p	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A01
2.q	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A01
2.r	18	Sentinel part cipants 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 part cipants 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 part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen	EX19A01

		(HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t	
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 s te 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
Exc	lusion Criteria Entr	IECAT = EXCLUSION	
2.1	Exclusion Number: [Exclusion Number]		
2.2	Cr terion Description [Criter on Descript of		
2.3	Cr terion met? [Criter on met?]	VES IEORRES Describe details if relevant IEDESC in SUPPIE	
2.4	Cr terion ID: (For Pfi only) [Criter on ID: (For Pi only)]		

IE=Inclusion/Exclusion Criteria Not Met

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

Inc	Inclusion Criteria					
#	Inclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)			
1.a	1	Male or female part cipants 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	L.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 restr ctions listed in the ICD and in this protocol	IN04A00			
Inc	Inclusion Criteria Entry IECAT = INCLUSION					
1.1	Inclusion Number: [Inclusion Number]					

1.2	Cr terion Description:	

		^{○4}
1.2	Cr terion Description: [Criter on Descript on]	✓ IETEST
1.3	Cr terion met? [Criter on met?]	VES IEORRES NO Describe details if relevant IEDESC in SUPPIE
	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	 IN01A00 IN02A00 IN03A00 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 deation/behavior/lab abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal 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 indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on		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 w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.1	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.m	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted		EX13A00
2.n	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study		EX14A00
2.0	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation		EX15A00
2.p	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A00
2.q	17	Sentinel part cipants 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 part cipants 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 part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t		EX19A00

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 s te 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
Exc	lusion Criteria Entr	IECAT = EXCLUSION	
2.1	Exclusion Number: [Exclusion Number]		
2.2	Cr terion Description [Criter on Descript of		
2.3	Cr terion met? [Criter on met?]	 YES IEORRES Describe details if relevant IEDESC in SUPPIE NO 	
2.4	Cr terion ID: (For Pfi only) [Criter on ID: (For Pr only)]		

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

Inc	nclusion Criteria				
#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)	
1.a		Male or female part cipants 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 wth all scheduled vists, vaccination plan, laboratory tests, lifestyle cons derat ons, 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 restr ctions listed in the ICD and in this protocol		IN04A00	
Inclusion Criteria Entry IECAT = INCLUSION					
1.1	Inclusion Number: [Inclusion Number]				

	[Inclusion Number]	02 IESPID 03 04
1.2	Cr terion Description: [Criter on Descript on]	✓ IETEST
1.3	Cr terion met?	O YES

1.2	Cr terion Description: [Criter on Descript on]	✓ IETEST
1.3	Cr terion met? [Criter on met?]	VES IEORRES NO Describe details if relevant IEDESC in SUPPIE
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	 IN01A00 IN02A00 <i>JETESTCD</i> IN03A00 IN04A00

#	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 deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00
2.b	2	Known infection w th 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 medicat ons intended to prevent COVID-19	EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal 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 indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examinat on	EX08A00
2.i	9	Individuals w th a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention	EX09A00
2.j	10	Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00
2.k	11	Women who are pregnant or breastfeeding	EX11A00
2.1	12	Previous vaccinat on with any coronavirus vaccine	EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or systemic cort costeroids	EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids	EX22A01
2.0	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A01
2.p	16	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A01
2.q	17	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A01
2.r	18	Sentinel part cipants 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 part cipants 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 part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen	EX19A01

		(HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV A at screening vis t	bs)	
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention	EX2	20A01
2.v	22	Investigator s te staff or Pfizer employees directly involved in the conduct of the study site staff otherwise supervised by the investigator, and their respective family member		21A01
Exc	lusion Criteria Entr	y IECAT = EXCLUSION		
2.1	Exclusion Number: [Exclusion Number]			
2.2	Cr terion Description [Criter on Descript o	n]		
2.3	Cr terion met? [Criter on met?]	VES IEORRES Describe details if relevant IEDESC in SUPPIE		
2.4	Cr terion ID: (For Pfi only) [Criter on ID: (For P only)]			

C	4591001: CASEBOOK SI	GNATURE FORM (INVSIG) NOT SUBMITTED
Ca	asebook Signature Form	
1.	Casebook Signature [Casebook Signature]	Click Here to Enable

ST	UDYID	LB=Laboratory Tes	t Results MB=Microbiology Specimen
C4 !	591001: CENTRAL LAB SAMPLE	COLLECTION (LAB)	
Cen	tral Lab Sample Collection		
	Collection Date: Collect on Date:]		
	Specimen Type: Specimen Type]	OBLOOD 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]	O HEMATOLOGY O CLINICAL CHEMISTRY	
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	O DIFFERENTIAL O BLOOD CHEMISTRY	
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	O YES NO	YN in SUPPMB

รтเ	IDYID	LB=Laboratory Test F	Results MB=Microbiology Specimen
C4	591001: CENTRAL LAB SAMPL	E COLLECTION - BASELINE (LAB BSL)	
Cen	tral Lab Sample Collection		
	Collection Date: Collect on Date:]		
	Specimen Type: Specimen Type]	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]	○ HEMATOLOGY ○ CLINICAL CHEMISTRY LBCAT MBCAT	
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	O DIFFERENTIAL O BLOOD CHEMISTRY NOT SUBMITTED O VIROLOGY	
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	O YES NO NO LBSCATYN in SUPPLB MBSCATYN	N in SUPPMB

LB=Laboratory Test Results

ST	UDYID				LB=La	aboratory	/ Test Results
C4	591001: LOCAL LABORATORY DAT	A - REPEATING C	HEMISTRY (LAE	B CHEM) -	Repeating F	orm	
#	Category for Lab Test	Vendor Name	Collection Da	te:	Specimen T	уре	Lab Result
1							
La	o Chemistry Details						
1.	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY	BCAT				
2.	Laboratory Name and Address [Vendor Name]	LBNAM					
3.	Collection Date: [Collect on Date:]	✓ /	LBDTC				
4.	Specimen Type: [Specimen Type]	BLOOD LBSPEC					
La	o Result						
#	Sponsor-Defined Identifier	Tes	it:	Result:	Not Done:	Lab I	Normal Range
5.a		C Reactive Protein_PX3	29				
La	b Result Entry				·		
5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSF	PID				
5.2	Test: [Test:]	C Reactive Protein_PX	329 LBTEST				
5.3	Result: [Result:]	LBORRES					
5.4	Not Done: [hidden] [Not Done:]	ONOT DONE	-				
5.5	LNMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t LBORRESU]				

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 CLINICAL CHEMISTRY 1. Lab Panel: [Category for Lab Test] 2. Laboratory Name and Address [Vendor Name] LBNAM 3. Collection Date: ✓ / ✓ / ~ LBDTC [Collect on Date:] 4. Specimen Type: ○ BLOOD LBSPEC [Specimen Type] Lab Result Sponsor-Defined Identifier Test: Result: Not Done: Lab Normal Range # ¥ C Reactive Protein_PX329 5.a 5.b Alanine Aminotransferase_PX30 Aspartate Aminotransferase_PX28 5.c 5.d Alkaline Phosphatase_PX35 5.e Bilirubin_PX21 5.f Blood Urea Nitrogen_PX47 5.g Creatinine_PX48 Lab Result Entry Sponsor ID: 5.1 LBSPID [Sponsor-Defined Identifier] 5.2 Test: ~ LBTEST [Test:] 5.3 Result: LBORRES [Result:] 5.4 Not Done: NOT DONE LBSTAT [Not Done:] LNMT 5.5 Low [Lab Normal Range] LBORNRLO

High

Un t 🗸

LBORNRHI

LBORRESU

S	TUDYID				LB=L	aboratory	Test Results
C4	591001: LOCAL LABORATO	RY DATA - REI	PEATING Hemato	logy (LAB HEM) ·	- Repeating Fo	orm	
#	Category for Lab Test		ame (DERIVED)	Collection Date		nen Type	Lab Result
1							
Lał	boratory Data Hematology						
	Lab Panel: [Category for Lab Test]	OHEMATO	DLOGY LBCAT				
	Laboratory Name and Address [Vendor Name (DERIVED)]	LBNA	И				
	Collection Date: [Collect on Date:]			2			
	Specimen Type: [Specimen Type]	OBLOOD	LBSPEC				
Lat	o Result						
#	Sponsor-Defined Identifi	ier	Test:	Result:	Not Done:	Lab No	rmal Range
✓ 5.a		Hem	oglobin_PX1				
5.b			atocrit_PX2				
5.c			nrocytes_PX3				
5.d			lets_PX5				
5.e			ocytes_PX7				
5.f		Neut	rophils_PX608				
5.g		Eosir	nophils_PX609				
5.h		Mono	ocytes_PX612				
5.i		Baso	phils_PX610				
5.j		Lymp	phocytes_PX611				
Lal	b Result Entry						
5.1	Sponsor ID: [Sponsor-Defined Identifier]		LBSPID				
5.2	Pest: [Test:]		LBTEST				
5.3	Result: [Result:]	LBOI	RRES				
5.4	Not Done: [Not Done:]	ONOT D	ONE LBSTAT				
5.5	ENMT [Lab Normal Range]	High Un t	BORNRLO BORNRHI				

