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

Visits SCR MAIN INFORMED CONSENT **DEMOGRAPHY DATE OF VISIT** INCLUSION/EXCLUSION CRITERIA (INCEXCS) INCLUSION/EXCLUSION CRITERIA (INC EXCS) INCLUSION/EXCLUSION CRITERIA (INCEXCS) INCLUSION/EXCLUSION CRITERIA (INC EXC) **DISPOSITION-SCREENING GENERAL MEDICAL HISTORY CONCOMITANT MEDICATIONS - BASELINE PHYSICAL EXAMINATION VITAL SIGNS - BASELINE ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION** MICROBIOLOGY SPECIMEN (COV19 SITE) CENTRAL LAB SAMPLE COLLECTION - BASELINE LAB URINALYSIS - PREGNANCY TEST V1_DAY1_VAX1_S **DATE OF VISIT PHYSICAL EXAMINATION VITAL SIGNS** LAB URINALYSIS - PREGNANCY TEST **ELECTRONIC SAMPLE TRACKING - NASAL SWAB** MICROBIOLOGY SPECIMEN (SWAB SITE) **RANDOMIZATION ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY** VACCINATION **VACCINATION DIARY** V2 DAY2 POSTVAX1 S **DATE OF VISIT PHYSICAL EXAMINATION VITAL SIGNS CENTRAL LAB SAMPLE COLLECTION** V3_WEEK1_POSTVAX1_S **DATE OF VISIT** PHYSICAL EXAMINATION **VITAL SIGNS CENTRAL LAB SAMPLE COLLECTION ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY** V4_WEEK3_VAX2_S **DATE OF VISIT**

FDA-CBER-2021-5683-0057822

VACCINATION SYMPTOMS DIARY-SYMPTOM RESOLVED DATES

PHYSICAL EXAMINATION

LAB URINALYSIS - PREGNANCY TEST

ELECTRONIC SAMPLE TRACKING - NASAL SWAB

VITAL SIGNS

```
MICROBIOLOGY SPECIMEN (SWAB SITE)
          CENTRAL LAB SAMPLE COLLECTION
          ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY
          VACCINATION
          VACCINATION DIARY
V5_WEEK1_POSTVAX2 S
          DATE OF VISIT
          PHYSICAL EXAMINATION
          VITAL SIGNS
          CENTRAL LAB SAMPLE COLLECTION
          ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY
V6 WEEK2 POSTVAX2 S
          DATE OF VISIT
          VACCINATION SYMPTOMS DIARY-SYMPTOM RESOLVED DATES
          PHYSICAL EXAMINATION
          VITAL SIGNS
          ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
          VACCINATION DIARY
V7_MONTH1_S
          DATE OF VISIT
          ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY
V4 WEEK3 VAX2 S R
          DATE OF VISIT
          VACCINATION SYMPTOMS DIARY-SYMPTOM RESOLVED DATES
          PHYSICAL EXAMINATION
          VITAL SIGNS
          LAB URINALYSIS - PREGNANCY TEST
          ELECTRONIC SAMPLE TRACKING - NASAL SWAB
          MICROBIOLOGY SPECIMEN (SWAB SITE)
          CENTRAL LAB SAMPLE COLLECTION
          ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
          VACCINATION
          VACCINATION DIARY
V5 WEEK1 POSTVAX2 S R
          DATE OF VISIT
          PHYSICAL EXAMINATION
          VITAL SIGNS
          CENTRAL LAB SAMPLE COLLECTION
          ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
V6 WEEK2 POSTVAX2 S R
          DATE OF VISIT
          VACCINATION SYMPTOMS DIARY-SYMPTOM RESOLVED DATES
          PHYSICAL EXAMINATION
          VITAL SIGNS
          ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY
          VACCINATION DIARY
 V7_MONTH1_S_R
```

DATE OF VISIT

```
ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY
V8_MONTH6_S
        DATE OF VISIT
        ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
V9 MONTH12 S
        DATE OF VISIT
        ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY
V10 MONTH24 S
        DATE OF VISIT
        ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
V1 DAY1 VAX1 NS
        DATE OF VISIT
        INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
        INCLUSION/EXCLUSION CRITERIA (INC EXC NS)
        INCLUSION/EXCLUSION CRITERIA (INC EXCNS)
        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 (INC EXC)
        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
        ELECTRONICSAMPLE TRACKING-IMMUNOGENICITY
        LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
V6 MONTH24 L
        DATE OF VISIT
```

ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

UNPLANNED_VACCINATION DATE OF VISIT

```
LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
POT COVID ILL
        DATE OF VISIT - ILLNESS
        CONTACT OUTCOME - MONTH 1
        SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
        SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
        MICROBIOLOGY SPECIMEN (COVID TEST)
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
        HEALTH CARE UTILIZATION
        HOSPITALIZATION DETAILS
        RESPIRATORY TREATMENT
        RESPIRATORY TREATMENT
        ILLNESS DETAILS
        ILLNESS DETAILS - SEVERE
        ILLNESS DETAILS - SEVERE
        LOCAL LABORATORY DATA - REPEATING CHEMISTRY
        LOCAL LABORATORY DATA - REPEATING CHEMISTRY
        LOCAL LABORATORY DATA-REPEATING HEMATOLOGY
        VITAL SIGNS - COVID
        VITAL SIGNS - PULSE OX ROOM AIR
        OXYGENATION PARAMETERS
        CONCOMITANT MEDICATIONS - VASOPRESSORS
        IMAGING
        VACCINATION DIARY
POT COVID CONVA
        DATE OF VISIT - ILLNESS CONVALESCENT
        ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
        VACCINATION DIARY
POT COVID REPEAT SWAB
        DATE OF VISIT - REPEAT SWAB
        ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
        VACCINATION DIARY
LOGS
        ADVERSE EVENT REPORT
        MEDICATION ERROR
        CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
        CONCOMITANT MEDICATIONS - PROHIBITED
        RADIATION TREATMENT
        TRANSFUSIONS
UNPL
        DATE OF VISIT
        CONTACT OUTCOME - UNPLANNED
        VITAL SIGNS - TEMP
        UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT
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VITAL SIGNS - TEMP
        LAB URINALYSIS - PREGNANCY TEST
        VACCINATION
        CONTACT OUTCOME - MONTH 1
        CONTACT OUTCOME - MONTH 6
V201 SURVEIL CONSENT
        DATE OF VISIT
        INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
        ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
V202 SURVEIL SWAB
        DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
        ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
DISP
        TREATMENT UNBLINDED
        WITHDRAWAL OF CONSENT
        DEATH DETAILS CODED
END_OF_TRT
        DISPOSITION-TREATMENT
REVAX_CONTACT
        DATE OF VISIT
V101_VAX3
        DATE OF VISIT
        INFORMED CONSENT - FURTHER VACCINATION
        INCLUSION/EXCLUSION CRITERIA-FURTHER VACCINATION(REVAXIE)
        DISPOSITION - SCREENING FOR FURTHER VACCINATION
        LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
        LAB URINALYSIS - PREGNANCY TEST
        ELECTRONIC SAMPLE TRACKING-IMMUNOGENICITY
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
        VACCINATION
V102_VAX4
        DATE OF VISIT
        LAB URINALYSIS - PREGNANCY TEST
        ELECTRONIC SAMPLE TRACKING - NASAL SWAB
        VACCINATION
V103_MONTH1
        DATE OF VISIT
        CONTACT OUTCOME
        LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
V104 MONTH6
        DATE OF VISIT
        CONTACT OUTCOME
        LAB CHEMISTRY
        LABORATORY DATA - HEMATOLOGY
V105_MONTH18
```

DATE OF VISIT

CONTACT OUTCOME

LAB CHEMISTRY

LABORATORY DATA - HEMATOLOGY

FURTHER_VACCINATION_EOT

DISPOSITION - TREATMENT FOLLOW_UP

DISPOSITION-FOLLOW-UP

Domains

AE=ADVERSE EVENTS

VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

ADVERSE EVENT REPORT

MEDICATION ERROR

CE=CLINICAL EVENTS

VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

ILLNESS DETAILS

ILLNESS DETAILS - SEVERE

ILLNESS DETAILS - SEVERE

CM=CONCOMITANT MEDICATIONS

CONCOMITANT MEDICATIONS - BASELINE

CONCOMITANT MEDICATIONS - VASOPRESSORS

CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

CONCOMITANT MEDICATIONS - PROHIBITED

CO=COMMENTS

ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION

MICROBIOLOGY SPECIMEN (COV19 SITE)

ELECTRONIC SAMPLE TRACKING - NASAL SWAB

MICROBIOLOGY SPECIMEN (SWAB SITE)

ELECTRONICSAMPLE TRACKING - IMMUNOGENICITY

MICROBIOLOGY SPECIMEN (COVID TEST)

ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

ELECTRONICSAMPLE TRACKING - REPEAT SWAB

DD=DEATH DETAILS

DEATH DETAILS CODED

DI=DEVICE IDENTIFIERS

MICROBIOLOGY SPECIMEN (COV19 SITE)

MICROBIOLOGY SPECIMEN (SWAB SITE)

MICROBIOLOGY SPECIMEN (COVID TEST)

DM=DEMOGRAPHICS

DEMOGRAPHY

REACTOGENICITY DIARY

DS=DISPOSITION

MAIN INFORMED CONSENT

DISPOSITION-SCREENING

RANDOMIZATION

TREATMENT UNBLINDED

WITHDRAWALOFCONSENT

DISPOSITION-TREATMENT

DISPOSITION - FOLLOW-UP

INFORMED CONSENT - FURTHER VACCINATION

DISPOSITION - SCREENING FOR FURTHER VACCINATION

INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

EC=EXPOSURE AS COLLECTED

VACCINATION

VACCINATION

EX=EXPOSURE

VACCINATION

VACCINATION

FA=FINDINGS ABOUT EVENTS OR INTERVENTIONS

VACCINATION DIARY

VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

HEALTH CARE UTILIZATION

UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

HO=HEALTHCARE ENCOUNTERS

HEALTH CARE UTILIZATION

HOSPITALIZATION DETAILS

IE=INCLUSION/EXCLUSION CRITERIA NOT MET

INCLUSION/EXCLUSION CRITERIA (INCEXCS)

INCLUSION/EXCLUSION CRITERIA (INC EXCS)

INCLUSION/EXCLUSION CRITERIA (INC EXCS)

INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

INCLUSION/EXCLUSION CRITERIA (INC EXC NS)

INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

INCLUSION/EXCLUSION CRITERIA (INC EXC)

INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)

IS=IMMUNOGENICITY SPECIMEN ASSESSMENTS

ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION

ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

LB=LABORATORY TEST RESULTS

CENTRAL LAB SAMPLE COLLECTION - BASELINE

LAB URINALYSIS - PREGNANCY TEST

CENTRAL LAB SAMPLE COLLECTION

LAB CHEMISTRY

LABORATORY DATA - HEMATOLOGY

LOCAL LABORATORY DATA - REPEATING CHEMISTRY

LOCAL LABORATORY DATA - REPEATING CHEMISTRY

LOCAL LABORATORY DATA - REPEATING HEMATOLOGY

OXYGENATION PARAMETERS

MB=MICROBIOLOGY SPECIMEN

MICROBIOLOGY SPECIMEN (COV19 SITE)

CENTRAL LAB SAMPLE COLLECTION - BASELINE

ELECTRONIC SAMPLE TRACKING - NASAL SWAB

MICROBIOLOGY SPECIMEN (SWAB SITE)

CENTRAL LAB SAMPLE COLLECTION

MICROBIOLOGY SPECIMEN (COVID TEST)

ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

ELECTRONICSAMPLE 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



C	C4591001: ADVERSE EVENT REPORT (AE) - Repeating Form												
#	Category AE			Is the		Serious		Relationship				Caused Study	
	Identifie	r Event	Date	Event Still	Grade		Result of a Medication Error		Taken with Study	Medication Given	Given	Discontinuation	Event Number
				Ongoing					Treatment				Number
1													
_	verse Event Repoi												
1.	Category: [Category]	OAD	VERSE	EVENT	ECAT								
2.	AE ID: [AE Identifier]	AE	SPID										
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms) [Adverse Event]	AE	TERN	1									
4.	Start Date Time: [Start Date]	- 1: =	/ -	✓ / ✓ 24-ho	our clock	ESTDT	C						
5.	Is the adverse eve still ongoing? [Is the Adverse Event Still Ongoin	O NC		~ /		EEND		ITPT= LAS	T SUBJE	CT ENCOU	INTER		
6.	Toxicity Grade: [Toxicity Grade]	03 04		XGR									
7.	Is the adverse everser ous? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hosp talization or prolongat on of existing hosp talization; Persistent or signif cant disabil ty/incapac (Congenital anomaly/birth defect; Important med cal event (i.e may jeopardize subject and may require med cal/surgical intervention to prevent above outcomes). [Serious]	Is Office of the control of the cont	this serves NO this s	erious even AESDTH erious even AESHO	ent result ent requir SP ent result AB at life three	in death: e or prolo in persist	? ong hospitali: tent or signif	nomaly or birth					
8.	Is this adverse event the result of study Medication Error? If Yes, record the type of medication error on the Medication Error Log. [Is AE a Result of Medication Error]	a	,	MERES		PPAE							
9.	Is this event relation study treatmen [Relationship to Study Treatment]	t: If I	OTHER If Othe LATED	OMITANT OMITANT R er, specify ERELT	udy treat DRUG TR NON-DRU : XT in S	EATMENT JG TREAT	MENT ALT	due to:					
10	with Study	NC NC	.og wi T APPL	THDRAWN	AEA(JN.							

