## Annotated Study Book for Study Design: C4591001

Study Design Version: 19.0

**Sponsor: Pfizer** 

Protocol: C4591001

Sponsor Drug Name: BLINDED THERAPY

C4591001 - COVID19

Generated by Central Designer TM

March 30, 2021 10:56AM

C	<b>159100</b>	1: ADVI	ERSE E	VEN	T REPO	ORT (A	E) - R	epeating	Form					
#	Category	AE Identifier			Adverse Event Still	Grade	Serious	Is AE a Result of a Medication Error	Relationship to Study Treatment	Taken with Study	Medication Given		Caused Study Discontinuation	
1					Ongoing					Treatment				
	verse Eve	ent Report												
1.	Categor [Categor		OAD	VERSE	EVENT									
2.	AE ID: [AE Ider	ntifier]												
3.	Adverse (If possi diagnosi individua sympton [Adverse	ble specify s, not al ns)												
4.	Start Da [Start D		~	/   ] :	<ul><li>✓ /</li><li>✓ 24-hc</li></ul>	<b>v</b> our clock								
5.	still ongo [Is the A		O NO		<b>~</b> /	₽-hour clo	ck							
6.	Toxicity [Toxicity		1 2 3 4											
7.	ser ous?		Is t	YES Is this ser ous event associated with congenital anomaly or birth defect?      YES										
	If Yes, N PFIZER IMMEDI/		Did		erious eve	ent result	in death	?						
	prolonga existing hosp tali Persister signif ca disabil ty Congenii anomaly defect; 1 med cal may jeo subject a require med cal/ interven	ing; t zation or it on of ization; nt or nt //incapac ty tal //birth Important event (i.e. pardize and may /surgical tion to	r; Oth	<ul> <li>YES</li> <li>NO</li> <li>Did this serious event require or prolong hospitalization?</li> <li>YES</li> <li>NO</li> <li>Did this serious event result in persistent or significant disabil ty/incapac ty?</li> <li>YES</li> <li>NO</li> <li>Is this ser ous event life threatening?</li> <li>YES</li> <li>NO</li> <li>Other med cally important ser ous event</li> <li>YES</li> <li>NO</li> </ul>										
	prevent outcome [Serious	es).												
8.	study Me Error? If Yes, re type of r error on Medicati Log. [Is AE a	e result of edication ecord the medication the	ONO											
9.	to study [Relat or	vent related treatment: nship to reatment]	If N	CONCO CONCO OTHER If Othe	ated to st OMITANT OMITANT	DRUG TRI NON-DRU	EATMENT		due to:					
1.0	l ata di t	ation Tol.			TUDDAW									
10	with Stu	ction Taker dy	~		THDRAWN ICABLE	4							E010 000060E	

	Treatment: [Act on Taken with Study Treatment]	0
11.	Was a Concomitant Medication given? [Concom tant Med cation Given]	VES NO
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	VES NO
13.	What was the outcome of this adverse event?: [Outcome]	<ul> <li>FATAL</li> <li>NOT RECOVERED/NOT RESOLVED</li> <li>RECOVERED/RESOLVED</li> <li>RECOVERED/RESOLVED WITH SEQUELAE</li> <li>RECOVERING/RESOLVING</li> <li>UNKNOWN</li> </ul>
14.	D d the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	VES NO
15.	Ser ous Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]	
16.	Comparison Term [hidden] [Comparison Term]	
17.	Lowest Level Term [hidden] [Lowest Level Term]	
18.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	
19.	D ctionary-Derived Term [hidden] [D ctionary-Derived Term]	
20.	Preferred Term Code [hidden] [Preferred Term Code]	
21.	High Level Term [hidden] [High Level Term]	
22.	High Level Term Code [hidden] [High Level Term Code]	
23.	High Level Group Term [hidden] [High Level Group Term]	
24.	High Level Group Term Code [hidden] [High Level Group Term Code]	
25.	Primary System Organ Class [hidden] [Primary System Organ Class]	
26.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	

# C4591001: INFORMED CONSENT - BOOSTER (BOOST CONS)

]	nformed Consent - Booster				
:	. Consent Was:	OBTAINED			
	[Consent Was:]	Date Written Consent Obtained			

C4	C4591001: INCLUSION/EXCLUSION CRITERIA - BOOSTER (BOOST 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	Exclusion Criteria Met Entry					
2.1	Description of Exclusion Cr terion Met [Criter on Descript on]					

## C4591001: BOOSTER DOSE TRIGGER FORM (BOOST TRIG)

#### Booster Dose Trigger Form

1.	Select appropriate response -
	Will the participant return for
	consent/eligibility assessment
	for the booster dose vis t?
	[Trigger Response 13]