LB=Laboratory Test Results

C2	591001: LAB URINALYSIS - PREG	NANCY	TEST (LAB PREG)		
La	b Urinalysis				
1.	Lab Panel: [Category for Lab Test]	OURINAL	YSIS LBCAT		
2.	Lab Sub-Panel: [Subcategory for Lab Test]	○ PREGNA	ANCY LBSCAT		
3.	Collection Date: [Collect on Date:]	~ /			
4.	Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]	LBNA	И		
5.	Specimen Type: [Specimen Type]	OURINE	LBSPEC		
La	b Result				
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:
6.a	1		Chor ogonadotropin Beta_PX113		
La	b Result Entry				
6.1	Sponsor ID: [Sponsor-Defined Identifier]		LBSPID		
6.2	Pest: [Test:]	O Chor o	ogonadotropin Beta_PX113		
6.3	Result:	O NEGAT	IVE LBORRES		
6.4	Not Done: [Not Done:]	ONOT D	DONE LBSTAT		

	<u>UDYID</u> 59100	1: MEDIC	ΑΤΤΟ	ON ERROR (MED	ERROR) - R	epeating Form	1		p 12-70701	rse Events
- 1				t Is the medication	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	
1										
1.	dication Category [Categor	/: [y]		MEDICATION ERROR	AECAT					
2.	of Medic	on Error (Type ation Error): on Error]		AETERM						
3.	error, re incorrect number dispense to the su	container	ŋ]	A	EIPKGID in S	UPPAE				
4.	Start Da [Start Da			✓/ ✓/ ✓	AESTDTC					
5.	still ongo	ned cat on erro	ŏ	YES NO AEENRTPT End Date:	= ONGOING		AST SUBJE(CT ENCOUNTER]	
6.	with Stu	ction Taken dy Treatment: ledication ct on]	00	NO ACTION TAKEN PERMANENTLY DISCO		N.				
7.	Med cati	oncomitant on given? a tant on Given]	-	NO AECONTRT	AECMGIV in	SUPPAE				
8.		on-Drug nt given? ug Treatment	-	NO AECONTRT	AENDGIV in	SUPPAE				
9.	cause th			NO AESUBJDC	in SUPPAE	Linked to relate	ed DS record	I via RELREC		
10.	error ass any adve [Med cat	medication sociated with erse events? on Error ed With AE]		YES AE ID: AE ID: AE ID: AE ID: AE ID: AE ID: NO	n SUPPAE	AEAENO in S AEAENO in S AEAENO in S AEAENO in S AEAENO in S	SUPPAE SUPPAE SUPPAE			
11.	Number: Only	Adverse Event For Pfizer Use Adverse Even	• └─	AEREFID						
12.	Compari [hidden] [Compar	son Term ison Term]		NOT SUBMITTEL	•					
13.	[hidden]	evel Term Level Term]		AELLT						
14.	Code [hi	evel Term dden] Level Term		AEL	LTCD					
15.	Term [hi	ry-Derived [dden] ary-Derived		AEDECOD						

		AE=Adverse Eve	ents
16.	Preferred Term Code [hidden] [Preferred Term Code]	AEPTCD	
17.	High Level Term <i>[hidden]</i> [High Level Term]	AEHLT	
18.	High Level Term Code [hidden] [High Level Term Code]	AEHLTCD	
19.	High Level Group Term <i>[hidden]</i> [High Level Group Term]	AEHLGT	
20.	High Level Group Term Code [hidden] [High Level Group Term Code]	AEHLGTCD	
21.	Primary System Organ Class [hidden] [Primary System Organ Class]	AEBODSYS AESOC	
22.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	AEBDSYCD AESOCCD	

-	591001: GENERAL MEDI Line/MH Number			l History Term		Start Date	Ongoing
L.	Line/MH Number		Medica	i History Term		Start Date	Ungoing
	ical History Details Entry						
1.1	Line/MH Number: [Line/MH Number]		MHSPID				
1.2	Disease/Syndrome/Surgery/Non- Drug Allergies/Drug Allergies: [Medical History Term]	MHTEF	RM				
1.3	Start Date: [Start Date]	/		C			
1.4	Ongoing: [Ongoing]	● YES MI ● NO End Date			MHENTPT= LA	ST SUBJECT ENC	OUNTER
1.5	Comparison Term [hidden] [Comparison Term]	NOT SU	IBMITTED				
1.6	Lowest Level Term [hidden] [Lowest Level Term]	MHLLT					
1.7	Lowest Level Term Code [hidden] [Lowest Level Term Code]		MHLLTCD				
1.8	Dict onary Derived Term [hidden] [Dictionary Derived Term]	MHDEC	OD				
1.9	Preferred Term Code [hidden] [Preferred Term Code]		MHPTCD				
1.10	High Level Term [hidden] [High Level Term]	MHHLT					
1.11	High Level Term Code [hidden] [High Level Term Code]		MHHLTCD				
1.12	High Level Group Term [hidden] [High Level Group Term]	MHHLG	T				
1.13	High Level Group Term Code [hidden] [High Level Group Term Code]		MHHLGTCD				
1.14	Primary System Organ Class [hidden] [Primary System Organ Class]	MHBOD	SYS MHSOC				
1.15	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]		MHBDSYCD	MHSOCCD			

LB=Laboratory Test Results LB=Laboratory Test Results C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form LBCAT= OXYGENATION PARAMETERS # Date Time of Assessment # Date Time of Assessment 1 LBSCAT= BLOOD CHEMISTRY Oxygenation Parameters LBDTC 1. Date Time of Assessment: 1. Date Time of Assessment: Image: All and All a

[Date fille of Assessment]	😧 : 🔽 24-hour clock
Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	LBORRES when LBTESTCD = PO2
FiO2 (Fract on of Inhaled Oxygen): [FiO2 (Fraction of Inhaled Oxygen)]	LBORRES when LBTESTCD = FIO2

PE=Physical Examination

ST	UDYID	P	E=Physical Examination
C4	591001: PHYSICAL EX	AMINATION (PHYS EXAM) PECAT=PHYSICAL EXAMINATION	
	sical Examination		
	Exam Date: [Exam Date]		
Phy	vsical 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		
2.1	EXTREMITIES		
2.m	NEUROLOGICAL		
2.n	LYMPH NODES		
Phy	sical Examination Result Entr	γ	
2.1	Body System Examined: [Body System Examined]	PETEST	
2.2	Result: [Result]	NORMAL PEORRES If abnormal findings, specify: (If clinically signif cant, record on the Medical History or Advert Are there clinically signif cant findings? YES PECLSIG in SUPPPE NO NO NOT DONE PESTAT	rse Event CRF as appropriate).

S	STUDYID IS=Immunogenicity Specimen Assessment CO=Comments								
C	C4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19) //SCAT=SEROLOGY								
Ele	Electronic Sample Tracking								
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPIS							
2.	Sample Type [Sample Type]	SERUM ISSPEC							
3.	Sample Collected? [Sample Collected]	NO COVAL when COREF=SAMPLE COLLECTED YES Date of Collect on: ▼ / ▼ / ▼ / ▼ / ▼ / ▼ 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.									
AI	Aliquot Entry								
Ple	ase enter barcode for each aliquo	t.							
5.	L Sample ID [Sample ID]	NOT SUBMITTED							

CM=Concomitant Medications

ST	STUDYID CM=Concomitant Medications										ations	
C4	591001: CONCO	DMITANT MED	ICATIONS -	PROHIBITE	D (PROHIB C	M) - Repeat	ing Fo	rm				
#	Sponsor-Defined Identifier	Category for Medication		Medications Pre- ecified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing	
1			· ·									
Cor	comitant Medication	is			·							
1.	What is the medicatio [Sponsor-Defined Ide		СМ	SPID								
2.	Category: [Category for Medicat	ion]	CORT	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY CORTICOSTEROIDS MMUNOGLOBULINS								
3.	Concomitant Medicati			ONO NOT SUBMITTED								
4.	Med cation:		CMTF	27								
Prov de the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]			here rade or nation	<u></u>								
5.	Dose: [Dose Description]		CMI	DOSE CMDO	STXT							
6.	Dose Unit: [Dose Unit]			CMDOSU								
7.	Dose Frequency: [Dose Frequency]			CMDOSFRQ								
8.	Route: [Route]			CMROUTE								
9.	Start Date: [Start Date]		🖌 /		CMSTDTC							
10.	Ongoing? [Ongoing]		ONO End D		ONGOING	MENTPT= LA	IST SU	BJECT ENC	OUNT	ER		
11.	Comparison Term [hic [Comparison Term]	dden]	NOT	SUBMITTED								
12.	Standardized Med cat derived. [hidden] [Standardized Med ca			COD								
13.	Standardized Med cat derived [hidden] [Standardized Med ca	,		C	MCODE in SU	PPCM						

