### 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
	PHYSICAL EXAMINATION
	VITAL SIGNS
	CENTRAL LAB SAMPLE COLLECTION
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
V6_WEEK2	_POSTVAX2_S
	DATE OF VISIT
	VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
	PHYSICALEXAMINATION
	VITAL SIGNS
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
	VACCINATION DIARY
V7_MONTH	11_S
	DATE OF VISIT
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
V4_WEEK3_	
	DATE OF VISIT
	VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
	PHYSICALEXAMINATION
	VITALSIGNS
	LAB URINALYSIS - PREGNANCY TEST
	ELECTRONIC SAMPLE TRACKING - NASAL SWAB
	MICROBIOLOGY SPECIMEN (SWAB SITE)
	CENTRAL LAB SAMPLE COLLECTION
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
	VACCINATION
	VACCINATION DIARY
V5_WEEK1_	_POSTVAX2_S_R
	DATE OF VISIT
	PHYSICAL EXAMINATION
	VITAL SIGNS
	CENTRAL LAB SAMPLE COLLECTION
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
V6_WEEK2	
	DATE OF VISIT
	VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
	PHYSICAL EXAMINATION
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
V7_MON	
	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_CO	IVID_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
рот со	IVID CONVA
	DATE OF VISIT - ILLNESS CONVALESCENT
	ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
	VACCINATION DIARY
рот со	VID_REPEAT_SWAB
-	DATE OF VISIT - REPEAT SWAB
	ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
	VACCINATION DIARY
LOGS	
	ADVERSE EVENT REPORT
	MEDICATION ERROR
	CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
	CONCOMITANT MEDICATIONS - PROHIBITED
	RADIATION TREATMENT
	TRANSFUSIONS
UNPL	
	DATEOFVISIT
	CONTACT OUTCOME - UNPLANNED
	VITAL SIGNS - TEMP
	UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT
UNPLAN	INED_VACCINATION
	DATE OF VISIT

```
VITAL SIGNS - TEMP
        LAB URINALYSIS - PREGNANCY TEST
        VACCINATION
        CONTACT OUTCOME - MONTH 1
        CONTACT OUTCOME - MONTH 6
V201 SURVEIL CONSENT
        DATE OF VISIT
        INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
        ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
V202 SURVEIL SWAB
        DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
        ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
DISP
        TREATMENT UNBLINDED
        WITHDRAWAL OF CONSENT
        DEATH DETAILS CODED
END_OF_TRT
        DISPOSITION – TREATMENT
REVAX_CONTACT
        DATE OF VISIT
V101_VAX3
        DATE OF VISIT
        INFORMED CONSENT - FURTHER VACCINATION
        INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION(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
```

**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

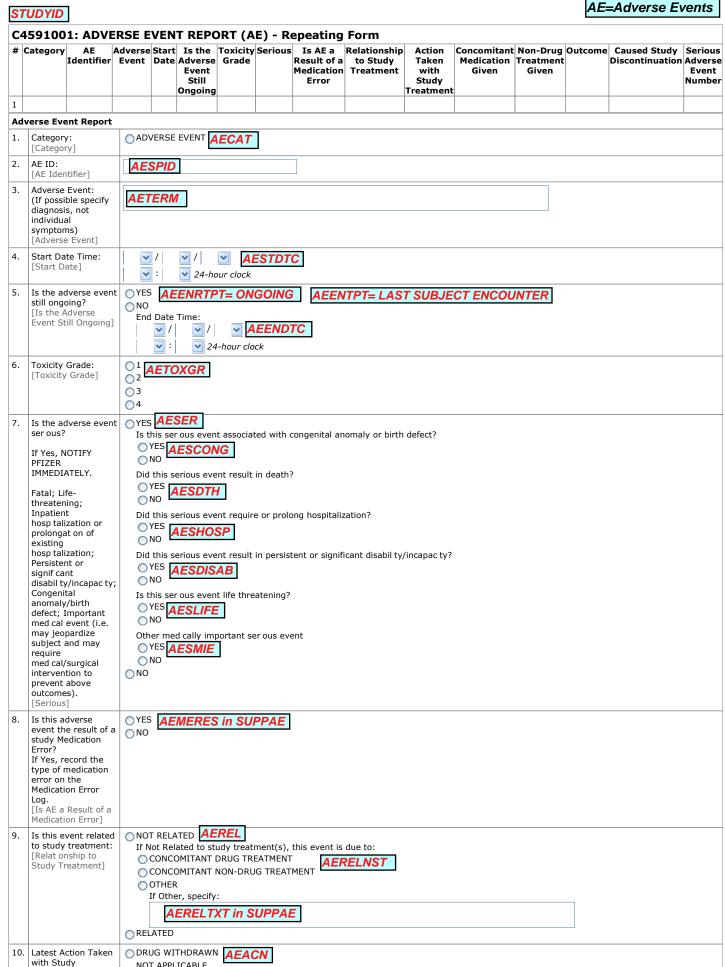
## REACTOGENICITY DIARY

## DS=DISPOSITION

MAIN INFORMED CONSENT DISPOSITION - SCREENING RANDOMIZATION

TREATMENT UNBLINDED	
WITHDRAWAL OF CONSENT	
DISPOSITION - TREATMENT	
DISPOSITION - FOLLOW-UP	
<b>INFORMED CONSENT - FURTHER VACCINATION</b>	
<b>DISPOSITION - SCREENING FOR FURTHER VACCINATION</b>	
INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE	
EC=EXPOSURE AS COLLECTED	
VACCINATION	
VACCINATION	
EX=EXPOSURE	
VACCINATION	
VACCINATION	
FA=FINDINGS ABOUT EVENTS OR INTERVENTIONS	
VACCINATION DIARY	
<b>VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DAT</b>	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	
<b>ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION</b>	
<b>ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY</b>	
LB=LABORATORY TEST RESULTS	
<b>CENTRAL LAB SAMPLE COLLECTION - BASELINE</b>	
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**



090177e196b6fd5d\Final\Final On: 06-Apr-2021 21:26 (GMT)

NOT APPLICABLE

	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]	<ul> <li>FATAL</li> <li>NOT RECOVERED/NOT RESOLVED</li> <li>RECOVERED/RESOLVED</li> <li>RECOVERED/RESOLVED WITH SEQUELAE</li> <li>RECOVERING/RESOLVING</li> <li>UNKNOWN</li> </ul>
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

|--|

La	ooratory Data Hematology						
1.	ab Panel: Category for Lab Test]						
2.	Laboratory Name and Address [Vendor Name (DERIVED)]	LBNA	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_F	PX4722 <b>LBTEST</b>				
5.3	Result: [Result:]	LBOF	RRES				
5.4	Not Done: [hidden] [Not Done:]		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	ohort Selection						
DC	ONOT 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]	<ul> <li>STAGE 1 SENTINEL COHORTS</li> <li>STAGE 1 NONSENTINEL COHORTS</li> <li>STAGE 2 COHORTS</li> <li>STAGE 3 COHORTS</li> </ul>					

ST	STUDYID         C4591001: CONCOMITANT MEDIC         #       Sponsor-Defined Identifier       Category for Medication         1				C	w=con	icomitant i	vieaica	itions
C4	591001: CONCO	MITANT MEDICA	TIONS - BASELINE (CONI	MED BSL) - R	epeating Fo	rm			
-	Sponsor-Defined	Category for	Concomitant Medications Pre- specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date
1									
Cor	ncomitant Medications								
1.			CMSPID						
2.		n]	O GENERAL CONCOMITANT MEDI	CATIONS CMCA	Τ				
3.	Concomitant Medication [Concom tant Medicatio		○ NO NOT SUBMITTED						
4.	Med cation:		CMTRT						
		ere applicable). Where vn, enter the full trade o de clarifying information e.g., Ingredient(s),	r						
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 or		CMDECOD						
12.	Standardized Med cat or derived [hidden] [Standardized Med cat of		CMCOL	DE 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