The participant will return for consent/eligibility assessment for the booster dose visit
 The participant will NOT return for consent/eligibility assessment for the booster dose visit
 The participant will return for consent/eligibility assessment for the LOW DOSE booster dose visit (Select this option for part cipant returning for 5 or 10 mcg booster)

C4	C4591001: LABORATORY DATA - HEMATOLOGY (CD4)						
Lat	ooratory Data Hematology						
	Lab Panel: [Category for Lab Test]	HEMAT	OLOGY				
2. Laboratory Name and Address [Vendor Name (DERIVED)]							
	Collection Date: [Collect on Date:]	<b>v</b> /	♥/				
	Specimen Type: [Specimen Type]	OBLOOD					
Lat	Result						
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:	Lab Normal Range	
5.a			CD4_PX4722				
Lał	Result Entry						
5.1	Sponsor ID: [Sponsor-Defined Identifier]						
5.2	Test: [Test:]	○CD4_I	PX4722				
5.3	Result: [Result:]						
5.4	5.4 Not Done: [hidden] [Not Done:]		DONE				
5.5	5.5 LNMT [Lab Normal Range]		Low				
			High				
		Un t 10^3, /uL %	/mm3				

# C4591001: COHORT SELECTION (COHORT SEL)

C	Cohort Selection				
D	O 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]	<ul> <li>STAGE 1 SENTINEL COHORTS</li> <li>STAGE 1 NONSENTINEL COHORTS</li> <li>STAGE 2 COHORTS</li> <li>STAGE 3 COHORTS</li> </ul>			

-		1	TIONS - BASELINE (CON	-		1	Dees	Deute	Chaut
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre- specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date
1									
Cor	comitant Medications								
1.	What is the medication [Sponsor-Defined Identi								
2.	Category: [Category for Medicat or	n]	GENERAL CONCOMITANT MEDI	CATIONS					
3.	Concomitant Medication [Concom tant Medication		<b>○</b> NO						
<ol> <li>Med cation:</li> <li>Prov de the complete gener c drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade oi proprietary name. Include clarifying information in the Med cat on text (e.g., Ingredient(s), route, use, formulation).</li> <li>[Name of Medication]</li> </ol>									
5.	Dose: [Dose Description]								
6.	Dose Unit: [Dose Unit]								
7.	Dose Frequency: [Dose Frequency]								
8.	Route: [Route]								
9.	Start Date: [Start Date]								
10.	Comparison Term [hidd [Comparison Term]	en]							
11.	Standardized Med catior derived. [hidden] [Standardized Med cat o	,							
12.	Standardized Med cat or derived [hidden] [Standardized Med cat o	,							

C	C4591001: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS (CONMED VAX) - Repeating Form								
#	Sponsor-Defined Identifier	Catego	ry for Medication	Concomitant	Medications Pre-specified	Name of Medication	Start Date		
1									
Co	oncomitant Medications								
1.	What is the medication identifier? [Sponsor-Defined Identifier]				]				
2.	Category: [Category for Med cat on]		○ VACCINATIONS						
3.	Concomitant Medications Pre-specific [Concomitant Medications Pre-specific		ONO						
4.	Medication: Provide the complete gener c drug na (including salt form, where applicabl 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.,							
5.	Date: [Start Date]		• / • /	*					
6.	Comparison Term [hidden] [Comparison Term]								
7.	Standardized Medication Name - Dict derived. [hidden] [Standardized Med cat on Name]	onary							
8.	Standardized Medicat on Code - Dicti derived [hidden] [Standardized Med cat on Code]	onary							

## C4591001: MAIN INFORMED CONSENT (CONSENT)

I	formed Consent				
1	Consent Was:	OBTAINED			
	[Consent Was:]	Date Written Consent Obtained			

C4501001.	CONTACT	OUTCOME .	MONTH 1	(CONTACT 1M)
C4391001.	CUNTACT	OUICOME -		(CONTACT IM)

Co	ntact Outcome	
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	CONTACT OUTCOME
2.	Contact Type: [Type of Contact/Visit]	O CLINIC VISIT
3.	Was contact made? [Was Contact Made]	<pre>   YES   Date of Contact:</pre>
4.	Comments: [Comments/Findings/Details]	

C4591001:	CONTACT	OUTCOME -	MONTH 6	(CONTACT 6M)	)
010010011	CONTROL	COLCOLLE			,

Co	ontact Outcome			
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	CONTACT OUTCOME		
2.	Contact Type: [Type of Contact/Visit]	O CLINIC VISIT		
3.	Was contact made? [Was Contact Made]	<pre>YES Date of Contact:</pre>		
4.	Comments: [Comments/Findings/Details]			