ST	TUDYID PR=Procedures									
C4	591001: I	RADIATION TREATMENT	(PROHIB ND) - Repeating Form							
#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?				
1										
Rac	liation Treat	ment								
1.	Category: [Category]		RADIATION THERAPY PRCAT							
2.	What is the t [Treatment I	reatment Identifier? dentifier]	PRSPID							
3.		Non-drug Treatment Pre-specified: ug Treatments Pre-specified]	O YES PRPRESP							
4.	Treatment: [Treatment]		PRTRT							
5.	Start Date: [Start Date]									
6.	Ongoing? [Ongoing?]		YES PRENRTPT= ONGOING PRENTPT= LAST SUBJECT ENCOUNTER NO End Date: Image: PRENDTC							
7. Comparison Term [hidden] [Comparison Term]			NOT SUBMITTED							
8.	Lowest Level [Lowest Leve	Term [hidden] I Term]	PRLLT in SUPPPR							
9.	Lowest Level	Term Code [hidden] I Term Code]	PRLLTCD in SUPPPR							
10.		erived Term [hidden] erived Term]	PRDECOD							
11.	Preferred Ter [Preferred Te	r m Code [<i>hidden</i>] rrm Code]	PRPTCD in SUPPPR							
12.	High Level Te [High Level T		PRHLT in SUPPPR							
13.	High Level Te [High Level T	erm Code [hidden] [[] erm Code]	PRHLTCD in SUPPPR							
14.	High Level G [High Level G	r oup Term [<i>hidden</i>] Group Term]	PRHLGT in SUPPPR							
15.		roup Term Code [hidden] Group Term Code]	PRHLGTCD in SUPPPR							
16.		em Organ Class [hidden] tem Organ Class]	PRBODSYS in SUPPPR PRSOC in SUP	PPR						
17.		rimary System Organ Class Code [hidden] Primary System Organ Class Code] PRBDSYCD in SUPPPR Primary System Organ Class Code]								

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

C 4	591001: VITAL SIGNS - 1	PULSE UX ROOM AIR (PULSE U	() - Repeating Form VOOAT-OLNERAL VITAL OIONO				
#	Date:	Vital Signs Details					
1							
Vit	al Signs						
	Date: [Date:]						
Vit	al Signs Details						
# •	Reco	ord Identifier:	Oxygen Saturation				
2.a	1						
Vit	al Signs Details Entry						
2.1	Record Identifier: O	¹ VSSPID					
2.2	SPO2 Pulse Oximetry % [Oxygen Saturation]	VSORRES when VSTEST	CD = OXYSAT				

STUDYID DS=Disposition C4591001: RANDOMIZATION (RAND) DSCAT=PROTOCOL MILESTONE Disposition 1. Randomizat on Date : Image: Standard
[Randomization Date :]		
Randomizat on Number: [Randomization Number]	DSREFID	
Randomizat on Group: [Randomization Group]	DSRANGRP in SUPPDS	

C4591001: REACTOGENICITY DIARY (REAC DIARY)

R	eactogenicity Diary	REACTOFL='Y' in SUPPDM when non-missing
1.	Select appropriate response -	O YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT of vaccination start date
	Reactogen c ty diary collection [Trigger Response 9]	ONO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT REACTOFL='N' in SUPPDM

DM=Demographics

ST	UDYID		FA=F	Findings About Events or Interventions					
				-					
	planned Assessment Of Loca		CAL REACTION - SYSTEMIC EV CTOGENICITY -UNPLANNED AS						
<u> </u>	CISR Category [hidden]								
	[CISR Category]								
	Date of Assessment: [Date of Assessment]		ADTC						
	Injection Site Location [Injection S te Location]	O DELTOID MUSCLE	DELTOID MUSCLE FALOC						
	Injection Site Body S de: [Injection S te Body Side]								
Rea	action								
#		ction:	R	eaction Present:					
5.a									
	SWELLING								
Rea	action Entry								
5.1	Reaction: [React on:]	 REDNESS SWELLING 							
	[React on Present:]	on Present: on Present:] YES FAORRES when FATESTCD=OCCUR Maximum Diameter (cm): FAORRES when FATESTCD=MAXDIAM Minimum Diameter (cm): FAORRES when FATESTCD=MINDIAM Meets Grade 4 Reaction Cr teria: YES FAORRES when FATESTCD=G4CRIMET NO NO							
Syr	nptom								
#		Symptom:		Symptom Present:					
6.a	PAIN AT INJECTION SITE								
6.b									
6.c									
6.d									
6.e	DIARRHEA NEW OR WORSENED MUSCLE	DATN							
6.f									
<u> </u>	CHILLS								
	nptom Entry								
⊢-	Symptom:	FAOBJ							
6.2	Symptom Present: [Symptom Present:]	Symptom Grade: 1 2 3 4 Event related to Study Tre	n FATESTCD=OCCUR nen FATESTCD=SEV eament? when FATESTCD=REL						

ST	UDYID					PR=P	rocedures	
_	591001: RESPIRATORY TREATME	NT (RESP TX) - Repea	atina Forn	PRCAT=GENE	RAL NON-DI			
#		Non-Drug Treatments Pre-sp		Treatment	Treatment	Start Date	Ongoing?	
1								
Res	spiratory Treatment				1	1	1	
1.	What is the treatment Identifier? [Treatment Identifier]	PRSPID						
2.	Concomitant Non-drug Treatment Pre-specified [Con Non-Drug Treatments Pre-specified]	OYES PRPRESP						
3.	Treatment: [Treatment]	NON-INVASIVE POSITIVE PRESSURE VENTILATION CPAP PRTRT MECHANICAL VENTILATION EXTRACORPOREAL MEMBRANE OXYGENATION HIGH FLOW OXYGEN THERAPY						
4.	Treatment: [Treatment]	PRTRT						
5.	Start Date: [Start Date]		STDTC					
6.	Ongoing? [Ongoing?]	YES PRENRTPT= OI NO End Date: ♥ / ♥ /	NGOING	PRENTPT= LA	ST SUBJECT	ENCOUNTE	R	
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]	PRLLTC	D in SUPP	PPR				
10.	D ctionary Derived Term [hidden] [D ctionary Derived Term]	PRDECOD						
11.	Preferred Term Code [hidden] [Preferred Term Code]	PRPTCI) in SUPPI	PR				
12.	High Level Term [hidden] [High Level Term]	PRHLT in SUPPPR						
13.	High Level Term Code [hidden] [High Level Term Code]	PRHLTC	CD in SUPI	PPR				
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]	PRHLG	TCD in SU	PPPR				
16.	Primary System Organ Class [hidden] [Primary System Organ Class]	PRBODSYS in SUPP	PR PRSO	C in SUPPPR				
17.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	PRBDS	YCD in SU	IPPPR PRSO	CCD in SUP	PPR		

PR-Procedures

S 7	PR=Procedures								
C4	591001: RESPIRATOR	Y TREATME	NT (RESP T	X) - Repeatir	ng Form <mark>/</mark>	PRCAT=GENE	RAL NON-D	RUG TREAT	MENT
#	Treatment Identifier	Con N	lon-Drug Treatr	ments Pre-specif	ied	Treatment	Treatment	Start Date	Ongoing?
1									
	spiratory Treatment								
1.	What is the treatment Identifier? [Treatment Identifier]	2	PRSPID						
2.	Concomitant Non-drug Treatmen [Con Non-Drug Treatments Pre-s		OYES PRPR	RESP					
3.	[Treatment]		 INTUBATION NON-INVASIVE POSITIVE PRESSURE VENTILATION CPAP OXYGEN THERAPY 						
4.	Treatment: [Treatment]		PRTRT						
5.	Start Date: [Start Date]			/ PRS	TDTC				
6.	Ongoing? [Ongoing?]		O YES NO End Date:	ENRTPT= ONG		RENTPT= LA	ST SUBJECI	ENCOUNTE	R
7.	Comparison Term [hidden] [Comparison Term]		NOT SUBI	MITTED					
8.	Lowest Level Term [hidden] [Lowest Level Term]		PRLLT in	SUPPPR					
9.	Lowest Level Term Code [hidden [Lowest Level Term Code]]		PRLLTCD	in SUPPP	R			
10.	D ctionary Derived Term [hidden [D ctionary Derived Term]]	PRDECOD						
11.	Preferred Term Code [hidden] [Preferred Term Code]			PRPTCD i	n SUPPPF	2			
12.	High Level Term [hidden] [High Level Term]		PRHLT in	SUPPPR					
13.	High Level Term Code [hidden] [High Level Term Code]			PRHLTCD	in SUPPF	PR			
14.	High Level Group Term [hidden] [High Level Group Term]		PRHLGT	in SUPPPR					
15.	High Level Group Term Code [hid [High Level Group Term Code]	dden]		PRHLGTC	D in SUPI	PPR			
16.	Primary System Organ Class [hid [Primary System Organ Class]	dden]	PRBODS	YS in SUPPPF	PRSOC	in SUPPPR			
17.	Primary System Organ Class Coo [Primary System Organ Class Co			PRBDSY	CD in SUP	PPR PRS	OCCD in SUF	PPPR	