S	τι	JD	Y	D	
_					_

C	C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)						
Co	Contact Outcome						
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	○ CONTACT OUTCOME NOT SUBMITTED					
2.	Contact Type: [Type of Contact/Visit]	CLINIC VISIT SVREFID					
3.	Was contact made? [Was Contact Made]	OYES       NOT SUBMITTED         Date of Contact:       SVENDTC SVENDTC when UNPLANNED VISITS         NO       If No, why?         NOT SUBMITTED					
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	SV=Subject Visit				
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	C4591001: CONTACT OUTCOME - UNPLANNED (CONTACT UV)				
Co	ontact Outcome				
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	O 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         YES       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			

<b>S</b> 1	<b>UDYID</b>		MB=Microbiology Specimen	l=Device Identi	fiers CC	-Comments
C	4591001: MICROBIOLOGY SPECIMEN (COV19 SITE) - Repeating Form MBCAT=CONFIRMATION OF INFECTION					
#	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]	SERUM BLOOD MBSPEC PLASMA				
3.	Assay Code and Description: [Assay Code and Description]	O 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]	POSITIVE     MBORRES when MBTESTCD = SARSCOV2     INDETERMINATE				
6.	Comments/Findings/Details: [Comments:]	COVAL when RDO	MAIN = MB			

			_						-
S	TUDYID		Л	/IB=Microbiology Sp	pecimen	DI=Dev	ice la	entifiers	CO=Comments
С	4591001: MI	CROBIOLO	GY SPECIMEN (COVI	D TEST) - Repeating	Form M	BCAT=CC	ONFIR	MATION O	F INFECTION
#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name		Comments:	Trade Name Other, Specify
1									
м	icrobiology Speci	men							
1.	Actual Date of Col [Date of Collection			BDTC					
2.	Specimen Type: [Specimen Type]		SWABBED MATERIAL	S MBSPEC					
3.	Specimen Collecti [Specimen Collect								
4.	Assay Code and D [Assay Code and I		SEVERE ACUTE RESP SYN	DROME CORONAVIRUS 2	BTEST				
5.	Device Type: [Device Type]		SARS-COV-2 DIAGNOSTIC	TEST <b>DIVAL when DIP</b>	ARMCD =	DEVTYP	E		
6.	Trade Name: [Trade Name]		DIVAL when D	IPARMCD = TRADEN	AM				
7.	Test Result: [Result]								
8.	Comments/Finding [Comments:]	gs/Details:	COVAL when RDO	OMAIN = MB					
9.	Trade Name Othe		SUPPMB in TRADE	ОТН					

Anno	tated Study Book - C4591001			
STL	IDYID			DD=Death Details
		LS CODED (DEATH DTL)	TAILS CODED	
	h Details			
0	ate of Collect on / Notification Death: Date of Collect on / Notif cat on Death]			
		Cause of Death Status	Cause of D	eath
2.				
	e of Death Entry			
2.1	Cause of Death Status: [Cause of Death Status]	OPRIMARY CAUSE OF DEATH SECONDARY 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		<u>م</u>
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		
.9	High Level Term Code [hidden] [High Level Term Code]	NOT SUBMITTED		
.10	High Level Group Term <i>[hidden]</i> [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		]

NOT SUBMITTED

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

#### C4591001: DEMOGRAPHY (DEMOG)

De	Demography					
1.	Subject ID [Subject ID]	SUBJID				
2.	Birth Date: [Birth Date]					
3.	Sex: [Sex]	O FEMALE SEX				
4.	Ethnicity: [Ethnicity]	<ul> <li>HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</li> <li>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</li> <li>NOT REPORTED</li> </ul>				
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]	OJAPANESE OTHER RACIALD in SUPPDM				

S	TUDYID	nked to related AE record via RELREC DS=Disposition
C	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]	O FOLLOW-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	<b>TUDYID</b>	nked to related AE record via RELREC DS=Disposition				
С	4591001: DISPOSITION - SCREENING (DIS	P SCR) DSCAT = DISPOSITION EVENT				
Di	Disposition - 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	C4591001: 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]

0

S	STUDYID SV=Subject Visits					
С	C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)					
Da	Date of Visit					
1.	Date of Visit	✓ /	<b>~</b> /	SVSTDTC		

2.	[Visit Error]	OFKOMEOUS VISIT NOT SUBMITTED
С	VID-19 Illness Visit	
	COVID-19 Illness Visit: [COVID-19 Illness Vis t]	VISIT

#### 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]	O ERRONEOUS VISIT NOT SUBMITTED		
С	COVID-19 Repeat Swab			
3.	COVID-19 Repeat Swab: [COVID-19 Repeat Swab]	VISIT		

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

C	C4591001: HIV STATUS (HIV) NOT SUBMITTED		
HI	HIV Status		
	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: OCLINICAL CHEMISTRY LBCAT						
2.	Laboratory Name and Address     [Vendor Name]						
3.	Collection Date: [Collect on Date:]						
4.	Specimen Type: [Specimen Type]	BLOOD <b>LBSPEC</b>					
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:]	O HIV RNA (Ultrasens tive)					
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

-	UDYID				igs About Events or Intervention	
C4	591001: HEALTH CA	ARE UTILIZATION (HLTHCARE)HOCAT=H	EALTHCA	ARE	FACAT=HEALTHCARE	
	Ith Care Utilization	UTILIZATIO	IN ASSES	SSMENT	UTILIZATION	
	Evaluation Interval: [hidden] [Evaluation Interval]			EVINTX	FAEVINTX	
	Disease Name: <i>[hidden]</i> [Disease Name]	© RESPIRATORY ILLNESS HCUIDIS in SUPPHO				
Hea	Ith Care Utilization					
# ✔	Pre-Specified	Type of Practitioner		Occurrence of Visits or Contacts		
3.a	YES	SPECIALIST				
3.b	YES	EMERGENCY ROOM				
3.c	YES	PRIMARY CARE PHYSICIAN				
3.d	YES	URGENT CARE				
3.e	YES	TELEPHONE CONSULTATION				
3.f	YES	OTHER				
Hea	alth Care Utilization Entry					
3.1	Pre-Specified: [hidden] [Pre-Specified]	O YES HOPRESP				
3.2	Physician or Healthcare Professional: [Type of Practitioner]	<ul> <li>SPECIALIST</li> <li>EMERGENCY ROOM</li> <li>PRIMARY CARE PHYSICIAN</li> <li>URGENT CARE</li> <li>TELEPHONE CONSULTATION</li> <li>OTHER</li> </ul>				
3.3	Occurrence of Visits or Contacts: [Occurrence of Vis ts or Contacts]	VES HOOCCUR Number of Vis ts or Contacts: FAORRES when FATESTCD=NU	IMBER			
Hea	Ith Care Utilization Other					
	Other Type of Pract tioner Specify: [Other Type of Pract t oner Specify]	HOTERM				
lea	Ith Care Utilization					
	Has the subject been nospitalized due to potential COVID-19 illness? [Been Hospitalized]	VES HCUHSP in SUPPHO Has the subject been in intensive care due to poten VES HCUICU in SUPPHO NO	ial COVID-19	9 illness?		

## HO=Healthcare Encounters

C	C4591001: HOSPITALIZATION 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	JDYID	CE=Clinical Events
		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]	VES Respiratory Illness Diagnosis:          CETERM         Date of Diagnosis:         ✓ /       ✓ CEDTC         NO       NOT SUBMITTED
3.	Toxicity Grade: [Toxicity Grade]	0 1 CETOXGR 2 3 4 5
4.	Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED
5.	Lowest Level Term [hidden] [Lowest Level Term]	CELLT
6.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	CELLTCD
7.	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	CEBDSYCD CESOCCD

ST	JDYID		CE=Clinical Events
C4	591001: ILLNESS DET	AILS - 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]	<ul> <li>SIGNIFICANT ACUTE RENAL DYSFUNCTION</li> <li>SIGNIFICANT ACUTE HEPATIC DYSFUNCTION</li> <li>SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION</li> </ul>	
3.	Was a diagnosis obtained? [Diagnosis Obtained]	YES Diagnosis:     CETERM     Start Date:	NCOUNTER
4.	Toxicity Grade: [Toxicity Grade]	01 2 3 CETOXGR 04 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 Code]	CEBDSYCD CESOCCD	

ST	UDYID				CE=Clinical Ever
C4	591001: ILLNESS DET	AILS - SEVE	RE (ILL SEVERE) - Repeating Forr	m	
#	Category of Clinical E	vent:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade
1					
Illn	ness Details				
1.	Category of Clinical Event: [Category of Clin cal Event:]	⊖SEVERE COV	ID-19 ILLNESS CECAT		
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	SIGNIFICAN	T ACUTE RENAL DYSFUNCTION T ACUTE HEPATIC DYSFUNCTION CESCAT T ACUTE NEUROLOGIC DYSFUNCTION		
3.	Was a diagnosis obtained? [Diagnosis Obtained]	VES Diagnosis: CETER Start Date: VES NO End Date	CESTDTC CENRTPT= ONGOING/BEFORE CEL	ENTPT= LAST SUBJECT E	NCOUNTER

SUBMITTED

CELLTCD

CEPTCD

CEHLTCD

CEHLGTCD

CESOC

CEBDSYCD

CETOXGR

NOT SUBMITTED

O NO

01

O2 O3

04 05

CELLT

CEDECOD

CEHLT

CEHLGT

CEBODSYS

4.