			AE=Adverse Events
	Treatment: [Act on Taken with Study Treatment]		
11.	Was a Concomitant Medication given? [Concom tant Med cat on Given]	YES AECONTRT AECMGIV in SUPPAE	
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	O YES AECONTRT AENDGIV in SUPPAE	
13.	What was the outcome of this adverse event?: [Outcome]	FATAL NOT RECOVERED/NOT RESOLVED RECOVERED/RESOLVED RECOVERED/RESOLVED WITH SEQUELAE RECOVERING/RESOLVING UNKNOWN	
14.	D d the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	O YES NO AESUBJDC in SUPPAE Linked to related DS record via RELREC	
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 [hidden] [High Level Term]	AEHLT	
22.	High Level Term Code [hidden] [High Level Term Code]	AEHLTCD	
23.	High Level Group Term [hidden] [High Level Group Term]	AEHLGT	
24.	High Level Group Term Code [hidden] [High Level Group Term Code]	AEHLGTCD	
25.	Primary System Organ Class [hidden] [Primary System Organ Class]	AEBODSYS AESOC	
26.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	AEBDSYCD AESOCCD	

S7	LB=Laboratory Test Results								
C4	1591001: LABORATORY DATA - HI	EMATOL	OGY (CD4)						
Lal	boratory Data Hematology								
1.	Lab Panel: [Category for Lab Test]	O HEMAT	OLOGY LBCAT						
2.	Laboratory Name and Address [Vendor Name (DERIVED)]	LBNAI	LBNAM						
3.	Collection Date: [Collect on Date:]	<u> </u> /	<u> </u>						
4.	Specimen Type: [Specimen Type]	Specimen Type]							
Lal	Lab Result								
#			Test:	Result:	Not Done:	Lab Normal R	ange		
5.a	1		CD4_PX4722						
La	b Result Entry								
5.1	Sponsor ID: [Sponsor-Defined Identifier]		LBSPID						
5.2	Test: [Test:]	OCD4_I	LBTEST						
5.3	Result: [Result:]	LBOI	RRES						
5.4	Not Done: [hidden] [Not Done:]	O NOT [DONE LBSTAT						
5.5 LNMT [Lab Normal Range] LBORNRLO High LBORNRHI Un t 10^3/mm3 LBORRESU //uL %									

C	4591001: COHORT SELECTION (COHORT SEL) NOT SUBMITTED								
Cc	Cohort Selection								
DO	DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.								
1.	Select appropriate response - Protocol version [Trigger Response 1]								
2.	Select appropriate response - What cohort does the subject belong to? [Trigger Response 10]	STAGE 1 SENTINEL COHORTS STAGE 1 NONSENTINEL COHORTS STAGE 2 COHORTS STAGE 3 COHORTS							

ST	STUDYID CM=Concomitant Medications											
C4	591001: CONCO	MITANT MEDICA	TIONS - BASELINE (CON	MED BSL) - R	epeating For	m						
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Prespecified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date			
1												
Con	comitant Medications											
1.	What is the medication [Sponsor-Defined Identi		CMSPID	CMSPID								
2.	Category: [Category for Medication	n]	○ GENERAL CONCOMITANT MEDICATIONS CMCAT									
3.	Concomitant Medication [Concom tant Medication		○NO NOT SUBMITTED									
4.	Med cation:		CMTRT									
	Prov de the complete ge (including salt form, wh generic name is unknow proprietary name. Inclu in the Med cat on text (e route, use, formulation) [Name of Medication]	ere applicable). Where in, enter the full trade o de clarifying informatior e.g., Ingredient(s),										
5.	Dose: [Dose Description]		CMDOSE CMDOSTXT	CMDOSE CMDOSTXT								
6.	Dose Unit: [Dose Unit]		™ CMDOSU									
7.	Dose Frequency: [Dose Frequency]		<u>CMDOSFRQ</u>									
8.	Route: [Route]		™ CMROUTE									
9.	Start Date: [Start Date]		V / V CMS	TDTC								
10.	Comparison Term [hiddle [Comparison Term]	en]	NOT SUBMITTED									
11.	Standardized Med cat or derived. [hidden] [Standardized Med cat or	•	CMDECOD									
12.	Standardized Med cat or derived [hidden]	,	CMCO	DE in SUPPCM	1							

Si	TUDYID					CM=C	oncomitant Med	dications
C	4591001: CONCOMITANT	MEDICA	TIONS - NON S	TUDY VACCINA	TIONS (CONMED	VAX) -	Repeating Forn	1
#	Sponsor-Defined Identifier	Categor	ory for Medication Concomitant Medications Pre-specifie			d N	ame of Medication	Start Date
1								
Concomitant Medications								
1.	What is the medication identifier? [Sponsor-Defined Identifier]		CMSPID					
2.	Category: [Category for Med cat on]		OVACCINATIONS	CMCAT				
3.	Concomitant Medications Pre-specifie [Concomitant Medications Pre-specifi		ONO NOT SUBI	MITTED				
4.	Medication: Provide the complete gener c drug na (including salt form, where applicable generic name is unknown, enter the or proprietary name. Include clarifyir information in the Med cat on text (e. Ingredient(s), route, use, formulation [Name of Medication]	e). Where full trade ig g.,	CMTRT					
5.	Date: [Start Date]		<u> </u> <u> </u> /	™ CMSTDTC				
6.	Comparison Term [hidden] [Comparison Term]		NOT SUBMIT	TED				
7.	Standardized Medicat on Name - Dict derived. [hidden] [Standardized Med cat on Name]	onary	CMDECOD					
8.	Standardized Med cat on Code - Dicti derived [hidden] [Standardized Med cat on Code]	onary		CMCODE in S	SUPPCM			

C4591001: MAIN INFORMED CONSENT (CONSENT)

Informed Consent

1. Consent Was:

[Consent Was:]

| OBTAINED | Date Written Consent Obtained | DSTERM/DSDECOD=INFORMED CONSENT OBTAINED | DSTAINED | DSTAINED | DSTERM/DSDECOD=INFORMED CONSENT OBTAINED | DSTAINED | DSTAIN

SV=Subject							
C	4591001: CONTACT OU	TCOME - MONTH 1 (CONTACT 1M)					
C	ontact Outcome						
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	© CONTACT OUTCOME NOT SUBMITTED					
2.	Contact Type: [Type of Contact/Visit]	OCLINIC VISIT OTELEHEALTH VISIT					
3.	Was contact made? [Was Contact Made]	Date of Contact:					
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED					

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

S	TUDYID	SV=Subject Visits							
C	C4591001: CONTACT OUTCOME (CONTACT SV)								
Co	ontact Outcome								
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	OCONTACT OUTCOME NOT SUBMITTED							
2.	Contact Type: [Type of Contact/Visit]	TELEPHONE VISIT SVREFID							
3.	Was contact made? [Was Contact Made]	O YES Date of Contact: V / V V SVSTDTC NO If No, why?							
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED							

Sī	TUDYID		Sv=Subject visits						
C	4591001: CONTACT OU	TCOME - UNPLANNED (CONTACT UV)							
Co	Contact 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]	Date of Contact: V							
4.	Comments: [Comments/Findings/Details]	NOT SUBMITTED							

S7	TUDYID		MB=Microbiology Specimen	DI=Device Identifie	ers CO=Comments		
C	4591001: MICROBIOLO	GY SPECIMEN (CO	V19 SITE) - Repeating Form ME	BCAT=CONFIRMATIO	N OF I	INFECTION	
#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	t Comments:	
1							
Mi	crobiology Specimen						
1.	Actual Date of Collection: [Date of Collection]	<u> </u>	MBDTC				
2.	Specimen Type: [Specimen Type]	SERUM BLOOD PLASMA					
3.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP S	YNDROME CORONAVIRUS 2 MBTEST				
4.	Device Type: [Device Type]	SARS-COV-2 DIAGNOS	TIC TEST DIVAL when DIPARMCD =	DEVTYPE			
5.	Test Result: [Result]	O POSITIVE O NEGATIVE O INDETERMINATE	ES when MBTESTCD = SARSCOV	2			
6.	Comments/Findings/Details: [Comments:]	COVAL when RDON	MAIN = MB				

S	TUDYID			MB=Mi	MB=Microbiology Specimen			rice Id	CO=Comments	
C	4591001: MI	CROBIOLO	GY SPECIMEN (OVID TES	T) - Repeating	Form M	BCAT=C	ONFIR	MATION O	F INFECTION
#	1	Specimen Type	Specimen Collect Location	ion As	ssay Code and Description	Device Type	Trade Name		Comments:	Trade Name Other, Specify
1										
М	icrobiology Specia	men								
1.	Actual Date of Col [Date of Collection		<u> </u>	✓ MBDTC						
2.	Specimen Type: [Specimen Type]			○ SWABBED MATERIAL ○ RESPIRATORY SECRETIONS MBSPEC						
3.	Specimen Collecti [Specimen Collect		○ NASOPHARYNX ○ LOWER RESPIRATORY SYSTEM MBLOC ○ THROAT							
4.	Assay Code and D [Assay Code and I		SEVERE ACUTE RES	P SYNDROME CORONAVIRUS 2 MBTEST						
5.	Device Type: [Device Type]		SARS-COV-2 DIAGN	IOSTIC TEST	IVAL when DIP	ARMCD =	DEVTYP	E		
6.	Trade Name: [Trade Name]		☑ DIVAL wh	en DIPARM	ICD = TRADEN	AM .				
7.	Test Result: [Result]		O POSITIVE O NEGATIVE O INDETERMINATE	MBORRES I	when MBTEST(CD = SAR	SCOV2			
8.	Comments/Finding [Comments:]	gs/Details:	COVAL when	RDOMAIN	= MB					
9.	Trade Name Othe [Trade Name Othe		SUPPMB in TR	PADEOTH						

ST	TUDYID DD=Death Details			
C4:	C4591001: DEATH DETAILS CODED (DEATH DTL) DDCAT = DEATH DETAILS CODED			
Death Details				
	Pate of Collect on / Notification f Death:	✓/ ✓ / DDDTC		
] [Date of Collect on / Notif cat on f Death]			
		Cause of Death Status	Cause of Dea	th
2.				
Cau	se of Death Entry			
2.1	Cause of Death Status: [Cause of Death Status]	O PRIMARY CAUSE OF DEATH O 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		
2.6	Dict onary-Derived Term [hidden] [Dictionary-Derived Term]	DDSTRESC		
2.7	Preferred Term Code [hidden] [Preferred Term Code]	NOT SUBMITTED		
2.8	High Level Term [hidden] [High Level Term]	NOT SUBMITTED		
2.9	High Level Term Code [hidden] [High Level Term Code]	NOT SUBMITTED		
2.10	High Level Group Term [hidden] [High Level Group Term]	NOT SUBMITTED		
2.11	High Level Group Term Code [hidden] [High Level Group Term Code]	NOT SUBMITTED		
2.12	Primary System Organ Class [hidden] [Primary System Organ Class]	NOT SUBMITTED		
2.13	Primary System Organ Class Code [hidden] [Primary System Organ Class	NOT SUBMITTED		

S	STUDYID DM=Demographics				
C	C4591001: DEMOGRAPHY (DEMOG)				
De	emography				
1.	Subject ID [Subject ID]	SUBJID			
2.	Birth Date: [Birth Date]	BRTHDTC			
3.	Sex: [Sex]	○ FEMALE SEX			
4.	Ethnicity: [Ethnicity]	O HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN O NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT REPORTED			
5.	Race: (Check X all that apply): [Race Of Subject]	BLACK OR AFRICAN AMERICAN AMERICAN INDIAN OR ALASKA NATIVE ASIAN NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WHITE NOT REPORTED			
6.	Racial Designation: [Racial Designat on]	OTHER RACIALD in SUPPDM			

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

STUDYID		inked to related AE record via RELREC DS=Disposition
С	4591001: DISPOSITION - SCREENING FOR	FURTHER VACCINATION (DISP RESCR) DSCAT = DISPOSITION EVENT
D	sposition - Screening for Further Vaccination	
1.	Date of Complet on/Discontinuation/Death: [Date of Completion/Discontinuation/Death:]	DSSTDTC
2.	Phase of Disposition: [Disposition Phase]	OREPEAT SCREENING 1 DSPHASE in SUPPDS
3.	Status: [Status]	<u> ✓ DSDECOD</u>
4.	Specify Status: [Specify Status]	DSTERM

S	TUDYID	Linked to related AE record via RELREC DS=Disposition			
C	4591001: DISPOSITION - SCREENING (DISP SCR) DSCAT = DISPOSITION EVENT				
Di	sposition - Screening				
1.	Date of Complet on/Discontinuation/Death [Date of Completion/Discontinuation/Death]	✓/ ✓/ ✓ DSSTDTC			
2.	Phase of Disposition: [Disposition Phase]	OSCREENING DSPHASE in SUPPDS			
3.	Status: [Status]	DSDECOD DSDECOD			
4.	Specify Status: [Specify Status]	DSTERM			

STUDYID		Linked to related AE record via RELREC DS=Disposition
C	4591001: DISPOSITION - TREATMENT (ISP TRT) DSCAT = DISPOSITION EVENT
Di	sposition - Treatment	
1.	Date of Complet on/Discontinuation/Death: [Date of Completion/Discontinuation/Death:]	▼/ ▼/ DSSTDTC
2.	Phase of Disposition: [Disposition Phase]	OVACCINATION DSPHASE in SUPPDS OPEN LABEL TREATMENT
3.	Status: [Status]	DSDECOD
4.	Specify Status: [Specify Status]	DSTERM

C4591001: DATE OF VISIT (DOV)

Date of Visit

1. Date of Visit
[Date of Visit]

2. Erroneous Visit
[Visit Error]

SV=Subject Visits

V | V | SVSTDTC | SVENDTC when UNPLANNED VISITS

S	STUDYID		SV=Subject Visits		
С	4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)				
D	ate of Visit				
1.	Date of Visit [Date of Visit]	▼/ ▼/ SVSTDTC			
2.	Erroneous Visit [Visit Error]	© ERRONEOUS VISIT NOT SUBMITTED			
C	COVID-19 Illness Visit				
3.	COVID-19 Illness Visit:	▼ VISIT			

S	TUDYID		SV=Subject Visits		
С	C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)				
Da	ate of Visit				
1.	Date of Visit [Date of Visit]	▼/ ▼/ SVSTDTC			
2.	Erroneous Visit [Visit Error]	© ERRONEOUS VISIT NOT SUBMITTED			
C	COVID-19 Illness Visit				
3.	COVID-19 Illness Visit:	▼ VISIT			

S	TUDYID		SV=Subject Visits
С	C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV)		
Da	ate of Visit		
1.	Date of Visit [Date of Visit]	SVSTDTC SVENDTC when UNPLANNED VISITS	
2.	Erroneous Visit [Visit Error]	© ERRONEOUS VISIT NOT SUBMITTED	
COVID-19 Surveillance Visit			
3.	COVID-19 Surveillance Vist: [COVID-19 Surveillance Visit]	™ NOT SUBMITTED	

S	TUDYID	SV=Subject Visits			
С	4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)				
D	Date of Visit				
1.	Date of Visit [Date of Visit]	▼/ ▼/ SVSTDTC			
2.	Erroneous Visit [Visit Error]	© ERRONEOUS VISIT NOT SUBMITTED			
C	COVID-19 Repeat Swab				
3.	COVID-19 Repeat Swab:	VISIT			

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

S7	TUDYID			LB=L	aboratory Test Results
C	591001: LAB CHEMISTRY (HIV RN	A)			
Lal	Chemistry Details				
1.	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY LBCAT			
2.	Laboratory Name and Address [Vendor Name]	LBNAM			
3.	Collection Date: [Collect on Date:]	LBDTC			
4.	. Specimen Type: [Specimen Type] BLOOD LBSPEC				
La	Result				
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.8	1	HIV RNA (Ultrasensitive)			
La	b Result Entry				
5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSPID			
5.2	Test: [Test:]	OHIV RNA (Ultrasens tive) LBTEST			
5.3	Result: [Result:]	LBORRES			
5.4	Not Done: [hidden] [Not Done:]	ONOT DONE LBSTAT			
5.5	LNMT [Lab Normal Range]	LBORNRLO High LBORNRHI Un t ()/mL LBORRESU			

ST	UDYID	HO=Healthcare Encoun	ters FA=Findings About Events or Interventions			
C4	 591001: HEALTH CA	ARE UTILIZATION (HLTHCARE)	ALTHCARE FACAT=HEALTHCARE			
	alth Care Utilization	UTILIZATIO	N ASSESSMENT UTILIZATION			
	Evaluation Interval: [hidden] [Evaluation Interval]	SINCE THE START OF THE RESPIRATORY ILLNESS EF	risode <mark>HOEVINTX FAEVINTX </mark>			
	Disease Name: [hidden] [Disease Name]	RESPIRATORY ILLNESS HCUIDIS in SUPPHO				
Hea	alth 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				
Physician or Healthcare Professional: [Type of Practitioner] PHYSICIAN PRIMARY CARE PHYSICIAN URGENT CARE TELEPHONE CONSULTATION OTHER						
3.3	3.3 Occurrence of Visits or Contacts: [Occurrence of Vis ts or Contacts] Over the contact of Visits or Contact o					
Health Care Utilization Other						
	4. Other Type of Pract tioner Specify: [Other Type of Pract t oner Specify]					
Hea	alth Care Utilization					
	Has the subject been hospitalized due to potential COVID-19 illness? [Been Hospitalized]	YES HCUHSP in SUPPHO Has the subject been in intensive care due to potenti YES NO NO NO	al COVID-19 illness?			