C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF)NOT SUBMITTED

F	rther Vaccination Confirmation							
1	Select appropriate response - Is part cipant willing to return for Vaccination 3? [Trigger Response 1]	 Participant is willing to return for Vaccinat on 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 eligible and NOT confirmed to have received only placebo at Vaccination 1/2 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 Informed Consent - Further Vaccination

1	Consent Was:	OBTAINED	DSSTDTC when	
	[Consent Was:]	Date Written Consent Obtained	DSTERM/DSDECOD=INFORMED	
			CONSENT OBTAINED	

ST	Τυργίρ	IE=Inclusion/Exclusion Criteria Not Met
C4	4591001: INCLUSION/EXCLUSION CRITERIA - FURTH	HER VACCINATION (REVAX IE)
	Criteri	rion Description
1.		
Inc	nclusion Criteria Not Met Entry	
1.1	1 Description of Inclusion Cr terion Not Met [Criter on Descript on]	V
	Criteri	rion Description
2.		
Exe	xclusion Criteria Met Entry	
2.1	1 Description of Exclusion Cr terion Met [Criter on Descript on]	Y

F	TUDYID	MB=Microbiology Specimen CO=Comments
С	4591001: ELECTRONIC	SAMPLE TRACKING - REPEAT SWAB (RSWAB) MBCAT=VIROLOGY
E	ectronic Sample Tracking	
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPMB
2.	Sample Type [Sample Type]	○ NASAL_SWAB ○ NASAL_SWAB_SELF
3.	Sample Collected? [Sample Collected]	NO NOT SUBMITTED YES Date of Collect on: ♥ / ♥ / ♥ / ♥ //
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

Aliquot Entry

5.

Please enter barcode for each aliquot

Fiea				
5.1	Sample ID	ΝΟΤ	SUBMITTED	
	[Sample ID]			

S	TUDYID	IS=Immunogenicity Specimen Assessment CO=Comments				
C	C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK)					
Ele	ectronic Sample Tracking					
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPIS				
2.	Sample Type [Sample Type]	O SERUM ISSPEC				
3.	Sample Collected? [Sample Collected]	NO YES COVAL when COREF=SAMPLE COLLECTED Date of Collect on: Image: Control in the second				
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.						
AI	Aliquot Entry					
Ple	Please enter barcode for each aliquot.					
5.	1 Sample ID [Sample ID]	NOT SUBMITTED				

C	C4591001: INFORM SCREENING (SCREEN) NOT SUBMITTED			
In	nForm Screening			
1.	InForm Initials [hidden] [InForm Initials]			
2.	Birth Date: [Birth Year]			

S	MB=Microbiology Specimen CO=Comments					
C	C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB) MBCAT=VIROLOGY					
Ele	ectronic Sample Tracking					
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPMB				
2.	Sample Type [Sample Type]	NASAL_SWAB_SELF MBSPEC				
3.	Sample Collected? [Sample Collected]	NO NOT SUBMITTED YES Date of Collect on: ▼ / ▼ / ▼ / ▼ /				
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

5.1 Sample ID [Sample ID]

Please enter barcode for each aliquot.

NOT SUBMITTED

Annotated Study Book - C4591001

STU	Original version	: VERSION 1: USED PRIOR TO JULY 6, 2020 ERSION 2: USED AFTER JULY 6, 2020 EVents or Intervention	ns CE=Clinical Events			
C45	C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD) FACAT=EFFICACY CECAT=EFFICACY					
Sign	s and Symptoms FASCAT=	RESPIRATORY ILLNESS CESCAT=SIGNS AND SYMPTOMS OF DISE	ASE			
	ate of Assessment: Date of assessment]					
	ate of First Symptom Started: First Symptom Started Date]	✓/ ✓/ FAORRES when FATESTCD=FSYMDATE CESTD	TC .			
	ymptoms Ongoing? Symptoms Ongoing]	OVES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOIN	IG CEENTPT= ONGOING			
		Date of Last Symptom Resolved:	AT CURRENT VISIT			
		▼ / ▼ / ▼ FAORRES when FATESTCD=LSYMDATE CEE	NDIC			
sym #	ptoms Event Pre-specified	Symptoms	Symptom Present			
v	NEC					
4.a 4.b	YES	FEVER 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 4.i	YES	DIARRHEA VOMITING				
	ptoms Entry	VOMITING				
<u> </u>	Event Pre-specified: [hidden]	O YES NOT SUBMITTED				
	[Event Pre-specified] Symptoms:					
43	[Symptoms] Was symptom present?					
4.5	[Symptom Present]	ONO FAORRES When FATESTCD=OCCOR				
5.		Symptoms - Other				
•						
Sym	ptoms - 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	NOT SUBMITTED				
	[Lowest Level Term Code]					
5.5	Dict onary 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]	NOT SUBMITTED				
5 12	[Primary System Organ Class] Primary System Organ Class	NOT SUBMITTED				
	Code [hidden] [Primary System Organ Class					

Code]

FA=Findings About Events or Interventions

Annotated Study Book - C4591001

090177e198d5262f/Final/Final On: 10-Dec-2021 03:01 (GMT)

STL	Original version	: VERSION 1: USED PRIOR TO JULY 6, 2020 ERSION 2: USED AFTER JULY 6, 2020 EVents or Interventio	t ons CE=Clinical Events
C4!			ECAT=EFFICACY
	ate of Assessment:		ASE
	Date of assessment]		
] [ate of First Symptom Started: First Symptom Started Date]	▼ / ▼ / ▼ FAORRES when FATESTCD=FSYMDATE CESTD	TC
	ymptoms Ongoing? Symptoms Ongoing]	OYES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOIN	G CEENTPT= ONGOING
		NO Image: Second control of Lord control control of Lord control contro contro control contro control control control control control c	AT CURRENT VISIT
E.um	ptoms	PAORRES WIEI PATESTODELSTINDATE	
3ym #	Event Pre-specified	Symptoms	Symptom Present
V		- ,	-,
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	
Sym	ptoms Entry		
4.1	Event Pre-specified: [hidden] [Event Pre-specified]	O YES NOT SUBMITTED	
4.2	Symptoms: [Symptoms]	FAOBJ CETERM	
4.3	Was symptom present? [Symptom Present]	● YES ● NO FAORRES when FATESTCD=OCCUR	
		Symptoms - Other	
5.			
<u> </u>	ptoms - 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	Dict onary 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 Orde [hidden] [Primary System Organ Class	NOT SUBMITTED	

Code]

FA=Findings About Events or Interventions

C	C4591001: STRATIFICATION (STRAT) NOT SUBMITTED	
St	ratification	
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	○Non-Sentinel Stage 1
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	 ○ Age 18 to 55 ○ Age 65 to 85
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	0 10 mcg 20 mcg 30 mcg
4.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	0 21 Day 0 60 Day
5.	Select appropriate response - BNT Number [Trigger Response 7]	(BNT162b1 or PBO) (BNT162b2 or PBO) (BNT162b3 or PBO)

С	C4591001: STRATIFICATION (STRAT) NOT SUBMITTED		
St	tratification		
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	O Stage 2	
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	 ○ Age 18 to 55 ○ Age 56 to 85 	
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	 10 mcg 20 mcg 30 mcg 	
4.	Select appropriate response - BNT Number [Trigger Response 7]	 ○ (BNT162b1 or PBO) ○ (BNT162b2 or PBO) ○ (BNT162b3 or PBO) 	