5.

6.

7.

8.

9.

10.

11.

13.

14.

15.

Toxicity Grade:

[Toxicity Grade]

Comparison Term: [hidden] [Comparison Term]

Lowest Level Term [hidden]

[Lowest Level Term]

[hidden]

[hidden]

[hidden]

[hidden]

Code]

Lowest Level Term Code

[Lowest Level Term Code] D ctionary Derived Term

[D ctionary Derived Term] Preferred Term Code [hidden] [Preferred Term Code]

High Level Term [hidden]

[High Level Term Code] 12. High Level Group Term

[hidden] [High Level Group Term]

High Level Group Term Code

Primary System Organ Class

[High Level Group Term Code]

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

High Level Term Code [hidden]

[High Level Term]

Page 42 of 131

CESOCCD

# MO=Morphology

S	TUDYID			MO=Morphology		
C	4591001: IMAGING (IMAG	GING) - Repeating Form MOCAT		F 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]	HEAD MOLOC HEAD OTHER If other, specify: LOCOTH in SUPPMC	2			
3.	[Imaging Method]	CT SCAN X-RAY ULTRASOUND MRI OTHER If other, specify: METHOTH in SUPPMO				
4.	[Overall Assessment]	ABNORMAL MOORRES If abnormal, specify findings: ASPECIFY IN SUPPMO INDETERMINATE NORMAL MOORRES UNKNOWN NOT EVALUABLE				

## IE=Inclusion/Exclusion Criteria Not Met

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	Participants who are willing and able to comply with all scheduled visits, vaccination plan, aboratory tests, lifestyle considerations, and other study procedures			
1.c	3	Healthy participants who are determined by medical history, physical examination, and IN03A00 clinical judgment of the investigator to be eligible for inclusion in the study			
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol			
Inclusion Criteria Entry IECAT = INCLUSION					
1.1	Inclusion Number: [Inclusion Number]				

		04
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)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

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	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	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	IECAT = EXCLUSION	
	Exclusion Number: [Exclusion Number]		
2.2 Cr terion Description: [Criter on Descript on]			
2.3	Cr terion met? [Criter on met?]	• YES <b>IEORRES</b> Describe details if relevant	

		IE=Inclusion/Exclusion Criteria N	lot 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	<b>/EXCLUSION CRITERIA</b>	(IN EX STG3)	
C4551001. INCLUSION	/ EXCLOSION CITIENTA	(111 EX 5105)	

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 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		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]	01 22 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
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 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?]	VES IEORRES Describe details if relevant IEDESC in SUPPIE		
2.4	Cr terion ID: (For Pfi	zer use		

only) [Criter on ID: (For Pfizer use only)] IE=Inclusion/Exclusion Criteria Not Met

Page 47 of 131

#### IE=Inclusion/Exclusion Criteria Not Met

C4591001 TNCLUSTON	/EXCLUSION CRITERIA	(IN FX STG3)
C4331001. INCLOSION	/ LACEUSIUN CRITERIA	

Inc	Inclusion Criteria			
#	Inclusion Number	Criterion Description	<b>Criterion met?</b>	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
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 <b>IESPID</b> 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     IN04000

-	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	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

Page 49 of 131

**Exclusion Criteria Met Entry** 

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

## STU

2.

ST	UDYID		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	Description of Inclusion Cr terion Not Met [Criter on Descript on]	IETEST when IEORRES=N	
		Criterion Description	
2			

✓ IETEST when IEORRES=Y

## C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

Incl	clusion Criteria					
#	Inclusion Number		Criterion Description	<b>Criterion met?</b>	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, ests, 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		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	nclusion Criteria Entry IECAT = INCLUSION					
1.1 Inclusion Number:						

	[Inclusion Number]	2 <b>IESPID</b> 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
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

Excl	xclusion 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 with known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00			
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 Entr	, 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					





IE=Inclusion/Exclusion Criteria Not Met

#### IE=Inclusion/Exclusion Criteria Not Met

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

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       1		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	nclusion Criteria Entry IECAT = INCLUSION				

1.1	Inclusion Number: [Inclusion Number]	0 1 0 2 1 1 1 1 1 2 1 1 2 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1	
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)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>	

-	lusion Criteria	Culturing Description	Cuiterian metal Cuiterian TD. (Ean Dfi		
#	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 with 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 ${\sf c}$ 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	Exclusion 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 SUPPIE

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

#### IE=Inclusion/Exclusion Criteria Not Met

C4	591001: INCL	USION/I	EXCLUSION CRITERIA (INC EXC NS)		
Stuc	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 IESPID 0 3 0 4		
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)]		<ul> <li>IN01A00</li> <li>IN02A00 <i>IETESTCD</i></li> <li>IN03A00</li> <li>IN04A00</li> </ul>		
Eve	volusion Criteria				

-	lusion 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	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
	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 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
		<sup>◯</sup> 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	lusion Criteria	usion 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			
		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			
Inc	lusion Criteria Entr	y IECAT = INCLUSION				

1.1	Inclusion Number: [Inclusion Number]	0 1 2 <b>IESPID</b> 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)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

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	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		

# IE=Inclusion/Exclusion Criteria Not Met

		(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	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:	

		04 04
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)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

#	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
			+

## IE=Inclusion/Exclusion Criteria Not Met

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	
2.4	Cr terion ID: (For Pfi only) [Criter on ID: (For Pr only)]		

#### C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

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

Inc	lusion Criteria		Iclusion Criteria			
#	Inclusion Number	Criterion Description	<b>Criterion met?</b>	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 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		
Inc	Inclusion Criteria Entry IECAT = INCLUSION					
1.1	Inclusion Number:					

1.1	Inclusion Number:	01	_
	[Inclucion Number]	-	IE

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)]	<ul> <li>IN01A00</li> <li>IN02A00 <i>IETESTCD</i></li> <li>IN03A00</li> </ul>

O IN04A00

Excl	xclusion 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 (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 with 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	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		

## IE=Inclusion/Exclusion Criteria Not Met

		(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	0A01
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		1A01
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	I591001: CASEBOOK SIGNATURE FORM (INVSIG) NOT SUBMITTED							
Casebook Signature Form								
1.	Casebook Signature [Casebook Signature]	Click Here to Enable						

<u>ST</u>	UDYID	LB=Laboratory Test	Results MB=Microbiology Specimen				
<b>C4</b>	591001: CENTRAL LAB SAMPLE	COLLECTION (LAB)					
Cen	tral Lab Sample Collection						
	Collection Date: [Collect on Date:]						
	Specimen Type: Specimen Type]	OBLOOD LBSPEC MBSPEC	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]	HEMATOLOGY     CLINICAL CHEMISTRY     LBCAT     MBCAT					
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] OYES [NO NO N							

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

# LB=Laboratory Test Results

<b>ST</b>	<b>STUDYID</b> LB=Laboratory Test Results											
C4	C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form											
#	Category for Lab Test	Vendor Name	Collection Da	te:	Specimen 1	Гуре	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	st:	Result:	Not Done:	Lab	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 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 5.1 Sponsor ID: 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