HO=Healthcare Encounters STUDYID C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form **Hospitalization Term Admission Date Hospitalization Category** Ongoing 1 **Hospitalization Details** OHOSPITALIZATION STATUS HOCAT 1. Hosp talization Category: [Hospitalization Category] **HOTERM** 2. Hosp talization Term: OICU OHOSPITAL [Hospitalization Term] **▼** HOSTDTC 3. Admission Date: **v** / [Admission Date] 4. Ongoing? YES HOENRTPT= ONGOING HOENTPT= ONGOING AT CURRENT VISIT [Ongoing] ONO Discharge Date: HOENDTC

ST	UDYID		CE=Clinical Events				
	C4591001: ILLNESS DETAILS (ILL POTEN) CECAT = EFFICACY						
	ess Details						
1.	Category of Clinical Event: [Category of Clin cal Event:]	OPOTENTIAL COVID-19 ILLNESS NOT SUBMITTED					
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	YES Respiratory Illness Diagnosis: CETERM Date of Diagnosis:					
3.	Toxicity Grade: [Toxicity Grade]	0 0 1 02 03 04 05					
4.	Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED					
5.	Lowest Level Term [hidden] [Lowest Level Term]	CELLT					
6.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	CELLTCD					
7.	D ctionary Derived Term [hidden] [D ctionary Derived Term]	CEDECOD					
8.	Preferred Term Code [hidden] [Preferred Term Code]	CEPTCD					
9.	High Level Term [hidden] [High Level Term]	CEHLT					
10.	High Level Term Code [hidden] [High Level Term Code]	CEHLTCD					
11.	High Level Group Term [hidden] [High Level Group Term]	CEHLGT					
12.	High Level Group Term Code [hidden] [High Level Group Term Code]	CEHLGTCD					
13.	Primary System Organ Class [hidden] [Primary System Organ Class]	CEBODSYS CESOC					
14.	Primary System Organ Class Code [hidden] [Primary System Organ Class	CEBDSYCD CESOCCD					

ST	JDYID	CE=Clinical Ever	nts
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 CECAT	
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	SIGNIFICANT ACUTE RENAL DYSFUNCTION SIGNIFICANT ACUTE HEPATIC DYSFUNCTION CESCAT SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION	
3.	Was a diagnosis obtained? [Diagnosis Obtained]	YES Diagnosis: CETERM Start Date: YES Ongoing?: YES NO End Date: YES NO NO NO NOT SUBMITTED CEENTPT= LAST SUBJECT ENCOUNTER NO NO NOT SUBMITTED	
4.	Toxicity Grade: [Toxicity Grade]	01 02 03 CETOXGR 04 05	
5.	Comparison Term: [hidden] [Comparison Term]	NOT SUBMITTED	
6.	Lowest Level Term [hidden] [Lowest Level Term]	CELLT	
7.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	CELLTCD	
8.	D ctionary Derived Term [hidden] [D ctionary Derived Term]	CEDECOD	
9.	Preferred Term Code [hidden] [Preferred Term Code]	CEPTCD	
10.	High Level Term [hidden] [High Level Term]	CEHLT	
11.	High Level Term Code [hidden] [High Level Term Code]	CEHLTCD	
12.	High Level Group Term [hidden] [High Level Group Term]	CEHLGT	
13.	High Level Group Term Code [hidden] [High Level Group Term Code]	CEHLGTCD	
14.	Primary System Organ Class [hidden] [Primary System Organ Class]	CEBODSYS CESOC	
15.	Primary System Organ Class Code [hidden] [Primary System Organ Class	CEBDSYCD CESOCCD	

ST	CE=Clinical Events							
C4	591001: ILLNESS DET/	AILS - SEVI	ERE (ILL SEVE	RE) - Repeating	Form			
#	Category of Clinical Ev	vent:	Subcateg	ory of Clinical Event		Diagnosis Obtained		Toxicity Grade
1								
_	ess Details	O CEVERE COV	/ID 10 ILLNESS -					
1.	Category of Clinical Event: [Category of Clin cal Event:]	O SEVERE CON	/ID-19 ILLNESS CE	CAT				
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	SIGNIFICAN	T ACUTE RENAL DYS T ACUTE HEPATIC DY T ACUTE NEUROLOG	SFUNCTION CESC	AT			
3.	Was a diagnosis obtained? [Diagnosis Obtained]	End Date	EENRTPT= ONG	TDTC GOING/BEFORE EENDTC	CEENTPT	= LAST SUBJECT	ENCOL	JNTER
4.	Toxicity Grade: [Toxicity Grade]	01 02 03 04 05						
5.	Comparison Term: [hidden] [Comparison Term]	NOT SUBI	MITTED					
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]	CEBODSY	CESOC CESOC					
15.	Primary System Organ Class Code [hidden] [Primary System Organ Class		CEBDSYCD	CESOCCD				

S	STUDYID MO=Morphology							
C	C4591001: IMAGING (IMAGING) - Repeating Form MOCAT=CLINICAL ASSESSMENT OF RADIOGRAPHS - IMAGING							
#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment				
1								
In	naging							
1.	Date of Assessment: [Date of Assessment]	✓/ ✓/ MODTC						
2.	[Location of Assessment]	CHEST MOLOC OTHER If other, specify: LOCOTH in SUPPMO						
3.	[Imaging Method]	CT SCAN X-RAY WOMETHOD 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						

37	77	ח'	VI	ח	
) I	U	U	T I	v	

C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3) Study eligibility requires subjects to meet all inclus on criteria (YES) and Not meet exclusion criteria (NO) # Inclusion Number **Criterion Description** Criterion met? Criterion ID: (For Pfizer use only) 1.a Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 IN01A00 vears, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study 1.b 2 Participants who are willing and able to comply wth all scheduled vists, vaccination plan, IN02A00 laboratory tests, lifestyle cons derat ons, and other study procedures IN03A00 Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study Capable of giving personal signed informed consent, which includes compliance with the 1.d 4 IN04A00 requirements and restrictions listed in the ICD and in this protocol IECAT = INCLUSION **Inclusion Criteria Entry** 1.1 Inclusion Number: $\bigcirc 1$ [Inclusion Number] **IESPID** 02 **3** 04 Cr terion Description: [Criter on Descript on] **IETEST** Cr terion met? O YES **IEORRES** [Criter on met?] ON O Describe details if relevant IEDESC in SUPPIE 1.4 Cr terion ID: (For Pfizer use IN01A00 O IN02A00 IETESTCD only) [Criter on ID: (For Pfizer use O0A001 only)] IN04A00 **Exclusion Criteria** Criterion met? Criterion ID: (For Pfizer use only) # Exclusion Number **Criterion Description** Other medical or psychiatric condition incl. recent (within past year) or active suicidal 1 EX01A00 deation/behavior/lab abnormal ty that may increase the risk of study participation 2.b 2 Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or EX02A00 hepatitis B virus (HBV) 3 EX03A00 History of severe adverse reaction associated with a vaccine and/or severe allergic 2.c reaction (eg, anaphylaxis) to any component of the study intervention(s) 4 Receipt of medicat ons intended to prevent COVID-19 EX04A00 8 Immunocompromised indiv duals with known or suspected immunodeficiency, as EX08A00 2.e determined by history and/or laboratory/phys cal examination 2.f 9 Individuals with a history of autoimmune disease or an active autoimmune disease FX09A00 requiring therapeutic intervention EX10A00 10 Bleeding diathesis or condition associated with prolonged bleeding that would, in the 2.g opinion of the investigator, contraindicate intramuscular inject on 2.h 11 Women who are pregnant or breastfeeding EX11A00 12 EX12A00 Previous vaccinat on with any coronavirus vaccine Individuals who receive immunosuppressive therapy, such as cytotoxic agents or 13 EX13A00 systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are permitted 14 Receipt of blood/plasma products or immunoglobulin, from 60 days before study EX14A00 intervention administrat on or planned receipt throughout the study 2.1 15 Participation in other studies involving study intervention w thin 28 days pr or to study EX15A00 entry and/or during study participation 2.m 16 Previous part cipation in other studies involving study intervent on containing lip d EX16A00 nanopart cles 21 EX21A00 2.n 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 **Exclusion Criteria Entry** Exclusion Number: [Exclusion Number] Cr terion Description: [Criter on Descript on] Cr terion met? O YES IEORRES [Criter on met?] Describe details if relevant

IEDESC in SUPPIE

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STODYID							
C4:	591001: INCL	USION/	EXCLUSION CRITERIA (IN EX STG3)				
			meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).				
Incl	usion Criteria		· , , , , , , , , , , , , , , , , , , ,				
#	Inclusion Number		Criterion Description	Criterion met? Criterion ID: (For Pfizer use only			
1.a	1		nale part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 isive, or 18 and 85 years, inclusive, at randomization (dependent upon study	IN01A00			
1.b	2		s 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		rticipants who are determined by medical history, physical examination, and gment of the investigator to be eligible for inclusion in the study	IN03A00			
1.d		requiremer	giving personal signed informed consent, which includes compliance with the ots and restrictions listed in the ICD and in this protocol	IN04A00			
Incl	usion Criteria Entr	y IECAT	= INCLUSION				
1.1	Inclusion Number: [Inclusion Number]		01 02 03 04				
1.2	Cr terion Description [Criter on Descript o		▼ IETEST				
1.3	Cr terion met? [Criter on met?]		YES IEORRES NO Describe details if relevant IEDESC in SUPPIE				
1.4	Cr terion ID: (For Pf only) [Criter on ID: (For P only)]		○ IN01A00 ○ IN02A00 ○ IN03A00 ○ IN04A00				
_	usion Criteria						
7 -	Exclusion Number		Criterion Description	Criterion met? Criterion ID: (For Pfizer use only			
2.a	1	deation/b	iical or psychiatric condition incl. recent (within past year) or active suicidal ehavior/lab abnormal ty that may increase the risk of study participation	EX01A00			
2.b	2	hepatitis B	ection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or virus (HBV)	EX02A00			
2.c	3		severe adverse reaction associated with a vaccine and/or severe allergic g, 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		mpromised indiv duals w th known or suspected immunodeficiency, as d by history and/or laboratory/phys cal examination	EX08A00			
2.f	10		iathesis or condition associated w th prolonged bleeding that would, in the the investigator, contraindicate intramuscular inject on	EX10A00			
2.g	11	Women wi	no are pregnant or breastfeeding	EX11A00			
2.h	12	Previous v	accinat on with any coronavirus vaccine	EX12A00			
2.i	13	Subjects w cort coster	tho receive immunosuppressive therapy, such as $\operatorname{cytotox} \operatorname{c}$ agents or systemic oids	EX13A01			
2.j	15		blood/plasma products or immunoglobulin, from 60 days before study on 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			or s te staff or Pfizer employees directly involved in the conduct of the study, therwise supervised by the investigator, and their respective family members	EX21A01			
Exc	lusion Criteria Entr	y IECAT	= EXCLUSION				
	Exclusion Number: [Exclusion Number]		▼ IESPID				
2.2	Cr terion Description [Criter on Descript o		■ IETEST				
2.3	Cr terion met? [Criter on met?]		YES IEORRES Describe details if relevant				
			IEDESC in SUPPIE				

ONO

2.4 Cr terion ID: (For Pfizer use

IETESTCD

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





C4	C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)						
Stud	dy eligibility requires	subjects to	meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).				
	usion Criteria						
_	Inclusion Number		Criterion Description	Criterion met? Criterion ID: (For Pfiz	er use only)		
1.a	1		nale 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 with all scheduled visits, vaccination plan, tests, lifestyle considerations, 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	4		giving personal signed informed consent, which includes compliance with the ts and restrictions listed in the ICD and in this protocol	IN04A00			
Inc	lusion Criteria Entr	y IECAT	= INCLUSION				
1.1	Inclusion Number: [Inclusion Number]		1				
1.2	Cr terion Description [Criter on Descript o		✓ IETEST				
1.3	1.3 Cr terion met? [Criter on met?]		YES IEORRES NO Describe details if relevant IEDESC in SUPPLE				
1.4	Crterion ID: (For Pfonly) [Criter on ID: (For Ponly)]		○ IN01A00 ○ IN02A00 ○ IN03A00 ○ IN04A00				
_	lusion Criteria						
# 2.a	Exclusion Number		Criterion Description ical or psychiatric condition incl. recent (within past year) or active suicidal	Criterion met? Criterion ID: (For Pfize EX01A00	er use only)		
2.b	2	deation/be	chavior/lab abnormal ty that may increase the risk of study participation	EX02A00			
2.c	3	hepatitis B	virus (HBV) severe adverse reaction associated with a vaccine and/or severe allergic	EX03A00			
2.d	4	· •	g, anaphylaxis) to any component of the study intervention(s) medicat ons intended to prevent COVID-19	EX04A00			
2.u 2.e	8	· ·	mpromised indiv duals with known or suspected immunodeficiency, as	EX08A00			
	9	determined	d by history and/or laboratory/phys cal examination				
2.f		requiring t	with a history of autoimmune disease or an active autoimmune disease herapeutic intervention	EX09A00			
2.g	10		iathesis or condition associated w th prolonged bleeding that would, in the the investigator, contraindicate intramuscular inject on	EX10A00			
2.h	11		no are pregnant or breastfeeding	EX11A00			
2.i 2.j	12		accinat on with any coronavirus vaccine ho receive immunosuppressive therapy, such as cytotox c agents or systemic	EX12A00 EX13A01			
2.k	15	cort coster		EX14A01			
2.1	16		n administrat on or planned receipt throughout the study on in other studies involving study intervention w thin 28 days pr or to study	EX15A01			
		entry and/	or during study participation				
	2.m 17 Previous part cipation in other studies involving study intervent on containing lip d nanopart cles			EX16A01			
2.n	22	site staff o	or s te staff or Pfizer employees directly involved in the conduct of the study, therwise supervised by the investigator, and their respective family members	EX21A01			
	lusion Criteria Entr	y IECAT					
	Exclusion Number: [Exclusion Number]		<u> ✓ [ESPID</u>				
	Cr terion Description [Criter on Descript o		✓ IETEST				
2.3	Cr terion met? [Criter on met?]		YES IEORRES Describe details if relevant				
			IEDESC in SUPPIE				

	○ NO
Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	▼ IETESTCD

S 7	TUDYID	IE=Inclusion/Exclusion Criteria Not Met				
C 4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)					
	Criterion	Description				
1.						
Inc	iclusion Criteria Not Met Entry					
1.1	1 Description of Inclusion Cr terion Not Met [Criter on Descript on]					
	Criterion	Description				
2.						
Ex	cclusion Criteria Met Entry					
2.1	1 Description of Exclusion Cr terion Met [Criter on Descript on]					