C4591001: STRATIFICATION (STRAT) NOT SUBMITTED

C	C4591001: STRATIFICATION (STRAT) NOT SUBMITTED		
SI	ratification		
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	O Stage 1 O Stage 2	
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	 Age 18 to 55 Age 56 to 85 Age 65 to 85 	
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	 Low dose level (3mcg) Medium dose level (10mcg) High dose level (30mcg) Low dose level (10mcg) Medium dose level (30mcg) High dose level (100mcg) Low dose level (0.1mcg) Medium dose level (0.3mcg) High dose level (0.3mcg) Mid-High dose level (50mcg) Low-Mid dose level (20mcg) 	
4.	Select appropriate response - Randomizat on Dose Group [hidden] [Trigger Response 6]	 21 Day 2-dose group 60 Day 2-dose group 1-dose group 	
5.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	0 21 Day 0 60 Day	
6.	Select appropriate response - BNT Number [Trigger Response 7]	 (BNT162a1 or PBO) (BNT162b1 or PBO) (BNT162b2 or PBO) (BNT162c2 or PBO) (BNT162b3 or PBO) 	

C	C4591001: SUBJECT STATUS (SUB STATU) NOT SUBMITTED					
Su	Subject Status					
1.	Subject Status [Subject Status]					
2.	Subject Status Date [Status Date]					

STUDYID DS=Disposition C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS) DSCAT=PROTOCOL MILESTONE

I	Informed Consent - Asymptomatic Surveillance				
1	Consent Was:	\sim	DSSTDTC when		
	[Consent Was:]		DSTERM/DSDECOD=INFORMED		
			CONSENT OBTAINED		

S 1	TUDYID	MB=Microbiology Specimen CO=Comments					
C	C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE) MBCAT=VIROLOGY						
El	ectronic Sample Tracking						
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPMB					
2.	Sample Type [Sample Type]	○ NASAL_SWAB MBSPEC					
3.	Sample Collected? [Sample Collected]	NO NOT SUBMITTED YES Date of Collect on: ▼ / ▼ / ▼ /					
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

5.1 Sample ID [Sample ID]

Please enter barcode for each aliquot.

NOT SUBMITTED

S	TUDYID				MB=Micr	obiology Specimen DI=	=Device Ide	entifiers C	O=Co	mments
C	4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form MBCAT=CONFIRMATION OF INFECTION									
#	Date of Collection	Specimen	1	Specimen Colle		Assay Code and Description	1	Trade Name	1	
1										
Mi	crobiology Specimen	1								
1.	Actual Date of Collecti [Date of Collection]	ion:	*	/ • / •	MBDTC					
2.	2. Specimen Type: ([Specimen Type]			BBED MATERIAL	MBSPEC					
3.	B. Specimen Collection Location: [Specimen Collection Location]			3LOC						
4.	Assay Code and Desci [Assay Code and Desci		OSEVI	ERE ACUTE RESP S	SYNDROME CORO	NAVIRUS 2 MBTEST				
5.	5. Device Type: [Device Type]			TIC TEST DIVA	L when DIPARMCD = DE	VTYPE				
6.	. ,, ,		CEP	HEID XPERT XPRE	SS SARS-COV-2 T	EST DIVAL when DIPARMO	CD = TRADE	NAM		
7.										
8.	Comments/Findings/D [Comments:]	Details:	COV	AL when RD	omain = mb]				

Annotated Study Book - C4591001

ST	JDYID	CE=Clinical Events FA=Findings About Events or Interventions AE=Adverse Events				
C4	591001: VACCINATIO	N SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE)				
	accination Symptoms Diary - Symptom Resolved Dates FACAT=REACTOGENICITY					
	Were medications to treat fever/pain given on the last day the Subject Diary was completed? [Fever/Pain Medication on Last Diary Day]	YES Ongoing? FAORRES YES NO FAENRTPT= ONGOING FAENRTPT= ONGOING FAENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD Stop Date: Image: Particular Stop Date: Image: Particular Stop Date: Image: Part				
#	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 WORSENED MUSCLE P	AIN				
2.h	NEW OR WORSENED JOINT PAI	N				
2.1	Symptom: [Symptom:]					
2.2	Were fever or system c 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?]	YES NOT SUBMITTED Ongoing Ongoing YES CEENRTPT= NO ONGOING Stop Date: DAY OF DIARY PERIOD NO RCENDTC in SUPPCE				
	Injection Site Location: [Injection S te Location:]	DELTOID MUSCLE CELOC AELOC				
	Injection Site Body S de: [Injection S te Body Side:]	OLEFT CELAT AELAT				
#	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 React on: [Injection Site Reaction:]	REDNESS CETERM FAOBJ AETERM SWELLING PAIN AT INJECTION SITE				
5.2	Were injection s te reactions present on the last day the Subject Diary was completed? [Were inject on site reactions present on the last day the Subject Diary was completed?]	Orgsing CEENRTPT= CEENTPT= ONGOING ONGNXVIS in AEENRTPT ONG ONGOING RELATIVE TO LAST ONGOING AEENRTPT NO DAY OF DIARY PERIOD ONGNXVIS in AEENRTPT NO RCENDTC in SUPPCE DAY OF DIARY				

_	TUDYID			PR=Procedures
C	4591001: TRANSFUSI	ONS (TRANSFUSE) - Repeating	Form PRCAT=TRANSFUSION DETAILS	
#		ansfusion Type	Date of Transfusion	
1				
1.	Transfus on Type: [Transfus on Type]	 PACKED RBC PLATELETS WHOLE BLOOD PLASMA OTHER Specify: 		
2.	Date of Transfus on: [Date of Transfusion]			

C4591	C4591001: TREATMENT UNBLINDED (TRN UNBLN)DSCAT=OTHER EVENT			
Treatme	ent Unblinded			
	Treatment Unblinded : : Treatment Unblinded :]			
	ary Reason for Unblinding: ary Reason for Unblinding]	SUBJECT SAFETY CONCERN DSTERM OTHER If other, specify: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION		

С	C4591001: UNPLANNED VISIT (UNPL) NOT SUBMITTED				
U	Unplanned Assessments				
1.	Assessments [Assessments]				

S 7	UDYID	EX=Exposure EC=Exposure as Collected
C4	591001: VA	CCINATION (VACIN TRT) EXCAT=INVESTIGATIONAL ECCAT=INVESTIGATIONAL ECSCAT=VACCINATION
Va 0	Was there a temporary delay of vaccinat on?	EXSCAT=VACCINATION PRODUCT PRODUCT YES EXTDV in SUPPEX ECTDV in SUPPEC Date of First Delay: Image: Compare the provided of the p
	[Temporary Delay of Vaccination]	Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS RECENT SYSTEMIC CORTICOSTEROID TREATMENT RECENT NON-STUDY VACCINATION ANTICIPATED NON-STUDY VACCINATION NO NO NO RECENT NON-STUDY VACCINATION NO NO RECENT NON-STUDY VACCINATION NO RECENT NON-STUDY VACCINATION SUPPEX RECENT NON-STUDY VACCINATION SUPPEX RECENT NON-STUDY VACCINATION SUPPEX RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION NO RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION NO RECENT NON-STUDY VACCINATION RECENT NON-STUDY VACCINATION
2.	Treatment Name [Treatment Name]	EXTRT ECTRT
3.	Formulat on: [Formulat on:]	OINJECTION EXDOSFRM ECDOSFRM
4.	Dose Date Time: [Dose Date Time:]	Image: Second conditional state of the second condition of the second c
5.	Anatomical Locat on: [Anatomical Locat on:]	ODELTOID MUSCLE EXLOC ECLOC
6.	Body Side: [Body S de:]	OLEFT EXLAT ECLAT
7.	Route: [Route:]	
8.	Planned Dose: [Planned Dose]	
9.	Planned Dose Unit: [Planned Dose Unit]	Oug <u>ECDOSU</u>
10.	Actual Dose: [Actual Dose:]	EXDOSE ECDOSE
11.	Unit: [Unit:]	
12.	Was the Actual Dose adjusted from planned? [Dose Adjusted From Planned]	YES EXDOSADJ in SUPPEX ECDOSADJ in SUPPEC What was the reason the dose was adjusted? 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, EXADJ2, etc. in SUPPEX EXDOSAJO in SUPPEX ECDOSAJO in SUPPEC
13.	Timeframe Subject Was Observed [Timeframe Subject Was	THE PROTOCOL SPECIFIED OBSERVATION PERIOD EXOBSVT in SUPPEX ECOBSVT in SUPPEC
14.	Observed] Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time] Comparison Term [hidden] [Comparison	VES EXOBSV in SUPPEX ECOBSV in SUPPEC NO If No, specify reason: EXOBSVD in SUPPEX ECOBSVD in SUPPEC
16.	Standardized Med cation	EXDECOD in SUPPEX ECDECOD in SUPPEC
	Name -	

			EX=Exposure EC=Exposure as Collected
	D ctionary Derived. [hidden] [Standardized Med cation Name]		
17.	Standardized Med cation Code - D ctionary Derived [<i>hidden</i>] [Standardized Med cation Code]	EXCD in SUPPEX ECCD in SUPPEC	