LBORNRHI

LBORRESU

Un t 🗸

<b>S</b> 7	TUDYID				LB=	Laboratory	Test Results	
C4	591001: LOCAL LABORATOR	RY DATA -	· REPEATING Hemato	logy (LAB HEM) -	Repeating Fo	orm		
#	Category for Lab Test		dor Name (DERIVED)	Collection Date	1	men Type	Lab Result	
1								
Lat	ooratory Data Hematology							
	Lab Panel: [Category for Lab Test]	OHE	EMATOLOGY <b>LBCAT</b>					
	Laboratory Name and Address [Vendor Name (DERIVED)]	LB	<b>BNAM</b>					
	Collection Date: [Collect on Date:]							
	Specimen Type: [Specimen Type]	OBL	OOD LBSPEC					
Lat	Result							
# ✓	Sponsor-Defined Identifie	er	Test:	Result:	Not Done:	Lab No	rmal Range	
5.a			Hemoglobin_PX1					
5.b			Hematocrit_PX2					
5.c			Erythrocytes_PX3					
5.d			Platelets_PX5					
5.e			Leukocytes_PX7					
5.f			Neutrophils_PX608					
5.g			Eosinophils_PX609					
5.h			Monocytes_PX612					
5.i			Basophils_PX610					
5.j			Lymphocytes_PX611					
Lał	o Result Entry							
5.1	Sponsor ID: [Sponsor-Defined Identifier]		LBSPID					
5.2	Test: [Test:]		✓ LBTEST					
5.3	Result: [Result:]		BORRES					
5.4	Not Done: [Not Done:]	01	NOT DONE LBSTAT					
5.5	LNMT [Lab Normal Range]	Low Higi Un t	LBORNRLO h LBORNRHI					

#### LB=Laboratory Test Results

C4	591001: LAB URINALYSIS - PREG	INANCY	TEST (	LAB PREG)					
La	b Urinalysis								
1.	Lab Panel: [Category for Lab Test]	OURINAL	YSIS LB	CAT					
2.	Lab Sub-Panel: [Subcategory for Lab Test]	OPREGNANCY LBSCAT							
3.	Collection Date: [Collect on Date:]	<b>v</b> /	✓ /		]				
4.	Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]	LBNAM							
5.	Specimen Type: [Specimen Type]	OURINE	LBSPE	C					
La	b Result								
#	Sponsor-Defined Identifier				Test:		Result:	N	ot Done:
6.a	1		Chor ogonadotropin Beta_PX113						
La	b Result Entry								
6.1	Sponsor ID: [Sponsor-Defined Identifier]			LBSPID					
6.2	Pest: [Test:]	Chor ogonadotropin Beta_PX113							
6.3	Result:	NEGATIVE LBORRES POSITIVE							
6.4	Not Done: [Not Done:]	NOT DONE LBSTAT							

			1	N ERROR (MED							
	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	Serious Adverse Eve Number	
1											
Ме 1.	dication I										
1.	[Categor		0.		AECAT						
2.	of Medic	on Error (Type ation Error): : on Error]		ETERM							
3.	error, re incorrect number dispense to the su	container	ן [ו	A	EIPKGID in S	SUPPAE					
4.	Start Da [Start Da			✓ / ✓ / ✓	AESTDTC						
5.	still ongo	ned cat on erro	. ŏ		ONGOING		AST SUBJEC	CT ENCOUNTER	]		
6.	with Stu [Study M	atest Action Taken ith Study Treatment: Study Medication rors Act on]									
7.	Med cation [Concorr	oncomitant on given? 1 tant on Given]	-	O YES NO AECONTRT AECMGIV in SUPPAE							
8.		on-Drug nt given? ug Treatment	-	O YES NO AECONTRT AENDGIV in SUPPAE							
9.	cause th discontin study? [Caused	D d the Medication Error cause the subject to be discontinued from the study? [Caused Study Discontinuat on]									
10.	error ass any adve [Med cat	medication sociated with erse events? on Error ed With AE]	А А А А	AE ID: AE ID: AE ID: AE ID: AE ID: AE ID:		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 Us Adverse Even	e   - <mark>/</mark>	AEREFID							
12.	Compari [hidden]	son Term		OT SUBMITTED	]						
13.	[hidden]	evel Term		ELLT							
14.	Code [hi	evel Term dden] Level Term		AEL	LTCD						
15.	Term [hi	ry-Derived idden] ary-Derived	A	EDECOD							

		AE=Adverse Events
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

MH=Medical History

	Line/MH Number	Medical History Term Start Date				Ongoing		
1.								
Medi	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]	MHTER	RM					
1.3	Start Date: [Start Date]	<b>v</b> /						
1.4	Ongoing: [Ongoing]	ONO End Date	MHENRTPT= ONGOING/BEFORE       MHENTPT= LAST SUBJECT ENCOUNTER         NO       End Date:         Image: The second se					
1.5	Comparison Term [hidden] [Comparison Term]	NOT SL	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	3					
1.11	High Level Term Code [hidden] [High Level Term Code]		MHHLTCD					
1.12	High Level Group Term [hidden] [High Level Group Term]	MHHLG	Τ					
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 MHSC	CCD				

# LB=Laboratory Test Results C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form LBCAT= OXYGENATION PARAMETERS # Date Time of Assessment Arterial Blood Gases Pa02 Fi02 (Fraction of Inhaled Oxygen) 1 LBSCAT= BLOOD CHEMISTRY 0xygenation Parameters Oxygenation Parameters

#	Date Time of Assessme	ent	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)
1				LBSCAT= BLOOD CHEMISTRY
0	cygenation Parameters			
1.	Date Time of Assessment: [Date Time of Assessment]		✓ / ▼ LBDTC ✓ 24-hour clock	
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	LB	ORRES when LBTESTCD = PO2	
3.	FiO2 (Fract on of Inhaled Oxygen): [FiO2 (Fraction of Inhaled Oxygen)]	LL	BORRES when LBTESTCD = FIO2	

PE=Physical Examination

ST	UDYID	PE	=Physical Examination
C4	591001: PHYSICAL EX	AMINATION (PHYS EXAM) PECAT=PHYSICAL EXAMINATION	
	sical Examination		
	Exam Date: [Exam Date]		
Phy	sical 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	У	
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 Advers Are there clinically signif cant findings? YES PECLSIG in SUPPPE NO NOT DONE PESTAT	e Event CRF as appropriate).

S	TUDYID	IS=Immunogenicity Specimen Assessment CO=Comments
C	4591001: ELECTRONIC	SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19)
Ele	ectronic 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:         ↓       ↓
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	iquot Entry	
Ple	ease enter barcode for each aliquo	t.
5.	Sample ID [Sample ID]	NOT SUBMITTED

### CM=Concomitant Medications

ST	UDYID					CN	1=Concom	itant l	Medic	ations
C4	591001: CONCO	OMITANT MED	ICATIONS - PROHIBITE	D (PROHIB C	M) - Repeat	ting Fo	rm			
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre- specified	- Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing
1					· ·					
Cor	ncomitant Medication	is								
1.	What is the medicatio [Sponsor-Defined Ide		CMSPID							
2.	Category: [Category for Medicat	ion]	CONCOMITANT IMMUNC CORTICOSTEROIDS	SUPPRESSIVE THE	RAPY					
3.	Concomitant Medicati [Concom tant Medicat		<sup>ONO</sup> NOT SUBMITT	ED						
4.	Med cation:		CMTRT							
	Prov de the complete (including salt form, v generic name is unkn proprietary name. Inc in the Med cat on text route, use, formulatio [Name of Medication]	where applicable). W own, enter the full tr clude clarifying inforr (e.g., Ingredient(s) n).	here rade or nation							
5.	Dose: [Dose Description]		CMDOSE CMDO	STXT						
6.	Dose Unit: [Dose Unit]									
7.	Dose Frequency: [Dose Frequency]									
8.	Route: [Route]									
9.	Start Date: [Start Date]			CMSTDTC						
10.	Ongoing? [Ongoing]		ONO End Date:		MENTPT= LA	AST SU	BJECT ENC	COUNT	ER	
11.	Comparison Term [hid [Comparison Term]	dden]	NOT SUBMITTED							
12.	Standardized Med cat derived. [hidden] [Standardized Med ca		Y CMDECOD							
13.	Standardized Med cat derived [hidden] [Standardized Med ca		·	MCODE in SU	РРСМ					