3/0	STODYID							
C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)							
Stud	ly eligibility requires :	subjects to i	meet all i	inclus on crite	eria (YES) and Not meet exclusion criteria (NO).			
Incl	usion Criteria	-			• • • • • • • • • • • • • • • • • • • •			
#	Inclusion Number				Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)	
_	1	Male or fem			een the ages of 18 and 55 years, inclusive, 65 and 85 ars, inclusive, at randomization (dependent upon study		IN01A00	
1.b	2				able to comply wth all scheduled vists, vaccination plan, rat ons, and other study procedures		IN02A00	
1.c	3				ermined by medical history, physical examination, and tor to be eligible for inclusion in the study		IN03A00	
1.d	4				f informed consent, which includes compliance with the ed in the ICD and in this protocol		IN04A00	
Incl	usion Criteria Entr	y IECAT	= INCL	USION				
1.1	Inclusion Number: [Inclusion Number]		01 02	ESPID				
	. ,		03					
1.2	Cr terion Description [Criter on Descript o		~	IETEST				
1.3	Cr terion met? [Criter on met?]		O YES	IEORRES				
			_	ribe details it	relevant			
			IEI	DESC in S	CUPPIE			
1.4	Cr terion ID: (For Pfi only) [Criter on ID: (For P only)]		O IN01 O IN02 O IN03 O IN04	A00 IETE	STCD			
F	usion Criteria							
#	Exclusion Number	<u>.</u>			Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)	
	1	Other med			dition incl. recent (within past year) or active suicidal	Criterion metr	EX01A00	
2.b	2				ty that may increase the risk of study participation number that may increase the risk of study participation or the that may be supported by the study of the st		EX02A00	
2.c	3	hepatitis B History of s			on associated with a vaccine and/or severe allergic		EX03A00	
2.d	4	,		· · ·	y component of the study intervention(s) to prevent COVID-19		EX04A00	
2.e		· ·			inical or microbiolog cal diagnosis of COVID-19		EX05A00	
_	8			<u> </u>				
		determined	d by histo	ory and/or lal	s w th known or suspected immunodeficiency, as poratory/phys cal examination		EX08A00	
2.g	10				ssociated with prolonged bleeding that would, in the raindicate intramuscular inject on		EX10A00	
2.h	11	Women wh	no are pr	egnant or bre	astfeeding		EX11A00	
2.i	12	Previous va	accinat o	n with any co	ronavirus vaccine		EX12A00	
2.j	13	Subjects w cort coster		ve immunosu	ppressive therapy, such as cytotox c agents or systemic		EX13A01	
2.k	15				s or immunoglobulin, from 60 days before study anned receipt throughout the study		EX14A01	
2.1	16			er studies inv study partic	olving study intervention w thin 28 days pr or to study ipation		EX15A01	
2.m	17	Previous pa		on in other st	udies involving study intervent on containing lip d		EX16A01	
2.n	2.n 22 Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members				EX21A01			
Exc	usion Criteria Entr	IECAT		LUSION				
2.1	Exclusion Number: [Exclusion Number]		~	IESPID				
2.2	2.2 Cr terion Description: [Criter on Descript on]		~	IETEST	_			
2.3	Cr terion met?	-	O YES	IEORRE	S			
	[Criter on met?]		_	ribe details it	relevant			
			IE	DESC in	SUPPIE			
			ONO					

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



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	ST	UĽ	ÒΥ	ID
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C4 !	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)					
Study eligibility requires subjects to meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).						
	usion Criteria					
_	Inclusion Number		Criterion Description		riterion 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	I	N01A00	
1.b	2		who are willing and able to comply with all scheduled visits, vaccination plan, ests, lifestyle considerations, and other study procedures ${\sf vaccination}$	I	N02A00	
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	I	N03A00	
1.d	4	requiremen	giving personal signed informed consent, which includes compliance with the ts and restrictions listed in the ICD and in this protocol	I	N04A00	
Inc	usion Criteria Entr	y IECAT :	= INCLUSION			
1.1	Inclusion Number: [Inclusion Number]		1			
1.2	Cr terion Description [Criter on Descript o		■ IETEST			
1 3	Cr terion met?	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	OYES IEORRES			
1.5	[Criter on met?]		NO NO			
			Describe details if relevant			
			IEDESC in SUPPIE			
1.4	Cr terion ID: (For Pf	izer use	○ IN01A00			
	only) [Criter on ID: (For P	fizer use	○ INO2A00 IETESTCD INO3A00			
	only)]		○ IN04A00			
Fyc	usion Criteria					
#	Exclusion Number	r	Criterion Description	Criterion met? C	riterion ID: (For Pfizer use only)	
2.a	1	Other med	cal or psychiatric condition incl. recent (within past year) or active suicidal havior/lab abnormal ty that may increase the risk of study participation		EX01A00	
2.b	2		ction w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or virus (HBV)	E	X02A00	
2.c	3		severe adverse reaction associated with a vaccine and/or severe allergic g, anaphylaxis) to any component of the study intervention(s)	E	EX03A00	
2.d	4	Receipt of	medicat ons intended to prevent COVID-19	E	X04A00	
2.e	5	Stages 1 a	nd 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19	E	X05A00	
2.f	8		mpromised indiv duals w th known or suspected immunodeficiency, as I by history and/or laboratory/phys cal examination	E	X08A00	
2.g	9	Individuals	with a history of autoimmune disease or an active autoimmune disease nerapeutic intervention	E	EX09A00	
2.h	10	Bleeding d	athesis or condition associated with prolonged bleeding that would, in the the investigator, contraindicate intramuscular inject on	E	EX10A00	
2.i	11	<u> </u>	o are pregnant or breastfeeding	E	X11A00	
2.j	12	Previous va	accinat on with any coronavirus vaccine	E	X12A00	
2.k	13	Subjects w	ho receive immunosuppressive therapy, such as cytotox c agents or systemic oids	E	EX13A01	
2.1	15		olood/plasma products or immunoglobulin, from 60 days before study n administrat on or planned receipt throughout the study	E	EX14A01	
2.m	16		Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		X15A01	
2.n	17	Previous part c	art cipation in other studies involving study intervent on containing lip d es	E	EX16A01	
2.0	22		r s te staff or Pfizer employees directly involved in the conduct of the study, therwise supervised by the investigator, and their respective family members	E	EX21A01	
Exc	usion Criteria Entr	y IECAT	= EXCLUSION			
2.1	Exclusion Number: [Exclusion Number]		■ IESPID			
2.2	Cr terion Description [Criter on Descript o		<u> ✓ IETEST</u>			
2.3	Cr terion met? [Criter on met?]		O YES IEORRES Describe details if relevant			
			IEDESC in SUPPIE			

	○ NO
Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	■ IETESTCD



C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)						
Stud	Study eligibility requires subjects to meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).						
	usion Criteria						
_	Inclusion Number		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)		
1.a			Male or female part cipants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)		IN01A00		
1.b	2		who are willing and able to comply with all scheduled visits, vaccination plan, tests, lifestyle considerations, and other study procedures		IN02A00		
1.c			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 restrictions listed in the ICD and in this protocol		IN04A00		
Inc	usion Criteria Entr	y IECAT :	= INCLUSION				
1.1	Inclusion Number: [Inclusion Number]		1				
1.2	Cr terion Description	n:	▼IETEST				
	[Criter on Descript o		127201				
1.3	Cr terion met? [Criter on met?]		YES IEORRES NO				
			Describe details if relevant				
			IEDESC in SUPPIE				
1.4	Cr terion ID: (For Pfi only)	izer use	O INOTAGO				
	[Criter on ID: (For P	fizer use	○ INO2A00 IETESTCD INO3A00				
	only)]		○ IN04A00				
Exc	usion Criteria						
#	Exclusion Number		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)		
2.a	1		ical or psychiatric condition incl. recent (within past year) or active suicidal shavior/lab abnormal ty that may increase the risk of study participation		EX01A00		
2.b	2		ection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or virus (HBV)		EX02A00		
2.c	3		severe adverse reaction associated with a vaccine and/or severe allergic g, 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	_	nd 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00		
2.f	8		mpromised indiv duals w th known or suspected immunodeficiency, as i by history and/or laboratory/phys cal examination		EX08A00		
2.g	9		with a history of autoimmune disease or an active autoimmune disease nerapeutic intervention		EX09A00		
2.h	10		athesis or condition associated w th prolonged bleeding that would, in the the investigator, contraindicate intramuscular inject on		EX10A00		
2.i	11	Women wh	o are pregnant or breastfeeding		EX11A00		
2.j	12	Previous v	accinat 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		on in other studies involving study intervention w thin 28 days pr or to study or during study participation		EX15A00		
2.n	16		Previous part cipation in other studies involving study intervent on containing lip d nanopart cles EX16A00		EX16A00		
2.0	21		or s te staff or Pfizer employees directly involved in the conduct of the study, therwise supervised by the investigator, and their respective family members		EX21A00		
Exc	usion Criteria Entr	y IECAT	= EXCLUSION				
2.1	Exclusion Number: [Exclusion Number]		▼ IESPID				
2.2	Cr terion Description [Criter on Descript o		<u>IETEST</u>				
2.3	Cr terion met? [Criter on met?]		YES IEORRES Describe details if relevant				
1			IEDESC in SUPPLE				

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

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STUDYID

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

O IN04A00

Stu	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 with all scheduled visits, vaccination plan, ests, lifestyle considerations, and other study procedures ${\sf vaccination}$		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	4		giving personal signed informed consent, which includes compliance with the ts and restrictions listed in the ICD and in this protocol		IN04A00
Inc	lusion Criteria Entr	y IECAT	= INCLUSION		
1.1	Inclusion Number: [Inclusion Number]		1		
1.2	Cr terion Description [Criter on Descript o		<u> ✓ IETEST</u>		
1.3	1.3 Cr terion met? [Criter on met?]		YES IEORRES NO Describe details if relevant IEDESC in SUPPIE		
1.4	Cr terion ID: (For Pf only) [Criter on ID: (For Ponly)]		○ IN01A00 ○ IN02A00 ○ IN03A00		

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 w th 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

			III/ EXCIDENTIAL TOTAL THE TIME	
		Ag), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) reening vis t		
2.u		nel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 sefore receipt of study intervention	EX20A01	
2.v		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		
Exc	lusion Criteria Entry	CAT = EXCLUSION		
2.1	Exclusion Number: [Exclusion Number]	<u> ■ IESPID</u>		
2.2	Cr terion Description: [Criter on Descript on]	<u>IETEST</u>		
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPIE NO		
2.4	Cr terion ID: (For Pfizer us only) [Criter on ID: (For Pfizer u only)]	IETESTOD		

STUDYID

C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

O IN01A00

O IN04A00

IN02A00 IETESTCD

Stuc	dy eligibility requires	subjects to meet all inclus on criteria (YES) and Not meet exclusion criteria (NO).		
Incl	usion Criteria			
#	Inclusion Number	Criterion Description	Criterion met? C	riterion 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)	I	N01A00
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	I	N02A00
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	I	N03A00
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	I	N04A00
Inc	lusion Criteria Entr	y IECAT = INCLUSION		
1.1	Inclusion Number: [Inclusion Number]	01 02 1 ESPID 03 04		
1.2	Cr terion Description [Criter on Descript o			
1.3	Cr terion met? [Criter on met?]	YES IEORRES NO Describe details if relevant IEDESC in SUPPIE		

Exclusion Criteria

only)]

1.4 Cr terion ID: (For Pfizer use

only) [Criter on ID: (For Pfizer use

#	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 with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	EX08A00
2.i	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention	EX09A00
2.j	10	Bleeding diathesis or condition associated 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	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 within 28 days prior to study entry and/or during study participation	EX15A00
2.p	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A00
2.q	17	Sentinel part cipants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit $$	EX17A00
2.r	18	Sentinel part cipants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator	EX18A00
2.s	19	Sentinel part cipants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t	EX19A00

2.t		Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 lours before receipt of study intervention	EX20A00
2.u		nvestigator s te staff or Pfizer employees directly involved in the conduct of the study, ite staff otherwise supervised by the investigator, and their respective family members	EX21A00
Exc	lusion Criteria Entry	IECAT = EXCLUSION	
2.1	Exclusion Number: [Exclusion Number]	■ IESPID	
2.2	Cr terion Description: [Criter on Descript on	■ IETEST	
2.3	Cr terion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPIE NO	
2.4	Cr terion ID: (For Pfiz only) [Criter on ID: (For Pfi only)]	IETESTOD	

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C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)

O IN04A00

Stu	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		nale 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 with all scheduled visits, vaccination plan, tests, lifestyle considerations, 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	4		giving personal signed informed consent, which includes compliance with the ts and restrictions listed in the ICD and in this protocol		IN04A00
Inc	lusion Criteria Entr	y IECAT :	= INCLUSION		
1.1	Inclusion Number: [Inclusion Number]		1		
1.2	Cr terion Description [Criter on Descript o		<u> ✓ IETEST</u>		
1.3	Cr terion met? [Criter on met?]		YES IEORRES NO Describe details if relevant IEDESC in SUPPIE		
1.4	Cr terion ID: (For Pf only) [Criter on ID: (For Ponly)]		○ IN01A00 ○ IN02A00 ○ IN03A00		

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 with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	EX08A00
2.i	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention	EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	EX10A00
2.k	11	Women who are pregnant or breastfeeding	EX11A00
2.1	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=Inclus	ion/Exclusion Criteria Not Met
		BsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) screening vis t	
2.u		ntinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 urs before receipt of study intervention	EX20A01
2.v	22 Inv	EX21A01	
Exc	lusion Criteria Entry	ECAT = EXCLUSION	
2.1	Exclusion Number: [Exclusion Number]	▼ IESPID	
2.2	Cr terion Description: [Criter on Descript on]	<u> ■ IETEST</u>	
2.3	Crterion met? [Criter on met?]	YES IEORRES Describe details if relevant IEDESC in SUPPIE NO	
2.4	Cr terion ID: (For Pfizer only) [Criter on ID: (For Pfizer only)]	<u> </u>	

С	4591001: CASEBOOK SIGNATURE FORM (INVSIG) NOT SUBMITTED							
Ca	sebook Signature Form							
1.	Casebook Signature [Casebook Signature]	OClick Here to Enable						

Si	TUDYID	LB=Laboratory Test F	Results MB=Microbiology Specimen
C 4	591001: CENTRAL LAB SAMPLE CO	DLLECTION (LAB)	
Cei	ntral Lab Sample Collection		
1.	Collection Date: [Collect on Date:]	☑ / ☑ / ☑ LBDTC MBDTC	
	Specimen Type: [Specimen Type]	OBLOOD LBSPEC MBSPEC	
Lat	Test		
#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected
3.a	CLINICAL CHEMISTRY	BLOOD CHEMISTRY	
3.b	HEMATOLOGY	DIFFERENTIAL	
Lal	Test Entry		
3.1	Lab Panel: [Category for Lab Test]	○ HEMATOLOGY ○ CLINICAL CHEMISTRY MBCAT 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]	O YES NO LBSCATYN in SUPPLB MBSCATYN	I in SUPPMB