C4	591001: VA	CCINATION (VACIN TRT) EXCAT=INVE	STIGATIONAL ECCAT=INVE	STIGATIONAL ECSCAT=VACCINA
	cination	EXSCAT=VACCINATION PRODUCT	PRODUCT	
1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	YES EXTDV in SUPPEX ECTDV in SUPPEX Date of First Delay: FDDTC in SUPPE Image: Construct of the second	X FDDTC in SUPPEC	LE selected, ECADJ=MULTIPL
2.	Treatment Name [Treatment Name]	EXTRT ECTRT		
3.	Formulat on: [Formulat on:]	OINJECTION EXDOSFRM ECDOSFRM		
4.	Dose Date Time: [Dose Date Time:]	Image: style="text-align: center;">Image: style="text-align: center;"/>Image: style="text-align: center;"///Image: style="text-align: center;"///Image: style="text-align: center;"///Image: style="text-	TC ECSTDTC ECENDTC	
5.	Anatomical Locat on: [Anatomical Locat on:]	O DELTOID MUSCLE EXLOC ECLOC		
6.	Body Side: [Body S de:]	OLEFT ORIGHT EXLAT ECLAT		
7.	Route: [Route:]	OINTRAMUSCULAR EXROUTE ECROUTE		
8.	Container Number: [hidden] [PAC / K t Number:]	NOT SUBMITTED		
9.	Actual Dose: [Actual Dose:]	EXDOSE ECDOSE		
10.	Unit: [Unit:]	OmL Oug EXDOSU ECDOSU		
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	THE PROTOCOL SPECIFIED OBSERVATION PERIOD EXOBSVT in SUPPEX ECOBSVT in SUPPEX	SUPPEC	
12.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	VES EXOBSV in SUPPEX ECOBSV in NO If No, specify reason: EXOBSVD in SUPPEX ECOBSVD in		
13.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED		
14.	Standardized Med cation Name - D ctionary Derived. [hidden] [Standardized Med cation Name]	EXDECOD in SUPPEX ECDECOD in	SUPPEC	
15.	-	EXCD in SUPPEX E	CCD in SUPPEC	

1
[Standardized
Med cation
Codel

EX=Exposure EC=Exposure as Collected

S	TUDYID						СІ	M=Concomit	ant Medi	cations
С	C4591001: CONCOMITANT MEDICATIONS - VASOPRESSORS (VASOPRESS) - Repeating Form									
#	Sponsor-Defined Identifier	Category f	or Medication		Concomitant Medicat	ions Pre-specified	Name	e of Medication	Start Date	Ongoing
1								CMSCAT=VA	SOPRESS	SORS
Co	oncomitant Medications							AGENTS		
1.	What is the medication identifier? [Sponsor-Defined Identifier]		CMSPID							
2.	Category: [Category for Med cat on]		GENERAL CONCOMITANT MEDICATIONS							
3.	Concomitant Medications Pre-spec [Concomitant Medications Pre-spec		ONO NOT	้รเ	UBMITTED					
4.	Medication:		CMTRT							

	Provide the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Start Date: [Start Date]	
6.	Ongoing? [Ongoing]	○ YES CMENRTPT= ONGOING CMENTPT= LAST SUBJECT ENCOUNTER ○ NO End Date: ○ 1 ○ 1 ○ 1 ○ CMENDTC
7.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED
8.	Standardized Medicat on Name - Dict onary derived. [hidden] [Standardized Med cat on Name]	CMDECOD
9.	Standardized Med cat on Code - Dictionary derived [hidden] [Standardized Med cat on Code]	CMCODE in SUPPCM

S 7	UDYID				VS=Vital Signs			
C4	C4591001: VITAL SIGNS - TEMP (VITAL TEMP) VSCAT=REACTOGENICITY - UNPLANNED TEMPERATURE							
Vita	al Signs			VSSCAT=SYSTEMIC				
	Date: [Date:]	✓ /	/ VSDTC					
Vita	al Signs Details							
#	Record Identifier:		Temperature	Temperature Unit	Temperature Location:			
2.a	1							
Vita	al Signs Details Entry							
2.1	Record Identifier: [Record Identifier:]							
2.2	Temperature: [Temperature]		SORRES when V	STESTCD =TEMP				
2.3	Unit: [Temperature Unit]	OF VSORRESU when VSTESTCD = TEMP						
2.4	Temperature Location: [Temperature Location:]	ORAL CAVIT EAR RECTUM AXILLA FOREHEAD	VSLOC when V	/STESTCD = TEMP				

STUDYID

ST	UDYID				VS=Vital Signs				
C4	4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS								
	ital Signs								
	Date: [Date:]	v /							
	Weight: [Weight]		VSORRES when V	/STESTCD = WEIGHT					
	Un t: [Weight Unit]	Okg OLB VSO	RRESU when VSTE	STCD = WEIGHT					
	Height: [Height]		VSORRES when V	STESTCD = HEIGHT					
	Un t: [Height Un t]	Orm On VSORRESU when VSTESTCD = HEIGHT							
	Body Mass Index: [Body Mass Index]	VSORRES when VSTESTCD = BMI							
Vita	al Signs Details								
#	Record Identifier:		Temperature	Temperature Unit	Temperature Location:				
7.a	1								
Vita	al Signs Details Entry								
7.1	Record Identifier: [Record Identifier:]		D						
7.2	Temperature: [Temperature]	VSORRES when VSTESTCD = TEMP							
7.3	Unit: [Temperature Unit]	O C OF VSORRESU when VSTESTCD = TEMP							
7.4	Temperature Location: [Temperature Location:]	ORAL CAV EAR RECTUM AXILLA FOREHEAL	ORAL CAVITY EAR VSLOC when VSTESTCD = TEMP RECTUM AXILLA						

STUDYID

VS=Vital Signs

C4	591001: VITAL SIG	NS - BASELIN	E (VITALS BSL) 🔽	SCAT=GENERAL VITAL S	IGNS			
Vita	al Signs							
	Date: [Date:]	V /						
	Weight: [Weight]		VSORRES when VS	STESTCD = WEIGHT				
	Un t: [Weight Unit]		RESU when VSTES	TCD = WEIGHT				
	Height: [Height]		VSORRES when VS	TESTCD = HEIGHT				
	Un t: [Height Un t]	ocm oin VSOR	RESU when VSTES	TCD = HEIGHT				
	Body Mass Index: [Body Mass Index]		/SORRES when VS1	TESTCD = BMI				
Vita	al Signs Details							
#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:
7.a	1						SITTING	
Vit	al Signs Details Entry							
7.1	Record Identifier: [Record Identifier:]		2					
7.2	Temperature: [Temperature]		SORRES when VST	ESTCD = TEMP				
7.3	Unit: [Temperature Unit]	OC F VSOR	RESU when VSTES	TCD = TEMP				
7.4	4 Temperature Location: [Temperature Location:] ORAL CAVITY EAR VSLOC when VSTESTCD = TEMP RECTUM AXILLA FOREHEAD							
7.5	Systol c: [Systolic:]	VSORRES when VSTESTCD = SYSBP						
7.6	Diastol c: [Diastol c:]	VSC	VSORRES when VSTESTCD = DIABP					
7.7	BP Posit on: [BP Position]		SPOS when VSTES	TCD = DIABP, SYSBP				
7.8	Pulse: [Pulse:]	VSO	RRES when VSTES	TCD = PULSE				

VS=Vital Signs

ST	UDYID				VS=Vital Signs				
C4	591001: VITAL SIG	NS - COVI	D (VITALS C	OV) - Repeating Form VSCAT=GENERA	VITAL SIGNS				
#	Date:			Vital Signs Details					
1									
Vita	al Signs								
1 1	Date: [Date:]	v /		/SDTC					
Vita	al Signs Details								
# ✓	Record Identifier:	Systolic:	Diastolic:	Respiratory Rate in respirations/minute	Heart Rate in beats/minute				
2.a	1								
Vit	al Signs Details Entry	·							
2.1	Record Identifier: [Record Identifier:]	O ¹ VS	SPID						
2.2	Systol c: [Systolic:]	VSORRES when VSTESTCD = SYSBP							
2.3	Diastol c: [Diastol c:]		VSORRES when VSTESTCD = DIABP						
2.4	Respiratory Rate in respirations/minute: [Respiratory Rate in respirations/minute]		VSORRES when VSTESTCD = RESP						
2.5	Heart Rate in beats/minute: [Heart Rate in beats/minute]		VSORRES wh	en VSTESTCD = HR					