ST	UDYID				PR=Pr	rocedures
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       NO     End Date:     Image: Comparison of the second secon	E LAST SUBJECT	ENCOUNTER	]
7.	Comparison <sup>-</sup> [Comparison	F <b>erm [hidden]</b> 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 <b>m Code [<i>hidden</i>]</b> 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] <sup>[</sup> erm Code]	PRHLTCD in SUPPPR			
14.	High Level G [High Level G	r <b>oup Term [<i>hidden</i>]</b> Group Term]	PRHLGT in SUPPPR			
15.		roup Term Code [hidden] Group Term Code]	PRHLGTCD in SUPPPR			
16.		<b>em Organ Class [hidden]</b> tem Organ Class]	PRBODSYS in SUPPPR PRSOC in SUP	PPR		
17.		em Organ Class Code [hidden] tem Organ Class Code]	PRBDSYCD in SUPPPR	PRSOCCD in SUP	PPR	

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

C4	591001: VITAL SIGNS -	PULSE OX ROOM AIR (PULSE OX) - Repeating Form VSCATEGENERAL VITAL SIGNS						
#	Date:		Vital Signs Details					
1								
Vita	al Signs							
I I	Date: [Date:]							
Vita	al Signs Details							
# ✓	Red	ord Identifier: Oxygen Saturation						
2.a	1							
Vit	al Signs Details Entry							
2.1	Record Identifier: ( [Record Identifier:]	O <sup>1</sup> 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: Ima

	[Randomization Date :]	DSTDTC WHEN DSTERIM/DSDECOD=RANDOMIZED
1	Randomizat on Number: [Randomization Number]	DSREFID
3.	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 <b>of vaccination start date</b>
	Reactogen c ty diary collection [Trigger Response 9]	ONO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT <b>REACTOFL='N' in SUPPDM</b>

DM=Demographics

	UDYID			Findings About Events or Interventions	
C4	591001: UNPLANNED		CAL REACTION - SYSTEMIC EV		
Unj	planned Assessment Of Loca		CTOGENICITY -UNPLANNED AS		
	CISR Category [hidden] [CISR Category]		T OF LOCAL REACTION/SYSTEMIC EVENT	OT SUBMITTED	
	Date of Assessment: [Date of Assessment]		ADTC		
	Injection Site Location [Injection S te Location]	O DELTOID MUSCLE	00		
	Injection Site Body S de: [Injection S te Body Side]	O LEFT <b>FALAT</b>			
Rea	iction				
#	Rea	ction:	R	eaction Present:	
5.a	REDNESS				
5.b	SWELLING				
Rea	Reaction Entry				
5.1	Reaction: [React on:]	© REDNESS © SWELLING FAOBJ			
	[React on Present:]	Maximum Diameter (cm): FAORRES Minimum Diameter (cm): FAORRES Meets Grade 4 Reaction C	when FATESTCD=MAXDIAM		
Syr	nptom				
#		Symptom:		Symptom Present:	
6.a	PAIN AT INJECTION SITE				
6.b	FATIGUE/TIREDNESS				
6.c	HEADACHE				
6.d	VOMITING				
6.e					
6.f	NEW OR WORSENED MUSCLE				
6.g	CHILLS				
⊢-	Symptom:				
	[Symptom:]				
0.2	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     OPAP     MECHANICAL VENTILATION     EXTRACORPOREAL MEMBR     HIGH FLOW OXYGEN THER	N ANE OXYGENA	TRT			
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

<b>S</b> 7	TUDYID							PR=F	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: [Treatment]		O INTUBATION NON-INVASI CPAP OXYGEN THE	IVE POSITIVE PRES	SSURE VENTII	ATION <b>PRTR</b>	Γ		
4.	Treatment: [Treatment]		PRTRT						
5.	Start Date: [Start Date]			/ <b>PRS</b>	TDTC				
6.	Ongoing? [Ongoing?]		OYES 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]	1]	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)

Further Vaccination Confirmation					
1. Select appropriate response - Is part cipant willing to return for Vaccination 3?       Participant is willing to return for Vaccination 3?         [Trigger Response 1]       Participant is willing to return for Vaccination 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	1.				

## 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         SAMPLE TRACKING - REPEAT SWAB (RSWAB)       MBCAT=VIROLOGY
	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: [Passon sample not collected]	COVAL when RDOMAIN = MB

Sample ID

### Aliquot Entry

5.

Please enter barcode for each aliquot.

Fiea			
5.1	Sample ID	NOT 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	InForm Screening		
1.	InForm Initials [hidden] [InForm Initials]		
2.	Birth Date: [Birth Year]		

S	TUDYID 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]	O SITE 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 ERSION 2: USED AFTER JULY 6, 2020	t ons CE=Clinical Events		
C45	C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD) FACAT=EFFICACY CECAT=EFFICACY				
Sign	igns and Symptoms FASCAT=RESPIRATORY ILLNESS CESCAT=SIGNS AND SYMPTOMS OF DISEASE				
	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]	O YES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOI	NG CEENTPT= ONGOING		
		Date of Last Symptom Resolved:			
Svm	ptoms				
#	Event Pre-specified	Symptoms	Symptom Present		
✓ 4.a	YES	FEVER			
4.b	YES	NEW OR INCREASED COUGH			
4.c	YES	NEW OR INCREASED SHORTNESS OF BREATH			
4.d	YES	CHILLS			
4.e	YES	NEW OR INCREASED MUSCLE PAIN			
4.f	YES	NEW LOSS OF TASTE OR SMELL			
4.g	YES	NEW OR INCREASED SORE THROAT			
4.h	YES	DIARRHEA			
4.i	YES	VOMITING			
<u> </u>	ptoms Entry				
	Event Pre-specified: [hidden] [Event Pre-specified]	VES NOT SUBMITTED			
	Symptoms: [Symptoms]				
4.3	Was symptom present? [Symptom Present]	O YES NO ► FAORRES when FATESTCD=OCCUR			
		Symptoms - Other			
5.  ✔					
	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 Primary System Organ Class Code [hidden] [Primary System Organ Class	NOT SUBMITTED			

Code]

FA=Findings About Events or Interventions

#### Annotated Study Book - C4591001

090177e196b6fd5d\Final\Final On: 06-Apr-2021 21:26 (GMT)

ST	Original version	: VERSION 1: USED PRIOR TO JULY 6, 2020 ERSION 2: USED AFTER JULY 6, 2020 ERSION 2: USED AFTER JULY 6, 2020	it ons <mark>CE=Clinical Events</mark>
C4			ECAT=EFFICACY
		RESPIRATORY ILLNESS CESCAT=SIGNS AND SYMPTOMS OF DIS	
1. C	ate of Assessment:		
2. C	Date of assessment] Date of First Symptom Started:	Image: Control of the second state of the second	
	First Symptom Started Date]		
	ymptoms Ongoing? Symptoms Ongoing]	OYES FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOIN	IG CEENTPT= ONGOING AT CURRENT VISIT
		Date of Last Symptom Resolved:	
Svm	ptoms		
#	Event Pre-specified	Symptoms	Symptom Present
✓ 4.a	YES	FEVER	
4.b	YES	LOSS OF TASTE/SMELL	
4.c	YES	NEW OR INCREASED COUGH	
4.d	YES	NEW OR INCREASED NASAL CONGESTION	
4.e	YES	NEW OR INCREASED NASAL DISCHARGE	
4.f	YES	NEW OR INCREASED SHORTNESS OF BREATH	
4.g	YES	NEW OR INCREASED SORE THROAT	
4.h	YES	NEW OR INCREASED SPUTUM PRODUCTION	
4.i	Ptoms Entry	NEW OR INCREASED WHEEZING	
<u> </u>	Event Pre-specified: [hidden] [Event Pre-specified]	VES NOT SUBMITTED	
4.2	Symptoms: [Symptoms]	FAOBJ CETERM	
4.3	Was symptom present? [Symptom Present]	O YES NO FAORRES when FATESTCD=OCCUR	
	I	Symptoms - Other	
5. V			
	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 Code [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]	<ul> <li>○ Age 18 to 55</li> <li>○ Age 65 to 85</li> </ul>
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	<ul> <li>10 mcg</li> <li>20 mcg</li> <li>30 mcg</li> </ul>
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]	<ul> <li>○ Age 18 to 55</li> <li>○ Age 56 to 85</li> </ul>	
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	<ul> <li>10 mcg</li> <li>20 mcg</li> <li>30 mcg</li> </ul>	
4.	Select appropriate response - BNT Number [Trigger Response 7]	<ul> <li>○ (BNT162b1 or PBO)</li> <li>○ (BNT162b2 or PBO)</li> <li>○ (BNT162b3 or PBO)</li> </ul>	