ST	UDYID		LB=Laboratory	Test Results	MB=Microbiology Specimen
C 4	591001: CENTRAL LAB SAMPLE C	OLLECTION - BASE	LINE (LAB BSL)		
Cei	ntral Lab Sample Collection				
1.	Collection Date: [Collect on Date:]	<u> </u>	LBDTC MBDTC		
2.	Specimen Type: [Specimen Type]	O BLOOD LBSPEC M	IBSPEC		
Lal	Test		·		
#	Category for Lab Test	Subcateg	ory for Lab Test		Lab Sub-Panel Collected
3.a	CLINICAL CHEMISTRY	BLOOD CHEMISTRY			
3.b	CLINICAL CHEMISTRY	VIROLOGY			
3.c	HEMATOLOGY	DIFFERENTIAL			
Lal	Test Entry				
3.1	Lab Panel: [Category for Lab Test]	O HEMATOLOGY O CLINICAL CHEMISTRY	LBCAT MBCAT]	
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	O DIFFERENTIAL O BLOOD CHEMISTRY VIROLOGY	NOT SUBMITTED		
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	O YES NO LBSCATYN	in SUPPLB MBS	CATYN in SUPI	РМВ

ST	TUDYID				LB=La	borator	y Test R	esults			
C	1591001: LOCAL LABORATORY D	ATA - REPEATING CI	HEMISTRY (LAB CHI	EM) -	Repeating Fo	orm					
#	Category for Lab Test	Vendor Name	Collection Date:		Specimen T	уре	Lab Ro	esult			
1											
Lab Chemistry Details											
1.	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY	BCAT								
2.	Laboratory Name and Address [Vendor Name]	LBNAM	LBNAM								
3.	3. Collection Date: [Collect on Date:]										
4.	4. Specimen Type: [Specimen Type] OBLOOD LBSPEC										
La	b Result										
#	Sponsor-Defined Identifier	Tes	t: Re	sult:	Not Done:	Lab	Normal Ran	ige			
5.a	1	C Reactive Protein_PX3	29								
La	b Result Entry		·								
5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBSF	PID								
5.2	P Test: [Test:]	C Reactive Protein_PX	LBTEST								
5.3	Result: [Result:]	LBORRES									
5.4	Not Done: [hidden] [Not Done:]	O NOT DONE LBSTAT									
5.5	LNMT [Lab Normal Range]	High LBORNRHI Un t LBORRESU									

S7	TUDYID				LB=Labo	ratory	Test Results
	591001: LOCAL LABORATORY	DATA - REPEATING C	HEMISTRY (LAB CH	IEM) - Re	peating Forn	1	•
#	Category for Lab Test	Vendor Name	Collection Date:		Specimen Type		Lab Result
1							
Lal	Chemistry Details						
1.	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY	LBCAT				
2.	Laboratory Name and Address [Vendor Name]	LBNAM					
3.	Collection Date: [Collect on Date:]		LBDTC				
4.	Specimen Type: [Specimen Type]	OBLOOD LBSPEC					
Lal	Result						
#	Sponsor-Defined Identifier	Те	st:	Result:	Not Done:	Lab N	Iormal Range
5.a		C Reactive Protein_PX329					
5.b		Alanine Aminotransferase_	PX30				
5.0		Aspartate Aminotransferas	e_PX28				
5.d		Alkaline Phosphatase_PX35	5				
5.e		Bilirubin_PX21					
5.f		Blood Urea Nitrogen_PX47					
5.g		Creatinine_PX48					
Lal	Result Entry						
5.1	Sponsor ID: [Sponsor-Defined Identifier]	LBS	SPID				
5.2	Test: [Test:]	<u> </u>					
5.3	Result: [Result:]	LBORRES					
5.4	Not Done: [Not Done:]	O NOT DONE LBSTA	T				
5.5	LNMT [Lab Normal Range]	Low LBORNRLO High LBORNRHI Un t LBORRESU					

Si	TUDYID				LB=L	aboratory	Test Results
C4	591001: LOCAL LABORATORY	DATA -	- REPEATING Hemato	ology (LAB HEM) -	Repeating Fo	rm	
#	Category for Lab Test		dor Name (DERIVED)	Collection Date		nen Type	Lab Result
1							
Lal	ooratory Data Hematology						
1.	Lab Panel: [Category for Lab Test]	Он	EMATOLOGY LBCAT				
	Laboratory Name and Address [Vendor Name (DERIVED)]	LE	BNAM				
	Collection Date: [Collect on Date:]		▼/ ▼/ ▼ LBDT	C			
	Specimen Type: [Specimen Type]	ОВ	LOOD LBSPEC				
Lal	Result						
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:	Lab Nor	mal 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				
Lal	Result Entry						
5.1	Sponsor ID: [Sponsor-Defined Identifier]		LBSPID				
5.2	Test: [Test:]		∠ LBTEST				
5.3	Result: [Result:]		LBORRES				
5.4	Not Done: [Not Done:]	0	NOT DONE LBSTAT				
5.5	LNMT [Lab Normal Range]	Hig Un	LBORNRLO h LBORNRHI				

S	TUDYID			LB=Laborato	ry Test Results		
C 4	591001: LAB URINALYSIS - PREG	SNANCY	TEST (LAB PREG)				
Lal	O Urinalysis						
1.	Lab Panel: [Category for Lab Test]	OURINAL	YSIS LBCAT				
2.	Lab Sub-Panel: [Subcategory for Lab Test]	O PREGNA	ANCY LBSCAT				
3.	Collection Date: [Collect on Date:]	<u>~</u> /	✓/ ✓ LBDTC				
4.	Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]	LBNAI	И				
	Specimen Type: [Specimen Type]	OURINE	LBSPEC				
Lal	Result						
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:		
6.a			Chor ogonadotropin Beta_PX113				
Lal	Result Entry						
6.1	Sponsor ID: [Sponsor-Defined Identifier]		LBSPID				
6.2	6.2 Test: [Test:] Chor ogonadotropin Beta_PX113 LBTEST						
6.3	Result: [Result:] NEGATIVE LBORRES POSITIVE						
6.4	Not Done: [Not Done:]	O NOT D	OONE LBSTAT				

ST	UDYID									AE=Adve	rse Events
C4	59100	1: MEDIC	ATIO	N ERROF	R (MED	ERROR) - F	Repeating Forn	1			
_		Medication Error		Is the med error S Ongo	dication Still	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	
1											
Ме	dication I	Error									
1.	Category [Categor	y]		IEDICATION	ERROR	AECAT					
2.	of Medica	on Error (Type ation Error): on Error]		AETERM							
3.	If this is a dispensing error, record the incorrect container number that was dispensed/administered to the subject: [hidden] [Incorrect package ID]						SUPPAE				
4.	Start Date [Start Date			v /	/	AESTDTC					
5.	still ongo	ned cat on erro	_ ON	nd Date:	IRTPT:	= ONGOING AEENDT		AST SUBJEC	CT ENCOUNTER]	
6.	with Study M [Study M Errors Ad		ÕР	O ACTION T ERMANENTL			<u></u>				
7.	Med catio	oncomitant on given? I tant on Given]	O Y	o AECC	NTRT	AECMGIV in	SUPPAE				
8.		on-Drug nt given? ug Treatment	O Y		NTRT	AENDGIV in	SUPPAE				
9.	cause th				IBJDC	in SUPPAE	Linked to relate	ed DS record	I via RELREC		
10.	error ass any adve [Med cat	medication sociated with erse events? on Error ed With AE]	A	E ID: AEI E ID: E ID: E ID: E ID:	MEFL i	n SUPPAE	AEAENO in S AEAENO in S AEAENO in S AEAENO in S AEAENO in S	SUPPAE SUPPAE SUPPAE			
11.	Number: Only	Adverse Event For Pfizer Use Adverse Event	•	AEREFID]						
12.	[hidden]	son Term	N	OT SUBI	MITTEL	0					
13.	[hidden]	evel Term Level Term]	A	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 [hidden] [High Level Term]	AEHLT
18.	High Level Term Code [hidden] [High Level Term Code]	AEHLTCD
19.	High Level Group Term [hidden] [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

STU	H=Medical History							
C4591001: GENERAL MEDICAL HISTORY (MEDHX) MHCAT=GENERAL MEDICAL HISTORY								
	Line/MH Number		Medical History Term		Start Date	Ongoing		
1.								
Medical 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]	<u>~</u> /	™ / MHSTDTC					
1.4	Ongoing: [Ongoing]	YES NO End Date:	:	MHENTPT= L	AST SUBJECT ENC	OUNTER		
1.5	Comparison Term [hidden] [Comparison Term]	NOT SU	<u>IBMITTED</u>					
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	COD					
1.9	Preferred Term Code [hidden] [Preferred Term Code]		MHPTCD					
1.10	High Level Term [hidden] [High Level Term]	MHHLT						
1.11	High Level Term Code [hidden] [High Level Term Code]		MHHLTCD					
1.12	High Level Group Term [hidden] [High Level Group Term]	MHHLG	T					
1.13	High Level Group Term Code [hidden] [High Level Group Term Code]		MHHLGTCD					
1.14	Primary System Organ Class [hidden] [Primary System Organ Class]	MHBOD	SYS MHSOC					
1.15	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]		MHBDSYCD MHSOCCD					

S	TUDYID		LB=Laboratory Test Results					
С	C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form LBCAT= OXYGENATION PARAMETERS							
#	Date Time of Assessn	nent Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)					
1			LBSCAT= BLOOD CHEMISTRY					
0	xygenation Parameters							
1.	Date Time of Assessment: [Date Time of Assessment]	▼ / ▼ /						
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	LBORRES when LBTESTCD = PO2						
3.	FiO2 (Fract on of Inhaled Oxygen): [FiO2 (Fraction of Inhaled Oxygen)]	LBORRES when LBTESTCD = FIO2						

ST	UDYID		PE=Physical Examination					
C4	C4591001: PHYSICAL EXAMINATION (PHYS EXAM) PECAT=PHYSICAL EXAMINATION							
	Physical Examination							
	Exam Date: [Exam Date]	▼/ ▼/ PEDTC						
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 Ent	гу						
2.1	Body System Examined: [Body System Examined]	PETEST PETEST						
2.2	Result: [Result]	NORMAL ABNORMAL If abnormal findings, specify: (If clinically signif cant, record on the Medical History or A Are there clinically signif cant findings? YES NO NOT DONE PESTAT	dverse Event CRF as appropriate).					

S	TUDYID	IS=Immunogenicity Specimen Assessment CO=Comment	s					
C	C4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19) ISCAT=SEROLOGY							
Ele	Electronic Sample Tracking							
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPIS						
2.	Sample Type [Sample Type]	SERUM ISSPEC						
3.	Sample Collected? [Sample Collected]	NO COVAL when COREF=SAMPLE COLLECTED YES Date of Collect on: W / W / W ISDTC CODTC						
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = IS						
		Sample ID						
5.								
AI	Aliquot Entry							
Ple	ase enter barcode for each aliquot							
5.	Sample ID [Sample ID]	NOT SUBMITTED						

ST	STUDYID CM=Concomitant Medications								ations		
C4	C4591001: CONCOMITANT MEDICATIONS - PROHIBITED (PROHIB CM) - Repeating Form										
#	Sponsor-Defined Identifier	Category for Medication		comitant Medications Pre- specified		Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing
1											
Cor	comitant Medication	าร									
1.	What is the medication [Sponsor-Defined Ide			CMSPID							
2.	Category: [Category for Medicat	cion]		CONCOMITANT IMMUNO CORTICOSTEROIDS IMMUNOGLOBULINS	SUPPRESSIVE TH	IERAPY					
3.	Concomitant Medicati [Concom tant Medicat			ONO NOT SUBMITTE	<u>ED</u>						
4.	Med cation:			CMTRT							
	Prov de the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]		CMTK1								
5.	Dose: [Dose Description]			CMDOSE CMDOS	STXT						
6.	Dose Unit: [Dose Unit]			™ CMDOSU							
7.	Dose Frequency: [Dose Frequency]			™ CMDOSFRQ							
8.	Route: [Route]			™ CMROUTE							
9.	Start Date: [Start Date]				CMSTDTC						
10.	Ongoing? [Ongoing]			YES CMENRTPT= NO End Date:		_	ST SU	BJECT ENC	OUNT	ER	
11.	Comparison Term [hi [Comparison Term]	dden]		NOT SUBMITTED							
12.	Standardized Med cat derived. [hidden] [Standardized Med ca		У	CMDECOD							
13.	Standardized Med cat derived [hidden] [Standardized Med ca	,	/	C	MCODE in S	UPPCM					

STUDYID PR=Procedures C4591001: RADIATION TREATMENT (PROHIB ND) - Repeating Form **Treatment Identifier** Con Non-Drug Treatments Pre-specified **Treatment Start Date** Ongoing? 1 **Radiation Treatment** RADIATION THERAPY PRCAT 1. Category: [Category] 2. What is the treatment Identifier? PRSPID [Treatment Identifier] OYES PRPRESP 3. Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified] 4. Treatment: PRTRT [Treatment] Start Date: **~** / **~** / ✓ PRSTDTC [Start Date] 6. Ongoing? O YES PRENRTPT= ONGOING PRENTPT= LAST SUBJECT ENCOUNTER [Ongoing?] End Date: **▽** PRENDTC **~** / Comparison Term [hidden] NOT SUBMITTED [Comparison Term] 8. Lowest Level Term [hidden] PRLLT in SUPPPR [Lowest Level Term] Lowest Level Term Code [hidden] PRLLTCD in SUPPPR [Lowest Level Term Code] 10. D ctionary Derived Term [hidden] PRDECOD [D ctionary Derived Term] Preferred Term Code [hidden] PRPTCD in SUPPPR [Preferred Term Code] High Level Term [hidden] PRHLT in SUPPPR [High Level Term] High Level Term Code [hidden] PRHLTCD in SUPPPR [High Level Term Code] High Level Group Term [hidden] PRHLGT in SUPPPR [High Level Group Term] High Level Group Term Code [hidden] PRHLGTCD in SUPPPR [High Level Group Term Code] Primary System Organ Class [hidden] PRBODSYS in SUPPPR PRSOC in SUPPPR [Primary System Organ Class] 17. Primary System Organ Class Code [hidden] PRBDSYCD in SUPPPR PRSOCCD in SUPPPR [Primary System Organ Class Code]

SI	TUDYID		VS=Vital Signs					
C	C4591001: VITAL SIGNS - PULSE OX ROOM AIR (PULSE OX) - Repeating Form VSCAT=GENERAL VITAL SIGNS							
#	Date:		Vital Signs Details					
1								
Vit	al Signs							
1.	Date: [Date:]	▼/						
Vit	al Signs Details							
#	R	ecord Identifier:	Oxygen Saturation					
2.8	1							
Vi	tal Signs Details Entry							
2.:	Record Identifier: [Record Identifier:]	O1 VSSPID						
2.2	SPO2 Pulse Oximetry % [Oxygen Saturation]	VSORRES when VSTEST	TCD = OXYSAT					

S	TUDYID	DS=Disposition						
C	C4591001: RANDOMIZATION (RAND) DSCAT=PROTOCOL MILESTONE							
D	isposition							
1	Randomizat on Date : [Randomization Date :]	DSSTDTC when DSTERM/DSDECOD=RANDOMIZED						
2	Randomizat on Number: [Randomization Number]	DSREFID						
3	Randomizat on Group: [Randomization Group]	DSRANGRP in SUPPDS						

C4591001: REACTOGENICITY DIARY (REAC DIARY)

Reactogenicity Diary

1. Select appropriate response - Reactogen c ty diary collection [Trigger Response 9]

O YES - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT REACTOFL='N' in SUPPDM