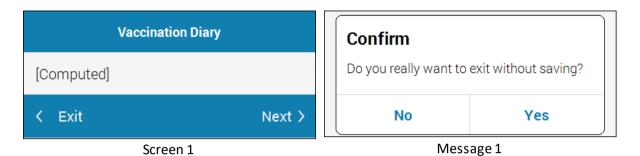
C4591001: VITAL SIGNS (VITALS FUP) VSCAT=GENERAL VITAL SIGNS Vital Signs 1. Date: ✓ / **~** / 4 VSDTC [Date:] Vital Signs Details **Record Identifier:** Temperature **Temperature Unit** Diastolic: **BP** Position Pulse: # **Temperature Location:** Systolic: 2.a 1 SITTING Vital Signs Details Entry 2.1 Record Identifier: [Record Identifier:] 2.2 Temperature: VSORRES when VSTESTCD = TEMP [Temperature] O^F VSORRESU when VSTESTCD = TEMP 2.3 Unit: [Temperature Unit] O ORAL CAVITY VSLOC when VSTESTCD = TEMP 2.4 Temperature Location: [Temperature Location:] O EAR ○ RECTUM ○ AXILLA ○ FOREHEAD VSORRES when VSTESTCD = SYSBP 2.5 Systol c: [Systolic:] 2.6 Diastol c: VSORRES when VSTESTCD = DIABP [Diastol c:] **SITTING** VSPOS when VSTESTCD = DIABP, SYSBP BP Posit on: 2.7 [BP Position] VSORRES when VSTESTCD = PULSE 2.8 Pulse: [Pulse:]

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

22-JUN-2020 Version 2

VSCAT=REACTOGENICITY VSSCAT=SYSTEMIC

3 Form: Vaccination Diary



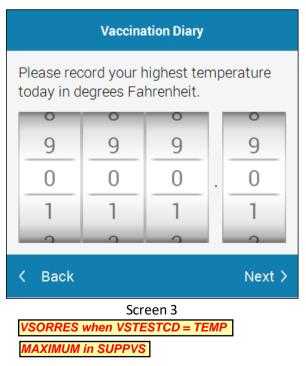
[Computed] Text will display "Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on {1}. You will answer these questions for {2} day(s)."

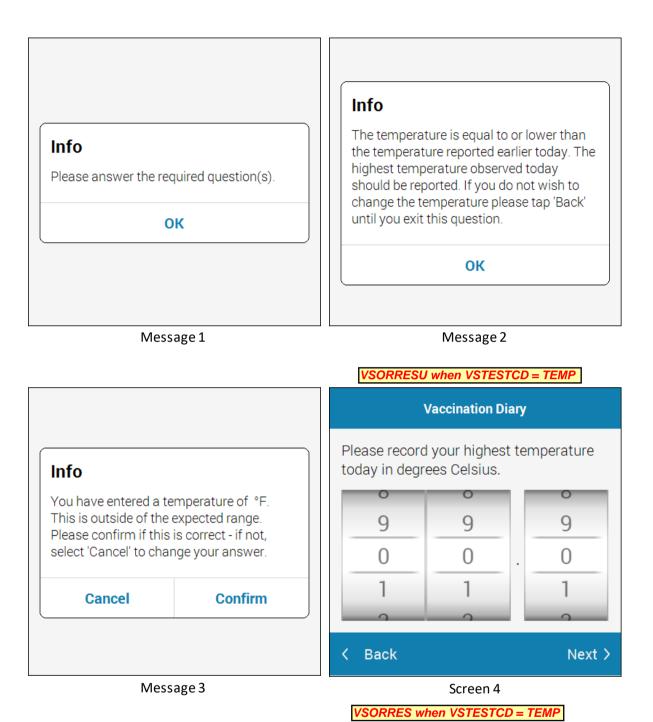
{1} Will display a date

{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).







MAXIMUM in SUPPVS

A-1426-0086 / C4591001-Post-12-July-2020 STUDYID App Subject Facing Screen Report English (USA) enUS FACAT=REACTOGENICITY 22-JUN-2020 Version 2

			Vaco	cination Diary
Info			Please confirm y today:	our highest temperature
You have entered a temperature of °C.			[Computed]	
This is outside of the expected range. Please confirm if this is correct - if not, select 'Cancel' to change your answer.			< Back	Next >
				Screen 5
Cancel Confirm				display the temperature Screen 3 or Screen 4

Message 3

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?
Ves
No
No
No
No
No
No
Next >

Screen 6 FAORRES when FATESTCD = OCCUR and FAOBJ = REDNESS

FASCAT = ADMINISTRATION SITE

A-1426-0086 / C4591001-Post-12-July-2020

App Subject Facing Screen Report English (USA) enUS

22-JUN-2020 Version 2

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.

ОК

Message 2

measuring device for redness.				
0	0			
9	9			
0	0			
1	1			

Vaccination Diary

Please tap on the number from the and the second
If your redness was greater than 21, please select 21.

< Back Next >



Info [Computed] The measurement is equal to or lower than that reported earlier today. The highest measurement observed today should be < Back reported. If you do not wish to change the Screen 8 measurement please tap 'Back' until you exit this question. Screen 7. ОК

Message 2

Vaccination Diary

Please confirm the number from the measuring device for redness:

Next >

[Computed] will display the number selected on

		FA=Findings About	ut Events or Interventions
A-1426-0086 / C4591001-Post-12-July-2020 FASCAT = ADMINISTRATION FAORRES when FATESTCD = FAOBJ = SWELLING	English (I SITE	ing Screen Report JSA) enUS <i>FASCAT = ADMINISTF</i> <i>FAORRES when FATE</i> <i>FAOBJ = SWELLING</i>	22-JUN-2020 Version 2 RATION SITE
Vaccination Dia	гу	Vaccinat	tion Diary
Today, have you had any sv injection site?	velling at the	Please select the nur measuring device for	
Yes	0	0	0
	0	9	9
No	\bigcirc	0	0
< Back	Next >	1	1
	HOAT 7	0	0
Screen 9		If your swelling was please select 21.	greater than 21,
		< Back	Next >



FASCAT = ADMINISTRATION SITE

Vaccination Diary	Vaccination Diary
Please confirm the number from the measuring device for swelling:	Today, have you had any pain at the injection site?
[Computed]	Yes
< Back Next >	No
Screen 11	
[Computed] will display the number selected on Screen 10.	< Back Next >
Screen 10.	Screen 12 FAORRES when FATESTCD = OCCUR and FAOBJ = PAIN AT INJECTION SITE

	FA=Findings About Events or Interventions
	ing Screen Report 22-JUN-2020 USA) enUS Version 2 <i>FASCAT = ADMINISTRATION SITE</i> <i>FAORRES when FATESTCD = SEV and</i> <i>FAOBJ = PAIN AT INJECTION SITE</i>
Vaccination Diary	Vaccination Diary
Pain at the injection site definitions: Mild = Does not interfere with activity	Please indicate whether the pain at the injection site was:
Moderate = Interferes with activity	Mild
Severe = Prevents daily activity	Moderate O
K Back Next >	Severe
Screen 13	
	< Back Next >
	Screen 14

Info Severe = Prevents da		Info The severity is equal to or lower than the severity reported earlier today. The most severe symptom observed today should be
correct tap 'Yes' to go forward or 'No' to change your answer. No Yes		reported. If you do not wish to change the severity please tap 'Back' until you exit this question.
		ОК
Mes	sage 2	Message 4

	FA=Findings About Events or Interventions
	acing Screen Report 22-JUN-2020 a (USA) enUS Version 2 FASCAT = SYSTEMIC FAORRES when FATESTCD = OCCUR and FAOBJ = FATIGUE
Vaccination Diary	Vaccination Diary
Did you go to the ER or were you hospitalized for this reaction?	Today, have you experienced fatigue (tiredness)?
Yes	Yes
No	No
K Back Next >	K Back Next >
Screen 15	Screen 16
Screen 15 FASCAT = SYSTE	Screen 16
	Screen 16 FAORRES when FATESTCD = SEV and
FASCAT = SYSTE	Screen 16 FAORRES when FATESTCD = SEV and FAOBJ = FATIGUE
FASCAT = SYSTE Vaccination Diary Fatigue (tiredness) definitions: Mild = Does not interfere with activity Moderate = Some interference with	Screen 16 FAORRES when FATESTCD = SEV and FAOBJ = FATIGUE Vaccination Diary Please indicate whether the fatigue
FASCAT = SYSTE Vaccination Diary Fatigue (tiredness) definitions: Mild = Does not interfere with activity	Screen 16 FAORRES when FATESTCD = SEV and FAOBJ = FATIGUE Vaccination Diary Please indicate whether the fatigue (tiredness) was:
FASCAT = SYSTE Vaccination Diary Fatigue (tiredness) definitions: Mild = Does not interfere with activity Moderate = Some interference with activity Adderate = Some interference with activity	Screen 16 FAORRES when FATESTCD = SEV and FAOBJ = FATIGUE Vaccination Diary Please indicate whether the fatigue (tiredness) was: Mild O