### C4591001: STRATIFICATION (STRAT) NOT SUBMITTED

C	4591001: STRATIFICAT	C4591001: STRATIFICATION (STRAT) NOT SUBMITTED		
SI	ratification			
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	OStage 1 OStage 2		
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	<ul> <li>Age 18 to 55</li> <li>Age 56 to 85</li> <li>Age 65 to 85</li> </ul>		
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	<ul> <li>Low dose level (3mcg)</li> <li>Medium dose level (10mcg)</li> <li>High dose level (30mcg)</li> <li>Low dose level (10mcg)</li> <li>Medium dose level (30mcg)</li> <li>High dose level (100mcg)</li> <li>Low dose level (0.1mcg)</li> <li>Medium dose level (0.3mcg)</li> <li>High dose level (0.3mcg)</li> <li>Mid-High dose level (50mcg)</li> <li>Low-Mid dose level (20mcg)</li> </ul>		
4.	Select appropriate response - Randomizat on Dose Group [hidden] [Trigger Response 6]	<ul> <li>21 Day 2-dose group</li> <li>60 Day 2-dose group</li> <li>1-dose group</li> </ul>		
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]	<ul> <li>(BNT162a1 or PBO)</li> <li>(BNT162b1 or PBO)</li> <li>(BNT162b2 or PBO)</li> <li>(BNT162c2 or PBO)</li> <li>(BNT162b3 or PBO)</li> </ul>		

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

<b>S</b> 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	STUDYID MB=Microbiology Specimen DI=Device Identifiers CO=Comments									
	C4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form MBCAT=CONFIRMATION OF INFECTION									
#	Date of Collection	Specimen T			Assay Code and Description	1	Trade Name	1		
1										
Mi	crobiology Specimer	1								
1.	Actual Date of Collect [Date of Collection]	ion:	✓ / ✓ / ✓	MBDTC						
2.	Specimen Type: [Specimen Type]	C	SWABBED MATERIAL	<b>IBSPEC</b>						
3.	Specimen Collection L [Specimen Collection	Location	NASAL CAVITY MBLO							
4.	Assay Code and Desc [Assay Code and Desc	ription: C	SEVERE ACUTE RESP SY	NDROME CORO	NAVIRUS 2 <b>MBTEST</b>					
5.	Device Type: [Device Type]	C	SARS-COV-2 DIAGNOST	IC TEST DIVA	L when DIPARMCD = DEV	TYPE				
6.	Trade Name: [Trade Name]	C	CEPHEID XPERT XPRESS	SARS-COV-2 T	EST DIVAL when DIPARMO	CD = TRADE	NAM			
7.	Test Result: [Result] OPOSITIVE NEGATIVE MBORRES when MBTESTCD = SARSCOV2 NINDETERMINATE									
8.	Comments/Findings/E [Comments:]	Details:	COVAL when RDO	MAIN = MB						

Annotated Study Book - C4591001

STI	TUDYID CE=Clinical Events FA=Findings About Events or Interventions AE=Adverse Events							
C4	591001: VACCINATIO	SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE CECAT=REACTOGENIC	ITY					
	cination Symptoms Diary - Sy							
1.	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: Comparison of the second seco	ORRES ENRTPT= ONGOING FAENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD					
#	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       CEENRTPT=         YES       CEENRTPT=         NO       ONGOING         Stop Date:       DAY OF DIARY PERIOD         NO       RCENDTC in SUPPCE	; <b>T</b>					
	Injection Site Location: [Injection S te Location:]	ODELTOID MUSCLE CELOC AELOC						
	Injection Site Body S de: [Injection S te Body Side:]	OLEFT ORIGHT						
#	Injection Site Reaction:	Were injection site reactions present on the last day the Subject Diary was completed?						
5.a		CESCAT=ADMINISTRATION SITE FASCAT=ADMINISTRATION SITE						
5.b		AESCAT=ADMINISTRATION SITE						
5.c								
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?]	YES       NOT SUBMITTED       AEENTPT=         Ongoing       CEENTTT=       ONGOING       AEENTPT=         YES       ONGOING       RELATIVE TO LAST       SUPPCE       ONGOING         NO       Stop Date:       DAY OF DIARY PERIOD       DAY OF DIARY PERIOD       DAY OF DIARY         NO       NO       RCENDTC in SUPPCE       PERIOD       PERIOD	Т					

_	TUDYID	PR=Procedures						
C	C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form PRCAT=TRANSFUSION DETAILS							
#		Transfusion Type	Date of Transfusion					
1								
1.	Transfus on Type: [Transfus on Type]	<ul> <li>PACKED RBC</li> <li>PLATELETS</li> <li>WHOLE BLOOD</li> <li>PLASMA</li> <li>OTHER Specify:</li> </ul>						
2.	Date of Transfus on:							

C	C4591001: TREATMENT UNBLINDED (TRN UNBLN)DSCAT=OTHER EVENT							
Tr	Treatment Unblinded							
1.	1.     Date Treatment Unblinded :       [Date Treatment Unblinded :]							
2.	Primary Reason for Unblinding: [Primary Reason for Unblinding]	SUBJECT SAFETY CONCERN DSTERM     OTHER     If other, specify:     ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION						

С	4591001: UNPLANNED	VISIT (UNPL) NOT SUBMITTED				
Unplanned Assessments						
1.	Assessments [Assessments]					

S7	<b>EX=Exposure EC=Exposure</b> as Collected							
C4	591001: VA	CCINATION (VACIN TRT) EXCAT=INVESTIGATIONAL ECCAT=INVESTIGATIONAL ECSCAT=VACCINATION						
<b>Vac</b> 1.	Was there a	EXSCAT=VACCINATION     PRODUCT       OYES     EXTDV in SUPPEX						
	temporary delay of vaccinat on? [Temporary Delay of Vaccination]	Date of First Delay:						
2.	Treatment Name [Treatment Name]							
3.	Formulat on: [Formulat on:]	OINJECTION EXDOSFRM ECDOSFRM						
4.	Dose Date Time: [Dose Date Time:]	Image: Second state of the second s						
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]	ECDOSE						
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 EXADJ1, EXADJ2, etc. in SUPPEX         OTHER SPECIFY       If other, specify:       ECDOSAJO in SUPPEX         EXDOSAJO in SUPPEX       ECDOSAJO in SUPPEC						
13.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	THE PROTOCOL SPECIFIED OBSERVATION PERIOD EXOBSVT in SUPPEX ECOBSVT in SUPPEC						
14.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	YES       EXOBSV in SUPPEX         NO       If No, specify reason:         EXOBSVD in SUPPEX       ECOBSVD in SUPPEC						
15.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED						
16.	Standardized Med cation Name -	EXDECOD in SUPPEX ECDECOD in SUPPEC						