REACTOFL='Y' in SUPPDM

O YES - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT REACTOFL='N' in SUPPDM

ST	UDYID		FA=F	indings About Events or Interventions					
	C4591001: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT (REACTION)								
_	Unplanned Assessment Of Local Reaction FACAT=REACTOGENICITY -UNPLANNED ASSESSMENT								
1.	CISR Category [hidden] [CISR Category]			OT SUBMITTED					
	Date of Assessment: [Date of Assessment]	▼/ ▼/ ▼F	ADTC						
	Injection Site Location [Injection S te Location]	ODELTOID MUSCLE	OC						
	Injection Site Body S de: [Injection S te Body Side]	OLEFT FALAT							
Rea	iction								
#	React	tion:	Re	eaction Present:					
5.a	REDNESS								
5.b	SWELLING								
Rea	action Entry								
5.1	Reaction: [React on:]	O REDNESS FAOBJ							
	[React on Present:]	Minimum Diameter (cm): FAORRES Meets Grade 4 Reaction C	ONO FACES WHEN FATESTCD=G4CRIMET						
Syn	nptom								
#		Symptom:		Symptom Present:					
6.a	PAIN AT INJECTION SITE								
6.b	FATIGUE/TIREDNESS								
6.c	HEADACHE								
6.d	VOMITING								
6.e	DIARRHEA								
6.f	NEW OR WORSENED MUSCLE F	PAIN							
6.g	NEW OR WORSENED JOINT PA	IN							
6.h	CHILLS								
Syr	nptom Entry								
6.1	Symptom: [Symptom:]	FAOBJ							
6.2	Symptom Present: [Symptom Present:]	Symptom Grade: 1 FAORRES WI 3 4 Event related to Study Tr	hen FATESTCD=SEV reament? when FATESTCD=REL						

[Primary System Organ Class Code]

ST	STUDYID PR=Procedures								
C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form PRCAT=GENERAL NON-DRUG TREATMENT									IENT
#	Treatment Identifier		on-Drug Treatmen		Treatn		Treatment	Start Date	Ongoing?
1									
1.	What is the treatment Identifier?		PRSPID						
2.	[Treatment Identifier] Concomitant Non-drug Treatment	Pro-specified:	OYES PRPRES						
	[Con Non-Drug Treatments Pre-sp								
3.	3. Treatment: [Treatment]		O NON-INVASIVE POSITIVE PRESSURE VENTILATION O CPAP O MECHANICAL VENTILATION O EXTRACORPOREAL MEMBRANE OXYGENATION O HIGH FLOW OXYGEN THERAPY						
4.	Treatment: [Treatment]		PRTRT						
5.	Start Date: [Start Date]		•/ •/	⊻ PRSTDTC					
6.	6. Ongoing? [Ongoing?]		PRENRTPT= ONGOING NO End Date: PRENDTC						
7.	Comparison Term [hidden] [Comparison Term]		NOT SUBMIT	TED					
8.	Lowest Level Term [hidden] [Lowest Level Term]		PRLLT in SU	PPPR					
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]			PRLLTCD in SUP	PPPR				
10.	D ctionary Derived Term [hidden] [D ctionary Derived Term]		PRDECOD						
11.	Preferred Term Code [hidden] [Preferred Term Code]			PRPTCD in SUPF	PPR				
12.	High Level Term [hidden] [High Level Term]		PRHLT in SUF	PPPR					
13.	High Level Term Code [hidden] [High Level Term Code]			PRHLTCD in SUF	PPPR				
14.	High Level Group Term [hidden] [High Level Group Term]		PRHLGT in S	UPPPR					
15.	High Level Group Term Code [hide [High Level Group Term Code]	den]		PRHLGTCD in St	JPPPR				
16.	Primary System Organ Class [hide [Primary System Organ Class]	den]	PRBODSYS ii	n SUPPPR PRS	OC in SUPF	PPR			
17.	Primary System Organ Class Code [Primary System Organ Class Code			PRBDSYCD in S	UPPPR I	PRSO	CCD in SUPI	PPR	

ST	STUDYID PR=Procedur								
C4	591001: RESPIRATORY TREATI	ATORY TREATMENT (RESP TX) - Repeating Form PRCAT=GENERAL NON-DRUG TREATMENT							
#		on Non-Drug Treatme		Treatment	Treatment	Start Date	Ongoing?		
1									
Res	piratory Treatment								
1.	What is the treatment Identifier? [Treatment Identifier]	PRSPID							
2.	Concomitant Non-drug Treatment Pre-specifi [Con Non-Drug Treatments Pre-specified]	ed: OYES PRPRE	SP						
3.	Treatment: [Treatment]	O INTUBATION NON-INVASIVI CPAP OXYGEN THER	E POSITIVE PRESSURE VEN APY	TILATION PRTRI					
4.	Treatment: [Treatment]	PRTRT							
5.	Start Date: [Start Date]	•/ •/	PRSTDTC						
6.	Ongoing? [Ongoing?]	End Date:	IRTPT= ONGOING PRENDTC		ST SUBJECT	ENCOUNTE	R		
7.	Comparison Term [hidden] [Comparison Term]	NOT SUBM	ITTED						
8.	Lowest Level Term [hidden] [Lowest Level Term]	PRLLT in S	SUPPPR						
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]		PRLLTCD in SUPF	PPR					
10.	D ctionary Derived Term [hidden] [D ctionary Derived Term]	PRDECOD							
11.	Preferred Term Code [hidden] [Preferred Term Code]		PRPTCD in SUPPI	PR					
12.	High Level Term [hidden] [High Level Term]	PRHLT in S	SUPPPR						
13.	High Level Term Code [hidden] [High Level Term Code]		PRHLTCD 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]		PRHLGTCD in SU	PPPR					
16.	Primary System Organ Class [hidden] [Primary System Organ Class]	PRBODSY	S in SUPPPR PRSC	C in SUPPPR					
17.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]		PRBDSYCD in SU	JPPPR PRSC	OCCD in SUP	PPPR			

C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF) NOT SUBMITTED Further Vaccination Confirmation 1. Select appropriate response - Is part cipant 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

OParticipant is NOT willing to return for Vaccination 3 OR otherwise not eligible

S	TUDYID		DS=Disposit	tion				
C	C4591001: INFORMED CONSENT - FURTHER VACCINATION (REVAX CONS) DSCAT=PROTOCOL MILESTONE							
Iı	Informed Consent - Further Vaccination							
1.	Consent Was: [Consent Was:]	Date Written Consent Obtained	DSSTDTC when DSTERM/DSDECOD=INFORMED CONSENT OBTAINED					

ST	TUDYID	IE=Inclusion/Exclusion Criteria Not Met						
C4	C4591001: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)							
	Criterion Description							
1.								
Inc	inclusion Criteria Not Met Entry							
1.1	Description of Inclusion Cr terion Not Met [Criter on Descript on]							
	Criterion Description							
2.								
Exc	clusion Criteria Met Entry							
2.1	Description of Exclusion Cr terion Met [Criter on Descript on]							

S	TUDYID		MB=Microbiology Spec	cimen	CO=Comments			
C	4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB) MBCAT=VIROLOGY							
Ele	ectronic Sample Tracking							
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPMB						
2.	Sample Type [Sample Type]	○ NASAL_SWAB ○ NASAL_SWAB_SELF						
3.	Sample Collected? [Sample Collected]	NO NOT SUBMITTED YES Date of Collect on:						
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = MB						
		Sample ID						
5.								
Al	iquot Entry							
Ple	ease enter barcode for each aliquo	t.						
5.	1 Sample ID [Sample ID]	NOT SUBMITTED						

S	TUDYID	IS=Immunogenicity Specimen Assessment CO=Comments						
C	C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK) ISCAT=SEROLOGY							
El	Electronic Sample Tracking							
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPIS						
2.	Sample Type [Sample Type]	SERUM ISSPEC						
3.	Sample Collected? [Sample Collected]	NO YES Date of Collect on: W / W / SDTC CODTC						
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = IS						
		Sample ID						
5.								
Al	Aliquot Entry							
Ple	ease enter barcode for each aliquo							
5.	1 Sample ID [Sample ID]	NOT SUBMITTED						

С	C4591001: INFORM SCREENING (SCREEN) NOT SUBMITTED				
Ir	InForm Screening				
1.	InForm Initials [hidden] [InForm Initials]				
2.	Birth Date: [Birth Year]	<u>•</u> /	~ /	<u> </u>	

Si	TUDYID		MB=Microbiology Specimen	CO=Comments					
C	C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB) MBCAT=VIROLOGY								
Ele	Electronic Sample Tracking								
1.	Data Origin [Data Origin]	OSITE ETRKDOR in SUPPMB							
2.	Sample Type [Sample Type]	NASAL_SWAB_SELF MBSPEC							
3.	Sample Collected? [Sample Collected]	NO NO YES Date of Collect on: W / W / MBDTC							
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = MB							
		Sample ID							
5.									
AI	Aliquot Entry								
Ple	ease enter barcode for each aliquot	t.							
5.	Sample ID [Sample ID]	NOT SUBMITTED							

STU	Original version: New version: VE	VERSION 1: USED PRIOR TO JULY 6, 2020 FA=Findings About Events or Intervention	ons CE=Clinical Events
C4	591001: STGNS AND SY	MPTOMS OF POTENTIAL COVID-19 (SOD) FACAT=EFFICACY C	ECAT=EFFICACY
_			
	ns and Symptoms FASCAT=F		EASE
1	Date of Assessment: Date of assessment] Date of First Symptom Started:	▼/ ▼/ FADTC CEDTC	
1	First Symptom Started Date]	FAORRES when FATESTCD=FSYMDATE CESTD	
	Symptoms Ongoing? Symptoms Ongoing]	YES FAORRES when FATESTCD=SYMONGO Date of Last Symptom Resolved: FAORRES when FATESTCD=LSYMDATE V / V / V FAORRES when FATESTCD=LSYMDATE	AT CURRENT VISIT
		FAORRES WIEITFATESTCD=ESTWDATE CLE	MUTC
Syn #	Event Pre-specified	Symptoms	Symptom Present
7	Event rie-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	
Syn	ptoms Entry		
4.1	Event Pre-specified: [hidden] [Event Pre-specified]	YES NOT SUBMITTED	
	Symptoms: [Symptoms]	FAOBJ CETERM	
4.3	Was symptom present? [Symptom Present]	YES NO FAORRES when FATESTCD=OCCUR	
_		Symptoms - Other	
5. ✓			
Svn	nptoms - Other Entry		
5.1	Symptoms - Other Text:		
5.2	[Symptoms - Other] Comparison Term: [hidden]	NOT SUBMITTED	
J.2	[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	

FA=Findings About Events or Interventions

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Code]

ST	Original version New version: V	r: VERSION 1: USED PRIOR TO JULY 6, 2020 FA=Findings About ERSION 2: USED AFTER JULY 6, 2020 Events or Intervention	ons CE=Clinical Events					
C4:	91001: SIGNS AND S	MPTOMS OF POTENTIAL COVID-19 (SOD) FACAT=EFFICACY C	ECAT=EFFICACY					
		RESPIRATORY ILLNESS CESCAT=SIGNS AND SYMPTOMS OF DIS						
1 1	vate of Assessment:		LAGE					
	Date of assessment]	FADIC CEDIC						
	First Symptom Started Date]	FAORRES WHEIT FATESTOD=FSTWIDATE CESTE	OTC					
	ymptoms Ongoing? Symptoms Ongoing]	O YES NO FAORRES when FATESTCD=SYMONGO CEENRTPT= ONGOIN	IG CEENTPT= ONGOING AT CURRENT VISIT					
		Date of Last Symptom Resolved: V	NDTC					
Sym	ptoms							
#	Event Pre-specified	Symptoms	Symptom Present					
4.a	YES	FEVER						
4.b	YES	LOSS OF TASTE/SMELL						
\vdash		NEW OR INCREASED COUGH						
4.c	YES							
4.d	YES	NEW OR INCREASED NASAL CONGESTION						
4.e	YES	NEW OR INCREASED NASAL DISCHARGE						
4.f	YES	NEW OR INCREASED SHORTNESS OF BREATH						
4.g	YES	NEW OR INCREASED SORE THROAT						
4.h	YES	NEW OR INCREASED SPUTUM PRODUCTION						
4.i	YES	NEW OR INCREASED WHEEZING						
Svn	ptoms Entry							
4.1	Event Pre-specified: [hidden] [Event Pre-specified]	O YES NOT SUBMITTED						
4.2	Symptoms: [Symptoms]	FAOBJ CETERM						
4.3	Was symptom present? [Symptom Present]	○ YES ○ NO FAORRES when FATESTCD=OCCUR						
		Symptoms - Other						
5.								
Syn	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								
5.8	High Level Term Code [hidden] [High Level Term Code]							
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						

FA=Findings About Events or Interventions

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Code]

C	C4591001: STRATIFICATION (STRAT) NOT SUBMITTED					
St	ratification					
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	Non-Sentinel Stage 1				
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	△ Age 18 to 55 △ Age 65 to 85				
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	○ 10 mcg ○ 20 mcg ○ 30 mcg				
4.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	②21 Day ③60 Day				
5.	Select appropriate response - BNT Number [Trigger Response 7]	(BNT162b1 or PBO) (BNT162b2 or PBO) (BNT162b3 or PBO)				

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

C	4591001: STRATIFICAT	TION (STRAT) NOT SUBMITTED					
St	tratification						
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	Stage 1 Stage 2					
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	Age 18 to 55Age 56 to 85Age 65 to 85					
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	Low dose level (3mcg) Medium dose level (10mcg) High dose level (30mcg) Low dose level (10mcg) Medium dose level (30mcg) High dose level (100mcg) Low dose level (0.1mcg) Medium dose level (0.1mcg) Medium dose level (0.3mcg) Migh dose level (1mcg) Migh dose level (50mcg) Low-Mid dose level (20mcg)					
4.	Select appropriate response - Randomizat on Dose Group [hidden] [Trigger Response 6]	21 Day 2-dose group 60 Day 2-dose group 1-dose group					
5.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	021 Day 060 Day					
6.	Select appropriate response - BNT Number [Trigger Response 7]	○ (BNT162a1 or PBO)○ (BNT162b1 or PBO)○ (BNT162b2 or PBO)○ (BNT162c2 or PBO)○ (BNT162b3 or PBO)					

С	C4591001: SUBJECT STATUS (SUB STATU) NOT SUBMITTED					
Sı	Gubject Status					
1.	Subject Status [Subject Status]	▼ ·				
2.	Subject Status Date [Status Date]					

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

Informed Consent - Asymptomatic Surveillance

1. Consent Was:
[Consent Was:
[Consent Was:]

DSSTDTC when
DSTERM/DSDECOD=INFORMED
CONSENT OBTAINED

S7	TUDYID		MB=Microbiology Specimen	CO=Comments						
C	C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE) MBCAT=VIROLOGY									
Ele	Electronic 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 NO YES Date of Collect on: W / W / MBDTC								
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	COVAL when RDOMAIN = MB								
		Sample ID								
5.										
Al	Aliquot Entry									
Ple	ase enter barcode for each aliquot	:.								
5.:	Sample ID [Sample ID]	NOT SUBMITTED								