Screen 18

		FA=Findings About Ever	nts or Interventions
-1426-0086 / 4591001-Post-12-July-202		icing Screen Report (USA) enUS	22-JUN-202 Version
	FASCAT = SYSTEMIC	FAORRES when FATESTO FAOBJ = HOSPITALIZED I (FATIGUE)	
		Vaccinatio	n Diary
Info		Did you go to the ER or hospitalized for this re	•
this is correct tap 'Yes' to	Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or		0
'No' to change your answ	ver.	No	0
No	Yes	< Back	Next >
		Screen	19
Messag ORRES when FATESTCD =	= OCCUR and		
OBJ = HEADACHE		AT = SYSTEMIC	
Vaccination	i Diary	Vaccinatio	n Diary
Today, have you experi	enced headache?	Headache definitions	S:
Yes	0	Mild = Does not interfe	re with activity
		Moderate = Some inter	ference with
No	\bigcirc	activity	
No K Back	○ Next >	Severe = Prevents daily	routine activity

Screen 21

		FA=Findings About	Events or Interventions
A-1426-0086 / C4591001-Post-12-July-2020	1001-Post-12-July-2020 English (USA) enUS		22-JUN-2020 Version 2
FASCAT = SYSTEMIC FAORRES when FATESTCD FAOBJ = HEADACHE	= SEV and	FASCAT = SYSTEMIC FAORRES when FATES FAOBJ = HOSPITALIZE	TCD = OCCUR and
Vaccination Di	ary	Vaccinatio	n Diary
Please indicate whether th was:	e headache	Did you go to the ER of hospitalized for this re	_
Mild	0	Yes	0
Moderate	0	No	0
Severe	0	< Back	Next >
< Back	Next >	Screen	23
K Back Screen 22 FAORRES when FATESTO FAOBJ = VOMITING		Screen	23
Screen 22	CD = OCCUR and		
Screen 22 FAORRES when FATESTO FAOBJ = VOMITING	CD = OCCUR and ary	FASCAT = SYSTEMIC	n Diary
Screen 22 FAORRES when FATESTO FAOBJ = VOMITING Vaccination Di	CD = OCCUR and ary	FASCAT = SYSTEMIC Vaccinatio Vomiting definitions Mild = 1 to 2 times in 2	n Diary : 24 hours
Screen 22 FAORRES when FATESTO FAOBJ = VOMITING Vaccination Di Today, have you experience	CD = OCCUR and ary	FASCAT = SYSTEMIC Vaccinatio Vomiting definitions	n Diary : 24 hours twice in 24 hours
Screen 22 FAORRES when FATESTO FAOBJ = VOMITING Vaccination Di Today, have you experience Yes	CD = OCCUR and ary	FASCAT = SYSTEMIC Vaccinatio Vomiting definitions Mild = 1 to 2 times in 2 Moderate = More than	n Diary : 24 hours twice in 24 hours

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FAORRES when FATESTCD = SEV and FAOBJ = VOMITING	FAS	CAT = SYSTEMIC	
Vaccination Diary			
Please indicate whether the vomiting was:		Info	
Mild	\bigcirc	Severe = Requires intravenous hydration. If this is correct tap 'Yes' to go forward or	
Moderate	\bigcirc	'No' to change your an	swer.
Severe	0	No	Yes
K Back Ne	xt >		

Screen 26

Message 2

Vaccination Diary		Vaccinat	ion Diary
Did you go to the ER or were you hospitalized for this reaction?		Today, have you exp	erienced diarrhea?
	0	Yes	\bigcirc
Yes	0	No	0
No	0		
< Back	Next >	< Back	Next >
Screen 27			en 28
FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR VOMITING		FAORRES when FATE FAOBJ = DIARRHEA FASCAT = S	
		FASCAT = S	YSTEMIC

		FA=Findings About Events of	
A-1426-0086 / C4591001-Post-12-July-24	•••••	cing Screen Report (USA) enUS FASCAT = SYSTEMIC	22-JUN-2020 Version 2
		FAORRES when FATESTCD = FAOBJ = DIARRHEA	SEV and
Vaccinati	on Diary	Vaccination Di	ary
Diarrhea definitions	5:	Please indicate whether th	ne diarrhea was:
Mild = 2 to 3 loose sto	ools in 24 hours	Mild	0
Moderate = 4 to 5 loo hours	se stools in 24	Moderate	0
Severe = 6 or more lo hours	ose stools in 24	Severe	0
< Back	Next >	< Back	Next >
Scree	n 29	Screen 30	
	FASCAT = SYSTEMIC	FAORRES when FATESTCD = 0 FAOBJ = HOSPITALIZED FOR L	
		Vaccination Di	ary
Info		Did you go to the ER or we hospitalized for this react	
Severe = 6 or more loo hours. If this is correct forward or 'No' to char	tap 'Yes' to go	Yes	0
		No	\bigcirc
No	Yes	< Back	Next >
		Screen 31	
Messa	age 2		

22-JUN-2020 Version 2

FAORRES when FATESTCD = OCCL FAOBJ = CHILLS	IR and	FASCAT = SYSTEMIC	
Vaccination Diary		Vaccinati	on Diary
Today, have you experienced chills?		Chills definitions: Mild = Does not interf	ere with activity
Yes	0	Moderate = Some inte activity	2
K Back N	ext >	Severe = Prevents dai	ly routine activity Next >
Screen 32 FASCAT = SYSTEMIC FAORRES when FATESTCD = SEV FAOBJ = CHILLS	/ and	Scree	
Vaccination Diary		Vaccinati	on Diary
Please indicate whether the chills we	re:	Did you go to the ER of hospitalized for this r	-
Mild	\bigcirc	Yes	0
Moderate	\bigcirc	No	
Severe	\bigcirc		0
	⊖ ext >	< Back	Next >

FASCAT = SYSTEMIC

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FAORRES when FATESTCD = OCCUR and FAOBJ = MUSCLE PAIN	ASCAT = SYSTEMIC
Vaccination Diary	Vaccination Diary
Today, have you had new or worsened muscle pain (other than at the injection site)?	Muscle pain definitions: Mild = No interference with activity
Yes	Moderate = Some interference with activity
No	Severe = Prevents daily routine activity
< Back Next >	< Back Next > Screen 37
Screen 36	FASCAT = SYSTEMIC FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR MUSCLE PAIN
Vaccination Diary	Vaccination Diary
Please indicate whether the new or worsened muscle pain was:	Did you go to the ER or were you hospitalized for this reaction?
Mild	Yes
Moderate O	No
Severe O	< Back Next >

Next >

Screen 39

Back

Screen 38 FAORRES when FATESTCD = SEV and FAOBJ = MUSCLE PAIN

FASCAT = SYSTEMIC

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

Vaccination Diary		Vaccination Diary
Today, have you had any new or worsened joint pain?		Joint pain definitions: Mild = No interference with activity
Yes	\bigcirc	Moderate = Some interference with activity
No	\bigcirc	Severe = Prevents daily routine activity
< Back	Next >	< Back Next >

Screen 40

Screen 41

Vaccination Diary		Vaccination	Diary
Please indicate whether the new of worsened joint pain was:	r	Did you go to the ER or hospitalized for this read	
Mild	\bigcirc	Yes	\bigcirc
Moderate	\bigcirc	No	\bigcirc
Severe	0	< Back	Next >
< Back	Next >	Screen 4	CD = OCCUR and
Screen 42 FAORRES when FATESTCD = SE FAOBJ = JOINT PAIN	/ and	FAOBJ = HOSPITALIZED FASCAT = SYST	
FASCAT = SYSTEMIC			

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FAORRES when FATESTCD = MEDT FAOBJ = MEDICATIONS	FVPN and	FASCAT = MEDICATIONS	S GIVEN
Vaccination Diary			
Today, have you taken any medica treat fever or pain?	ition to	Info	
Yes	0	You have reported ta treat fever or pain. Is	king medication to your answer correct?
No	0	No	Yes
< Back	Next >		
6			

Screen 44

Message 2

Vaccination Diary	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 '.	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 today, please select ' Update Symptoms ' from the main menu to update your symptoms.	If your symptoms worsen again today, please select ' Update Symptoms ' from the main menu to update your	
[Computed]	symptoms. [Computed]	
Save		
	Save	
< Back		
< Back Screen 45	Save	
Screen 45		
	< Back	
Screen 45 [Computed] will display "Please continue to fill	< Back Screen 46	
Screen 45 [Computed] will display "Please continue to fill out your diary for the next {1} day(s)."	K Back Screen 46 [Computed] will display "Please continue to fill	

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