			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	

<b>S</b> 7	STUDYID EX=Exposure EC=Exposure as Collected						
C4	591001: VA	CCINATION (VACIN TRT) EXCAT=IN	IVEST	<b>IGATIONAL</b>	ECCAT=INVESTIG	ATIONAL	ECSCAT=VACCINATION
1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	EXSCAT=VACCINATION       PRODUCT         YES       EXTDV in SUPPEX       ECTDV in SUPPEX         Date of First Delay:       Image: Construction       FDDTC in SUP         Reason(s) for Temporary Delay of Vaccination       FEVER OR ACUTE ILLNESS       RECENT SYSTEMIC CORTICOSTEROID TREA         RECENT NON-STUDY VACCINATION       ANTICIPATED NON-STUDY VACCINATION       NO	SUPPL	EC FDDTC in SU EXADJ when selected, EX and individu	PRODUCT IPPEC In more than one (ADJ=MULTIPLE al responses are ADJ2, etc. in	selected	vhen more than one , ECADJ=MULTIPLE vidual responses are ECADJ2, etc. in
2.	Treatment Name [Treatment Name]	EXTRT ECTRT					
3.	Formulat on: [Formulat on:]	OINJECTION EXDOSFRM ECDOSFRM	'				
4.	Dose Date Time: [Dose Date Time:]	Image: 1   Image: 1   Image: 24-hour clock	NDTC	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 ECROUT	Έ				
8.	Container Number: [hidden] [PAC / K t Number:]	NOT SUBMITTED					
9.	Actual Dose: [Actual Dose:]	EXDOSE ECDOSE					
10.	Unit: [Unit:]	O <sup>mL</sup> EXDOSU ECDOSU					
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	THE PROTOCOL SPECIFIED OBSERVATION PER  EXOBSVT in SUPPEX ECOBSVT		PPEC			
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 NO If No, specify reason: EXOBSVD in SUPPEX ECOBSVL					
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 SUI	PPEC			
15.	Standardized Med cation Code - D ctionary Derived [hidden]	EXCD in SUPPEX	ECC	D in SUPPEC	2		

1
[Standardized
Med cation
Codel

EX=Exposure EC=Exposure as Collected

S	TUDYID							С	M=Concomit	tant Medi	cations
C	C4591001: CONCOMITANT MEDICATIONS - VASOPRESSORS (VASOPRESS) - Repeating Form										
#	Sponsor-Defined Identifier	Category f	or Medication	Conco	omitant Medic	ations Pre-spe	cified	Name	e of Medication	Start Date	Ongoing
1									CMSCAT=VA	SOPRES	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 :	<b>UBMIT</b>	TED						
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]	CMTRT
5.	Start Date: [Start Date]	
6.	Ongoing? [Ongoing]	O YES       CMENRTPT= ONGOING       CMENTPT= LAST SUBJECT ENCOUNTER         End Date:       Image:
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

2.4 Temperature Location: [Temperature Location:]

ORAL CAVITY

🔵 EAR ○ RECTUM O AXILLA ○ FOREHEAD

_									
<b>S</b> 7	STUDYID VS=Vital Signs								
C4	591001: VITAL SIGNS	- TEM	P (VITAL TEMP) VSC	AT=REACTOGENICITY - UNPL	ANNED TEMPERATURE				
Vita	al Signs			VSSCAT=SYSTEMIC					
	Date: [Date:]	<b>v</b> /							
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:]	O1 VSSPID							
2.2	Temperature: [Temperature]	VSORRES when VSTESTCD =TEMP							
2.3	Unit: [Temperature Unit]		C VSORRESU when VSTESTCD = TEMP						

VSLOC when VSTESTCD = TEMP

# STUDYID

ST	UDYID				VS=Vital Signs				
C4	4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS								
	tal Signs								
	Date: [Date:]	<b>v</b> /							
	Weight: [Weight]		VSORRES when V	STESTCD = WEIGHT					
	<b>Un t:</b> [Weight Unit]	Okg OLB <b>VSO</b>	RRESU when VSTE	STCD = WEIGHT					
	Height: [Height]		VSORRES when V	STESTCD = HEIGHT					
	<b>Un t:</b> [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:]	<sup>O 1</sup> VSSP	D						
7.2	Temperature: [Temperature]		VSORRES when VS	TESTCD = TEMP					
7.3	Unit: [Temperature Unit]	OC F VSOI	RRESU when VSTE	STCD = TEMP					
7.4	Temperature Location: [Temperature Location:]	ORAL CAV EAR RECTUM AXILLA FOREHEAI	VSLOC when VS	TESTCD = TEMP					

# STUDYID

VS=Vital Signs

C4	4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS								
Vit	/ital Signs								
	Date: [Date:]	V /							
	Weight: [Weight]		VSORRES when VS	TESTCD = WEIGHT					
	<b>Un t:</b> [Weight Unit]		RESU when VSTES	TCD = WEIGHT					
	Height: [Height]		VSORRES when VS	TESTCD = HEIGHT					
	<b>Un t:</b> [Height Un t]	orm oin	RESU when VSTES	TCD = HEIGHT					
	Body Mass Index: [Body Mass Index]		SORRES when VS1	ESTCD = BMI					
Vit	al Signs Details								
#		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:]	O <sup>1</sup> VSSPIL	2						
7.2	Temperature: [Temperature]		VSORRES when VSTESTCD = TEMP						
7.3	Unit: [Temperature Unit]	OC F <b>VSOR</b>							
7.4	Temperature Location:       ORAL CAVITY         [Temperature Location:]       EAR         VSLOC when VSTESTCD = TEMP         AXILLA         FOREHEAD								
7.5	Systol c: [Systolic:]	VSO	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 SIGN	NS - COVI	D (VITALS C	COV) - Repeating Form VSCAT=GENERAL	VITAL SIGNS				
#	Date:			Vital Signs Details					
1									
Vita	al Signs								
1 1	Date: [Date:]	<b>v</b> /		VSDTC					
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	hen VSTESTCD = HR					

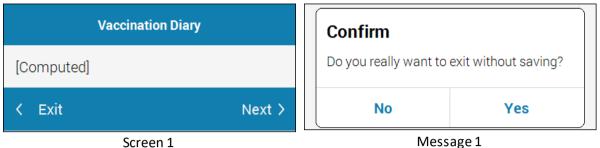
#### C4591001: VITAL SIGNS (VITALS FUP) VSCAT=GENERAL VITAL SIGNS Vital Signs 1. Date: ✓ / **~** / 4 VSDTC [Date:] Vital Signs Details **Record Identifier:** Temperature **Temperature Unit** Diastolic: **BP** Position Pulse: # **Temperature Location:** Systolic: 2.a 1 SITTING Vital Signs Details Entry 2.1 Record Identifier: [Record Identifier:] 2.2 Temperature: VSORRES when VSTESTCD = TEMP [Temperature] O<sup>F</sup> 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)."

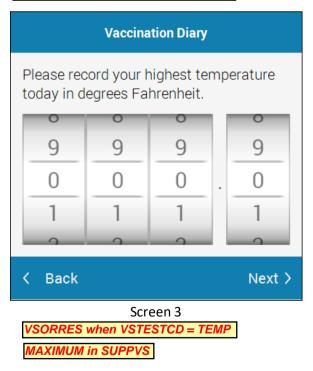
{1} Will display a date

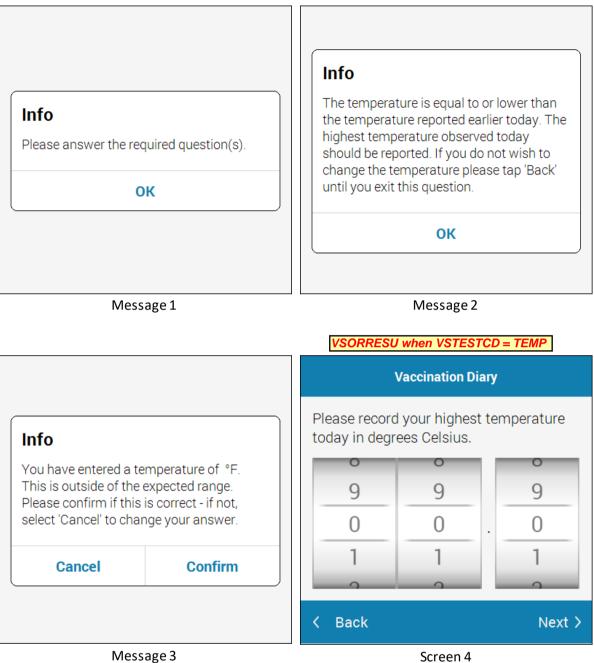
{2} Will display a number of days.

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).



## /SORRESU when VSTESTCD = TEMP





Message 3

VSORRES when VSTESTCD = TEMP 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

			Vaccination Diary
Info			Please confirm your highest temperature today:
You have entered a temperature of °C. This is outside of the expected range. Please confirm if this is correct - if not, select 'Cancel' to change your answer.			[Computed]
			K Back Next
		_	Screen 5
Cancel Confirm			[Computed] will display the temperature
			selected on 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?