STUDYID					IV	1B=Micro	biology	Specimen	DI=	Device Ide	ntifiers C	O=Co	mments
C	C4591001: MICROBIOLOGY SPECIMEN (SW					SITE) -	Repeating	J Form MB(CAT:	=CONFIRMA	TION OF IN	IFECT	ION
#	Date of Collection	Specimer	1 Туре	Specimen	Collection	Location	Assay Coo	le and Descrip	tion	Device Type	Trade Name	Result	Comments:
1													
Mi	crobiology Specimen	ı											
1.	Actual Date of Collection [Date of Collection]	ion:	~	//	™	EDTC							
2.	Specimen Type: [Specimen Type]			ABBED MATER		SPEC							
3.	Specimen Collection L [Specimen Collection		O NAS	SAL CAVITY	IBLOC								
4.	Assay Code and Desci [Assay Code and Desci		○ SEV	'ERE ACUTE R	ESP SYNDE	NDROME CORONAVIRUS 2 MBTEST							
5.	Device Type: [Device Type]		O SAR	RS-COV-2 DIA	GNOSTIC T	STIC TEST DIVAL when DIPARMCD = DEVTYPE							
6.	Trade Name: [Trade Name]		O CEP	© CEPHEID XPERT XPRESS SARS-COV-2 TEST DIVAL when DIPARMCD = TRADENAM									
7. Test Result: [Result]		O NEG	O POSITIVE NEGATIVE INDETERMINATE MBORRES when MBTESTCD = SARSCOV2										
8. Comments/Findings/Details: [Comments:]			CO	VAL when	RDOMA	AIN = MB							

STUDYID		CE=Clinical Events FA=Findings About Events or Interventions AE=Adverse Events
C4	591001: VACCINATIO	N SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE CECAT=REACTOGENICITY
	cination Symptoms Diary - Sy	
	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? YES Ongoing? YES FAENRTPT= ONGOING FAENTPT= ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD Stop Date: V / V / FAORRES when FATESTCD = STPDMEDP
#	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:]	<u> </u>
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?]	Orgoing RELATIVE TO LAST DAY OF DIARY PERIOD ORGOING Stop Date: Orgoing ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD ORGOING RELATIVE TO LAST DAY OF DIARY PERIOD
	Injection Site Location: [Injection S te Location:]	DELTOID MUSCLE CELOC AELOC
	Injection Site Body S de: [Injection S te Body Side:]	OLEFT CELAT AELAT
#	Injection Site Reaction:	Were injection site reactions present on the last day the Subject Diary was completed?
5.a	REDNESS	CESCAT=ADMINISTRATION SITE FASCAT=ADMINISTRATION SITE
5.b		AESCAT=ADMINISTRATION SITE
5.c	PAIN AT INJECTION SITE	
5.1	Injection Site React on: [Injection Site Reaction:]	O REDNESS CETERM FAOBJ AETERM O 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 Ongoing YES ONG NO Stop Date: NO NO NO RELATIVE TO LAST DAY OF DIARY PERIOD AEENTPT ONGOING RELATIVE TO LAST DAY OF DIARY PERIOD

S. C. S. M. S. C.				PR=Procedures
C	C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form PRCAT=TRANSFUSION DETAILS			
#		Transfusion Type	Date of Transfusi	
1				
1.	Transfus on Type: [Transfus on Type]	PACKED RBC PLATELETS WHOLE BLOOD PLASMA OTHER Specify:		
2.	Date of Transfus on:	▼/ ▼/ PRSTDTC		

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

C4591001: UNPLANNED VISIT (UNPL) NOT SUBMITTED			
ι	Unplanned Assessments		
1	. Assessments [Assessments]	CONTACT OUTCOME	

ST	EX=Exposure EC=Exposure as Collected			
C4591001: VACCINATION (VACIN TRT) EXCAT=INVESTIGATIONAL ECCAT=INVESTIGATIONAL ECSCAT=VACCIN				
1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	PRODUCT PR		
2.	Treatment Name [Treatment Name]	EXTRT ECTRT		
3.	Formulat on: [Formulat on:]	OINJECTION EXDOSFRM ECDOSFRM		
4.	Dose Date Time: [Dose Date Time:]	W / W EXSTDTC EXENDTC ECSTDTC ECENDTC W : W 24-hour clock		
5.	Anatomical Locat on: [Anatomical Locat on:]	DELTOID MUSCLE EXLOC ECLOC		
6.	Body Side: [Body S de:]	OLEFT EXLAT ECLAT		
7.	Route: [Route:]	OINTRAMUSCULAR EXROUTE ECROUTE		
8.	Planned Dose: [Planned Dose]	<u>ECDOSE</u>		
9.	Planned Dose Unit: [Planned Dose Unit]	○ug ECDOSU		
10.	Actual Dose: [Actual Dose:]	EXDOSE ECDOSE		
11.	Unit: [Unit:]	Oug EXDOSU ECDOSU		
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 ■ OTHER SPECIFY If other, specify: EXDOSAJO in SUPPEX ■ CONSAJO 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		
	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 ECOBSV in SUPPEC NO If No, specify reason: EXOBSVD in SUPPEX ECOBSVD in SUPPEC		
	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 [hidden] [Standardized Med cation Code]	EXCD in SUPPEX ECCD in SUPPEC		

STUDYID EX=Exposure EC=Exposure as C			
C4591001: VACCINATION (VACIN TRT) EXCAT=INVESTIGATIONAL ECCAT=INVESTIGATIONAL ECSC			
Vac	cination	EXSCAT=VACCINATION PRODUCT PRODUCT	
1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	YES EXTDV in SUPPEX ECTDV in SUPPEC Date of First Delay: ✓ / ✓ / ✓ FDDTC in SUPPEX FDDTC in SUPPEC Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS RECENT SYSTEMIC CORTICOSTEROID TREATMENT RECENT NON-STUDY VACCINATION ANTICIPATED NON-STUDY VACCINATION NO NO NO SUPPEX FDDTC in SUPPEC EXADJ when more than one selected, EXADJ=MULTIPLE and individual responses are EXADJ1, EXADJ2, etc. in SUPPEC SUPPEX SUPPEC SUPPEC SUPPEX SUPPEC SUPPEC SUPPEC SUPPEC SUPPEC SUPPEC ON SUPPEX SUPPEC SUPPEC SUPPEC ON SUPPEX SUPPEC SUPPEC SUPPEC ON SUPPEX SUPPEC SUPP	
2.	Treatment Name [Treatment Name]	EXTRT ECTRT	
3.	Formulat on: [Formulat on:]	INJECTION EXDOSFRM ECDOSFRM	
4.	Dose Date Time: [Dose Date Time:]	EXSTDTC EXENDTC ECSTDTC ECENDTC 24-hour clock	
5.	Anatomical Locat on: [Anatomical Locat on:]	DELTOID MUSCLE EXLOC ECLOC	
6.	Body Side: [Body S de:]	OLEFT ORIGHT EXLAT ECLAT	
7.	Route: [Route:]	OINTRAMUSCULAR EXROUTE ECROUTE	
8.	Container Number: [hidden] [PAC / K t Number:]	NOT SUBMITTED	
9.	Actual Dose: [Actual Dose:]	EXDOSE ECDOSE	
10.	Unit: [Unit:]	oug EXDOSU ECDOSU	
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	THE PROTOCOL SPECIFIED OBSERVATION PERIOD EXOBSVT in SUPPEX ECOBSVT in SUPPEC	
12.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	YES EXOBSV in SUPPEX ECOBSV in SUPPEC NO If No, specify reason: EXOBSVD in SUPPEX ECOBSVD in SUPPEC	
13.	Comparison Term [hidden] [Comparison Term]	NOT SUBMITTED	
14.	Standardized Med cation Name - D ctionary Derived. [hidden] [Standardized Med cation Name]	EXDECOD in SUPPEX ECDECOD in SUPPEC	
15.	Standardized Med cation Code - D ctionary Derived [hidden]	EXCD in SUPPEX ECCD in SUPPEC	

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EX=Exposure | EC=Exposure as Collected

[Standardized Med cation Code]

STUDYID CM=Concom				CM=Concomit	ant Medic	cations			
C	1591001: CONCOMITANT	MEDICA	TIONS - VA	SOPRESSORS	(VASOPRESS) - I	Repeati	ng Form		
#	Sponsor-Defined Identifier	Category fo	or Medication	Concomitant N	ledications Pre-specifie	ed Na	me of Medication	Start Date	Ongoing
1							CMSCAT=VA	SOPRESS	SORS
Co	ncomitant Medications						AGENTS		
1.	What is the medication identifier? [Sponsor-Defined Identifier]		CMSPID						
2.	Category: [Category for Med cat on]		GENERAL CO	ONCOMITANT MEDIC	ATIONS CMCAT				
3.	Concomitant Medications Pre-specif [Concomitant Medications Pre-spec		ONO NOT S	SUBMITTED					
4. Medication: 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.	5. Start Date: [Start Date]		<u> </u>	CMST	DTC				
6.	6. Ongoing? [Ongoing]		YES CME NO End Date:		OING CMENTPT=	LAST S	UBJECT ENCO	UNTER	
7.	7. Comparison Term [hidden] [Comparison Term]		NOT SUB	MITTED					
8.	Standardized Medicat on Name - Di derived. [hidden] [Standardized Med cat on Name]	ct onary	CMDECOL)					
9.				CMCOL	E in SUPPCM				

S	STUDYID VS=Vital Signs						
C4	C4591001: VITAL SIGNS - TEMP (VITAL TEMP) VSCAT=REACTOGENICITY - UNPLANNED TEMPERATURE						
Vit	al Signs		VSSCAT=SYSTEMIC				
1.	Date: [Date:]	▼/ ▼/ ▼ VSDTC					
Vit	al Signs Details						
#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:			
2.a	1						
Vit	al Signs Details Entry						
2.1	Record Identifier: [Record Identifier:]	O1 VSSPID	○¹ VSSPID				
2.2	Temperature: [Temperature]	VSORRES when \	VSORRES when VSTESTCD =TEMP				
2.3	Unit: [Temperature Unit]	VSORRESU when VSTESTCD = TEMP					
2.4	Temperature Location: [Temperature Location:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD					

S1	TUDYID VS=Vital Signs					
C	C4591001: VITAL SIGNS - BASELINE (VITALS BSL) VSCAT=GENERAL VITAL SIGNS					
Vit	al Signs					
1.	Date: [Date:]	<u>~</u> /	✓ / ✓ VSDTC			
2.	Weight: [Weight]		VSORRES when \	VSTESTCD = WEIGHT		
3.	Un t: [Weight Unit]	Okg OLB	SORRESU when VSTE	ESTCD = WEIGHT		
4.	Height: [Height]		VSORRES when V	/STESTCD = HEIGHT		
5.	Un t: Height Un t] O cm VSORRESU when VSTESTCD = HEIGHT					
6.	Body Mass Index: [Body Mass Index]		VSORRES when VS	STESTCD = BMI		
Vit	al Signs Details					
#	Record Identifier:		Temperature	Temperature Unit	Temperature Location:	
7.8	1					
Vit	tal Signs Details Entry					
7.1	Record Identifier: [Record Identifier:]	O¹VS:	SPID			
7.2	Temperature: [Temperature]					
7.3	Unit: [Temperature Unit]	it] OC VSORRESU when VSTESTCD = TEMP				
7.4	Temperature Location: [Temperature Location:]	O EAR O RECTU	ORAL CAVITY			

ST	UDYID						VS=Vital	Signs
C4	591001: VITAL SIGN	S - BASELIN	E (VITALS BSL) VS	SCAT=GENERAL VITAL S	IGNS			
Vita	al Signs		<u> </u>					
	Date: [Date:]	<u> </u>	/ VSDTC					
	Weight: [Weight]		VSORRES when VS	TESTCD = WEIGHT				
	Un t: [Weight Unit]	Okg OLB VSOR	RESU when VSTES	TCD = WEIGHT				
	Height: [Height]		VSORRES when VS	TESTCD = HEIGHT				
	Un t: [Height Un t]	om VSOR						
	Body Mass Index: [Body Mass Index]		SORRES when VS1	TESTCD = BMI				
Vit	al Signs Details							
#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:
7.a	1						SITTING	
Vit	al Signs Details Entry							
7.1	Record Identifier: [Record Identifier:]	O1 VSSPIE						
7.2	Temperature: [Temperature]	V	SORRES when VST	ESTCD = TEMP				
7.3	Unit: [Temperature Unit]							
7.4	Temperature Location: [Temperature Location:] ORAL CAVITY EAR RECTUM AXILLA FOREHEAD							
7.5	Systol c: [Systolic:] VSORRES when VSTESTCD = SYSBP							
7.6	Diastol c: [Diastol c:]	VSORRES when VSTESTCD = DIABP						
7.7	BP Posit on: [BP Position]	SITTING	SPOS when VSTES	TCD = DIABP, SYSBP				
7.8	Pulse:	VSO	RRES when VSTES	TCD = PULSE				

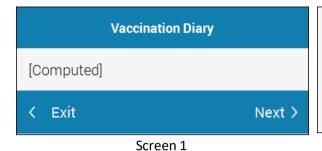
ST	UDYID					VS=Vital Signs	
C4	4591001: VITAL SIGNS - COVID (VITALS COV) - Repeating Form VSCAT=GENERAL VITAL SIGNS						
#	Date:			Vital Signs Details	•		
1	1						
Vita	al Signs						
	Date: [Date:]	<u>~</u> /	v /	VSDTC			
Vita	al Signs Details						
#	Record Identifier:	Systolic:	Diastolic:	Respiratory Rate in respirations/minute	Heart Rate	e in beats/minute	
2.a	1						
Vit	al Signs Details Entry						
2.1	Record Identifier: [Record Identifier:]	O 1	SPID				
2.2	Systol c: [Systolic:]						
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 W	when VSTESTCD = HR			

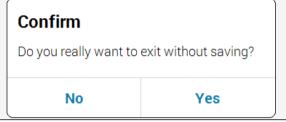
ST	TUDYID VS=Vital Signs							
C4	591001: VITAL SIGN	NS (VITALS F	UP) VSCAT=GENER	RAL VITAL SIGNS				
	al Signs							
	Date: [Date:]	<u> </u> /	/ VSDTC					
Vita	al Signs Details							
#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:
2.a	1						SITTING	
Vita	al Signs Details Entry							
2.1	Record Identifier: [Record Identifier:]	O1 VSSPIL						
2.2	Temperature: [Temperature]	VSORRES when VSTESTCD = TEMP						
2.3	Unit: [Temperature Unit]	OF VSORI	VOUNNEOU WIELL VOLEOTOD = LEINE					
2.4	Temperature Location: [Temperature Location:] ORAL CAVITY EAR RECTUM AXILLA FOREHEAD							
2.5	Systolic: [Systolic:]	VSORRES when VSTESTCD = SYSBP						
2.6	Diastol c: [Diastol c:]	VSORRES when VSTESTCD = DIABP						
2.7	BP Posit on: [BP Position]	SITTING	SPOS when VSTEST	TCD = DIABP, SYSBP				
2.8	Pulse: [Pulse:]	VSO	RRES when VSTES	TCD = PULSE				

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VSCAT=REACTOGENICITY VSSCAT=SYSTEMIC

3 Form: Vaccination Diary





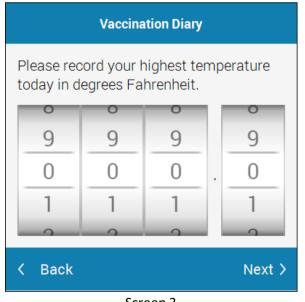
Message 1

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

- {1} Will display a date
- {2} Will display a number of days.