No

Ves

No

K

Message 1

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 second

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

#### < Back Next >



## Vaccination Diary Please confirm the number from the measuring device for redness: 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 measurement please tap 'Back' until you Screen 8 exit this question. Screen 7. ОК

Message 2

Next >

[Computed] will display the number selected on

		FA=Findings Abou	ut Events or Interventions
A-1426-0086 / C4591001-Post-12-July-2020 FASCAT = ADMINISTRATION SI FAORRES when FATESTCD = C FAOBJ = SWELLING	English (I	ing Screen Report JSA) enUS <i>FASCAT = ADMINISTR</i> <i>FAORRES when FATE</i> <i>FAOBJ = SWELLING</i>	22-JUN-2020 Version 2 RATION SITE STCD = DIAMETER and
Vaccination Diary		Vaccinat	ion Diary
Today, have you had any swe injection site?	lling at the	Please select the nur measuring device for	
Vac	0	0	0
Yes	0	9	9
No	$\bigcirc$	0	0
		1	1
< Back	Next >		
Screen 9		If your swelling was g 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 >
Scieen 10.	Screen 12
	FAORRES when FATESTCD = OCCUR and FAOBJ = PAIN AT INJECTION SITE

		FA=Findings About	Events or Interventions
A-1426-0086 / C4591001-Post-12-July-2020			TCD = SEV and
Vaccination Dia	ry	Vaccination	ı Diary
Pain at the injection site Mild = Does not interfere w		Please indicate whether injection site was:	r the pain at the
Moderate = Interferes with activity		Mild	0
Severe = Prevents daily act	ivity	Moderate	0
< Back	Next >	Severe	0
Screen 13			
		< Back	Next >
		Screen	14

Info		Info The severity is equal to or lower than the
Severe = Prevents daily activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.		severity reported earlier today. The most severe symptom observed today should be reported. If you do not wish to change the severity please tap 'Back' until you exit this question.
No	Yes	
		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 Events or Int	erventions
A-1426-0086 / C4591001-Post-12-July-2		ing Screen Report USA) enUS	22-JUN-2020 Version 2
	FASCAT = SYSTEMIC	FAORRES when FATESTCD = OCCU FAOBJ = HOSPITALIZED FOR TIRE (FATIGUE)	
		Vaccination Diary	
Info		Did you go to the ER or were yo hospitalized for this reaction?	u
Severe = Prevents dail this is correct tap 'Yes	to go forward or	Yes	0
'No' to change your ar	iswer.	No	$\bigcirc$
No	Yes	< Back	Next >
		Screen 19	
Mess	·		
AORRES when FATESTC AOBJ = HEADACHE	D = OCCUR and FASCAT	T = SYSTEMIC	
Vaccinat	ion Diary	Vaccination Diary	
Today, have you expe	erienced headache?	Headache definitions:	
Yes	0	Mild = Does not interfere with a	ctivity
No	0	Moderate = Some interference activity	with
		Severe = Prevents daily routine	activity
K Back Scree	Next >	< Back	Next >
Scree		Screen 21	

		FA=Findings About	Events or Interventions
A-1426-0086 / C4591001-Post-12-July-2020		ing Screen Report 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	<b>n Diary</b> : 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

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

22-JUN-2020 Version 2

FAORRES when FATESTCD = SEV and FAOBJ = VOMITING	FAS	CAT = SYSTEMIC	
Vaccination Diary			
Please indicate whether the vomiting was:		Info	
Mild	$\bigcirc$	Severe = Requires intra 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?	L	Today, have you expe	erienced diarrhea?
	0	Yes	$\bigcirc$
Yes	0	No	0
No	0		
< Back	Next >	< Back	Next >
Server 27		Scree	en 28
Screen 27 FAORRES when FATESTCD = OCCUR and		FAORRES when FATESTCD = OCCUR and FAOBJ = DIARRHEA	
FAORRES When FATESTCD = OCCOR and FAOBJ = HOSPITALIZED FOR VOMITING		FASCAT = S	YSTEMIC
FASCAT = SYSTEMIC			

A-1426-0086 / C4591001-Post-12-July-2		FA=Findings About Events or Inter cing Screen Report (USA) enUS FASCAT = SYSTEMIC FAORRES when FATESTCD = SEV a FAOBJ = DIARRHEA	22-JUN-2020 Version 2
Vaccina	tion Diary	Vaccination Diary	
Diarrhea definition	IS:	Please indicate whether the diar	rhea was:
Mild = 2 to 3 loose st	tools in 24 hours	Mild	0
Moderate = 4 to 5 loose stools in 24 hours Severe = 6 or more loose stools in 24 hours		Moderate	0
		Severe	0
< Back	Next >	< Back	Next >
Scree	en 29	Screen 30	
	FASCAT = SYSTEMIC	FAORRES when FATESTCD = OCCUR FAOBJ = HOSPITALIZED FOR DIARRI	
		Vaccination Diary	
Info		Did you go to the ER or were you hospitalized for this reaction?	L
Severe = 6 or more lo hours. If this is correct forward or 'No' to cha	t tap 'Yes' to go	Yes	$\bigcirc$
		No	$\bigcirc$
No	Yes	< Back	Next >
		Screen 31	
Mess	sage 2		

22-JUN-2020 Version 2

FAORRES when FATESTCD = OCCUR ar FAOBJ = CHILLS	FASCAT = SYSTEMIC
Vaccination Diary	Vaccination Diary
Today, have you experienced chills?	Chills definitions: Mild = Does not interfere with activity
Yes C	Moderate = Some interference with activity
K Back Next	Severe = Prevents daily routine activity Severe = Prevents daily routine activity Severe = Prevents daily routine activity Next >
FASCAT = SYSTEMIC FAORRES when FATESTCD = SEV and FAOBJ = CHILLS	Screen 33
Vaccination Diary	Vaccination Diary
Please indicate whether the chills were:	Did you go to the ER or were you hospitalized for this reaction?
Mild	Yes O
Moderate	No O
Severe	
K Back Next	✓ Back Next >
Screen 34	Screen 35 FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR CHILLS

FASCAT = SYSTEMIC

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

FAORRES when FATESTCD = OCCUR and FAOBJ = MUSCLE PAIN	FASCAT = 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 36	Screen 37 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

22-JUN-2020 Version 2

#### 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 or worsened joint pain was:		Did you go to the ER or were you hospitalized for this reaction?	
Mild	$\bigcirc$	Yes	$\bigcirc$
Moderate	$\bigcirc$	No	$\bigcirc$
Severe	0	< Back	Next >
< Back	Next >	Screen FAORRES when FATES	TCD = OCCUR and
Screen 42 FAORRES when FATESTCD = SEV and FAOBJ = JOINT PAIN		FAOBJ = HOSPITALIZED FOR JOINT PAIN FASCAT = SYSTEMIC	
FASCAT = SYSTEMIC			

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

22-JUN-2020 Version 2

FAORRES when FATESTCD = ME FAOBJ = MEDICATIONS	EDTFVPN and	FASCAT = MEDICATION	IS GIVEN
Vaccination Diary			
Today, have you taken any medication to treat fever or pain?		Info	
Yes	$\bigcirc$	You have reported taking medication to treat fever or pain. Is your answer correct?	
No	0	No	Yes
< Back	Next >		
Screen 44		Message 2	

Vaccination Diary	Vaccination Diary	
Thank you! You have now completed the diary for today. Please save your answers by selecting ' <b>Save</b> '. If you wish to change your answers, select ' <b>Back</b> '.	Thank you! You have now updated the diary for today. Please save your answers by selecting ' <b>Save</b> '. If you wish to change your answers, select ' <b>Back</b> '.	
If your symptoms worsen today, please select ' <b>Update Symptoms</b> ' from the main menu to update your symptoms. [Computed]	If your symptoms worsen again today, please select ' <b>Update Symptoms</b> ' from the main menu to update your symptoms. [Computed]	
[Compated]		
Save	Save	
< Back	< Back	
Screen 45		
	Screen 46 [Computed] will display "Please continue to fill out your diary for the next {1} day(s)." Where {1} = a number of days	
[Computed] will display "Please continue to fill out your diary for the next {1} day(s)."		
Where {1} = a number of days		
Example: Please continue to fill out your diary		

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

for the next 4 day(s).