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

VSORRESU when VSTESTCD = TEMP



Screen 3

VSORRES when VSTESTCD = TEMP

MAXIMUM in SUPPVS

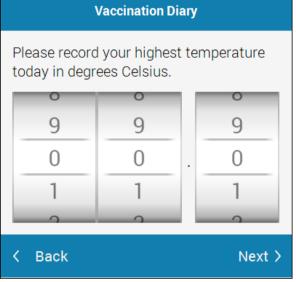


Info The temperature is equal to or lower than the temperature reported earlier today. The highest temperature observed today should be reported. If you do not wish to change the temperature please tap 'Back' until you exit this question. OK

Message 1 Message 2

VSORRESU when VSTESTCD = TEMP





Message 3 Screen 4

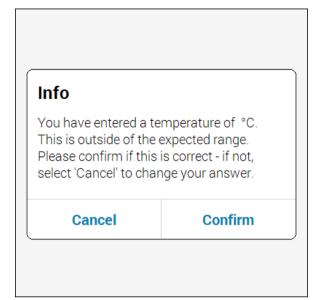
VSORRES when VSTESTCD = TEMP

MAXIMUM in SUPPVS

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FACAT=REACTOGENICITY

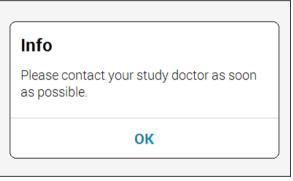
22-JUN-2020 Version 2



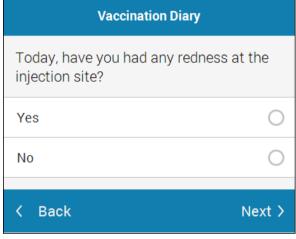
Message 3



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



Message 1



Screen 6

FAORRES when FATESTCD = OCCUR and FAOBJ = REDNESS

FASCAT = ADMINISTRATION SITE

App Subject Facing Screen Report English (USA) enUS

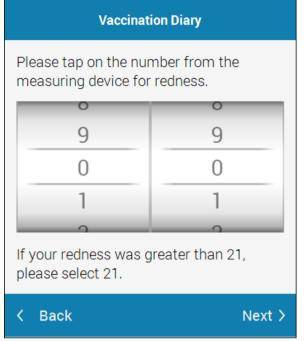
22-JUN-2020 Version 2

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. OK

Message 2



Screen 7

Info

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

OK

Message 2

Please confirm the number from the measuring device for redness: [Computed] Computed Next >

Screen 8

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

App Subject Facing Screen Report English (USA) enUS 22-JUN-2020 Version 2

FASCAT = ADMINISTRATION SITE

FAORRES when FATESTCD = OCCUR and FAOBJ = SWELLING

Vaccination Diary

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

Yes

No

No

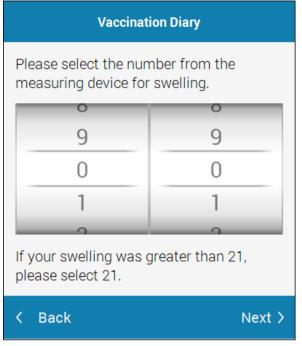
No

Next >

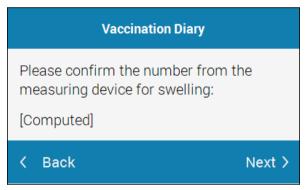
Screen 9

FASCAT = ADMINISTRATION SITE

FAORRES when FATESTCD = DIAMETER and FAOBJ = SWELLING

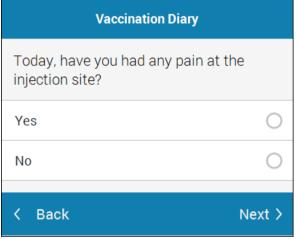


Screen 10



Screen 11

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



Screen 12

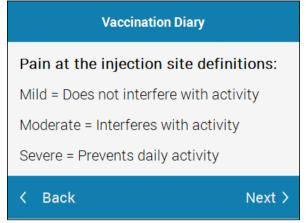
FAORRES when FATESTCD = OCCUR and FAOBJ = PAIN AT INJECTION SITE

FASCAT = ADMINISTRATION SITE

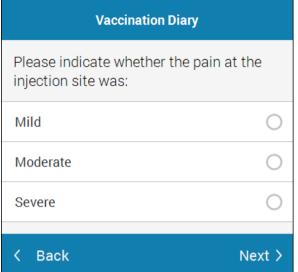
App Subject Facing Screen Report English (USA) enUS 22-JUN-2020 Version 2

FASCAT = ADMINISTRATION SITE

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

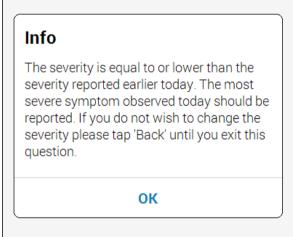


Screen 13



Screen 14





Message 2 Message 4

Back

Screen 17

FA=Findings Abou	ıt Events or	Interventions
------------------	--------------	---------------

		FA=Findings About	Events or Interventions
	nglish (l	ing Screen Report USA) enUS FASCAT = SYSTE FAORRES when FATI FAOBJ = FATIGUE	22-JUN-2020 Version 2 MIC ESTCD = OCCUR and
Vaccination Diary		Vaccinati	on Diary
Did you go to the ER or were you hospitalized for this reaction?		Today, have you expe (tiredness)?	rienced fatigue
Yes	0	Yes	0
No	0	No	0
< Back Ne	xt >	< Back	Next >
Screen 15		Scree	n 16
FASCAT = S	YSTEM	FAORRES when FATE FAOBJ = FATIGUE	STCD = SEV and
Vaccination Diary		Vaccinati	on Diary
Fatigue (tiredness) definitions: Mild = Does not interfere with activity		Please indicate wheth (tiredness) was:	ner the fatigue
Moderate = Some interference with activity		Mild	0
Sovere - Provents daily routine activity	,	Moderate	\circ

Severe

Back

Next >

Screen 18

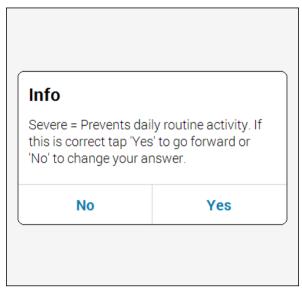
Next >

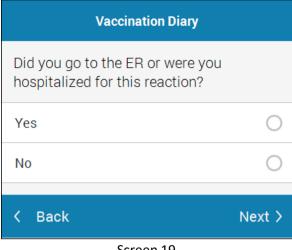
App Subject Facing Screen Report English (USA) enUS

22-JUN-2020 Version 2

FASCAT = SYSTEMIC

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



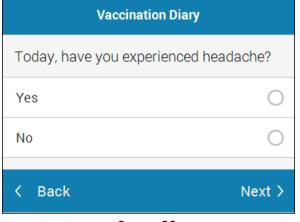


Screen 19

Message 2

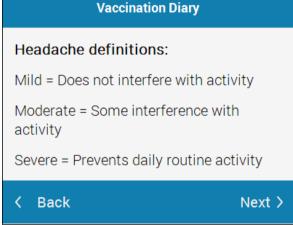
FAORRES when FATESTCD = OCCUR and FAOBJ = HEADACHE

FASCAT = SYSTEMIC



Screen 20

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Screen 21

FA=Findings About Events or Interventions

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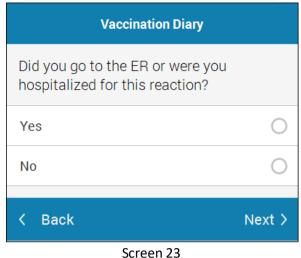
FASCAT = SYSTEMIC

FAORRES when FATESTCD = SEV and FAOBJ = HEADACHE

FASCAT = SYSTEMIC

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR HEADACHE

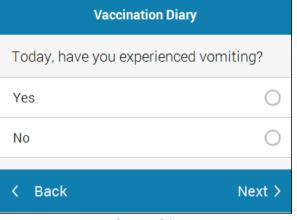
Vaccination Diary				
Please indicate whether the headache was:				
Mild (\circ			
Moderate (\circ			
Severe (0			
< Back Next	>			



Screen 22

FAORRES when FATESTCD = OCCUR and FAOBJ = VOMITING

FASCAT = SYSTEMIC



Vaccination Diary

Vomiting definitions:

Mild = 1 to 2 times in 24 hours

Moderate = More than twice in 24 hours

Severe = Requires intravenous hydration

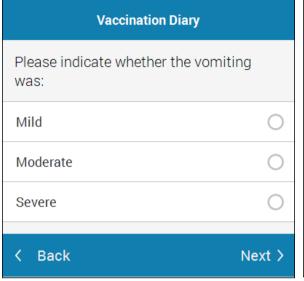
Compared to the property of the p

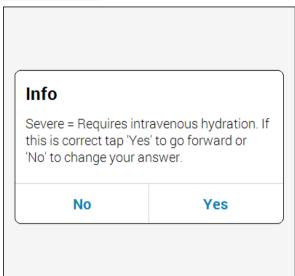
Screen 24 Screen 25

App Subject Facing Screen Report English (USA) enUS 22-JUN-2020 Version 2

FAORRES when FATESTCD = SEV and FAOBJ = VOMITING

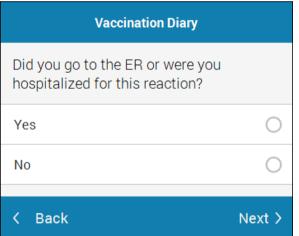
FASCAT = SYSTEMIC





Message 2

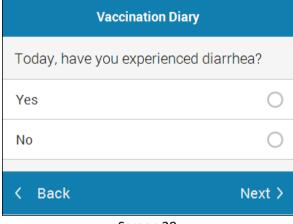
Screen 26



Screen 27

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR VOMITING

FASCAT = SYSTEMIC



Screen 28

FAORRES when FATESTCD = OCCUR and FAOBJ = DIARRHEA

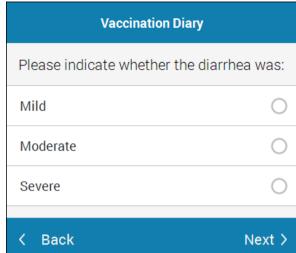
FASCAT = SYSTEMIC

App Subject Facing Screen Report English (USA) enUS 22-JUN-2020 Version 2

FASCAT = SYSTEMIC

FAORRES when FATESTCD = SEV and FAOBJ = DIARRHEA



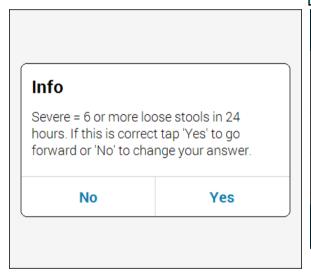


Screen 29

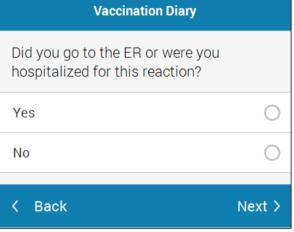
Screen 30

FASCAT = SYSTEMIC

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR DIARRHEA



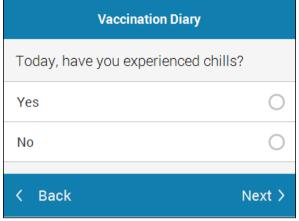
Message 2



Screen 31

FAORRES when FATESTCD = OCCUR and FAOBJ = CHILLS

FASCAT = SYSTEMIC



Screen 32

FASCAT = SYSTEMIC

FAORRES when FATESTCD = SEV and FAOBJ = CHILLS

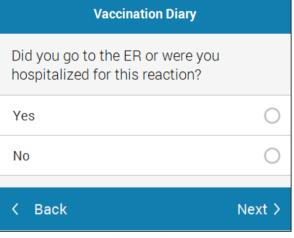


Screen 33



Screen 34

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Screen 35

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR CHILLS

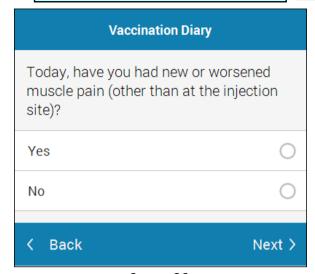
FASCAT = SYSTEMIC

App Subject Facing Screen Report English (USA) enUS

22-JUN-2020 Version 2

FAORRES when FATESTCD = OCCUR and FAOBJ = MUSCLE PAIN

FASCAT = SYSTEMIC



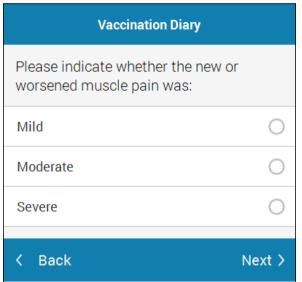
Screen 36



Screen 37

FASCAT = SYSTEMIC

FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR MUSCLE PAIN

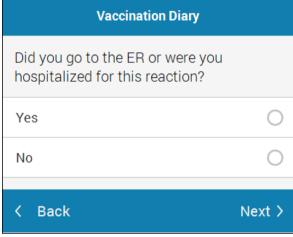


FAORRES when FATESTCD = SEV and FAOBJ = MUSCLE PAIN

Screen 38

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FASCAT = SYSTEMIC



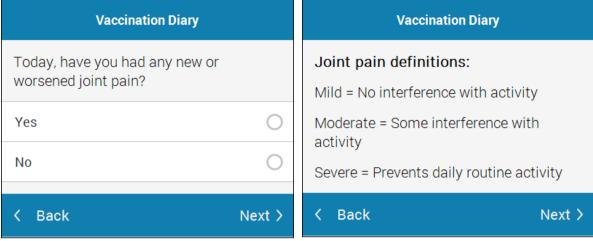
Screen 39

App Subject Facing Screen Report English (USA) enUS 22-JUN-2020 Version 2

FAORRES when FATESTCD = OCCUR and FAOBJ = JOINT PAIN

FASCAT = SYSTEMIC

FASCAT = SYSTEMIC

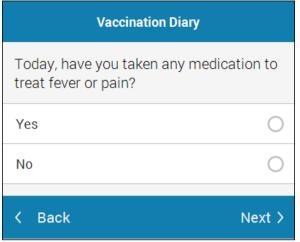


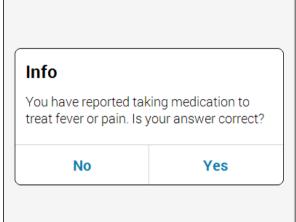
Screen 40 Screen 41

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	Yes
Moderate	No
Severe	○
< Back Ne	Screen 43 FAORRES when FATESTCD = OCCUR and FAOBJ = HOSPITALIZED FOR JOINT PAIR
Screen 42 FAORRES when FATESTCD = SEV and FAOBJ = JOINT PAIN	

FAORRES when FATESTCD = MEDTFVPN and FAOBJ = MEDICATIONS

FASCAT = MEDICATIONS GIVEN





Screen 44

Vaccination Diary

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

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

[Computed]

Save <

Screen 45

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

Where {1} = a number of days

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

Vaccination Diary

Message 2

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

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

[Computed]



Screen 46

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

Where $\{1\}$ = a number of days

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