С	C4591001: CONTACT OUTCOME (CONTACT SV)			
Co	ontact Outcome			
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	O CONTACT OUTCOME		
2.	Contact Type: [Type of Contact/Visit]	TELEPHONE VISIT		
3.	Was contact made? [Was Contact Made]	<pre>YES Date of Contact:</pre>		
4.	Comments: [Comments/Findings/Details]			

# C4591001: CONTACT OUTCOME - UNPLANNED (CONTACT UV)

Co	Contact Outcome				
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	O CONTACT OUTCOME			
2.	Contact Type: [Type of Contact/Visit]	O TELEPHONE VISIT			
3.	Was contact made? [Was Contact Made]	YES         Date of Contact:         ✓			
4.	Comments: [Comments/Findings/Details]				

#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	Comments:		
1								
Mi	crobiology Specimen							
1.	Actual Date of Collection: [Date of Collect on]							
2.	Specimen Type: [Specimen Type]	SERUM BLOOD PLASMA	BLOOD					
3.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP SYN	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2					
4.	Device Type: [Device Type]	SARS-COV-2 DIAGNOSTI	SARS-COV-2 DIAGNOSTIC TEST					
5.	Test Result: [Result]	<ul> <li>POSITIVE</li> <li>NEGATIVE</li> <li>INDETERMINATE</li> </ul>	<b>O</b> NEGATIVE					
6.	Comments/Findings/Details: [Comments:]							

C	C4591001: MICROBIOLOGY SPECIMEN (COVID TEST) - Repeating Form								
#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:	Trade Name Other, Specify
1									
Mi	icrobiology Speci	men							
1.	Actual Date of Co [Date of Collect o								
2.	Specimen Type: [Specimen Type]		SWABBED MATERIAL	5					
3.		imen Collection Location: cimen Collection Location] ONASOPHARYNX LOWER RESPIRATORY SYSTEM THROAT							
4.	Assay Code and I [Assay Code and		SEVERE ACUTE RESP SYND	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2					
5.	Device Type: [Device Type]		SARS-COV-2 DIAGNOSTIC	SARS-COV-2 DIAGNOSTIC TEST					
6.	Trade Name: [Trade Name]								
7. Test Result: [Result] OPOSITIVE ONEGATIVE OINDETERMINATE									
8.	. Comments/Findings/Details: [Comments:]								
9.	Trade Name Othe								

C45	91001: DEATH DETAI	LS CODED (DEATH DTL)	
Deat	h Details		
oi []	ate of Collect on / Notification f Death: Date of Collect on / Notif cat on f Death]		
		Cause of Death Status	Cause of Death
2.			
Caus	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]		
2.3	Comparison Term [hidden] [Comparison Term]		
2.4	Lowest Level Term [hidden] [Lowest Level Term]		
2.5	Lowest Level Term Code [hidden] [Lowest Level Term Code]		
2.6	Dict onary-Derived Term [hidden] [Dictionary-Derived Term]		
2.7	Preferred Term Code [hidden] [Preferred Term Code]		
2.8	High Level Term [hidden] [High Level Term]		
2.9	High Level Term Code [hidden] [High Level Term Code]		
2.10	High Level Group Term [hidden] [High Level Group Term]		
2.11	High Level Group Term Code [hidden] [High Level Group Term Code]		
2.12	Primary System Organ Class [hidden] [Primary System Organ Class]		
2.13	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]		

#### C4591001: DEMOGRAPHY (DEMOG)

_			
De	emography		
1.	Subject ID [Subject ID]		
2.	Birth Date: [Birth Date]		
3.	Sex: [Sex]	O FEMALE MALE	
4.	Ethnicity: [Ethnicity]	<ul> <li>HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</li> <li>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</li> <li>NOT REPORTED</li> </ul>	
5.	Race: (Check X all that apply): [Race Of Subject]	BLACK OR AFRICAN AMERICAN AMERICAN INDIAN OR ALASKA NATIVE ASIAN NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WHITE NOT REPORTED	
6.	Racial Designation: [Racial Designat on]	O JAPANESE O OTHER	

С	C4591001: DISPOSITION - SCREENING FOR BOOSTER DOSE (DISP BOOST)			
D	Disposition - Screening for Booster Dose			
1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]			
2.	Phase of Disposition: [Disposition Phase]	© REPEAT SCREENING 2		
3.	Status: [Status]			
4.	Specify Status: [Specify Status]			

# C4591001: DISPOSITION - FOLLOW-UP (DISP FUP)

Di	visposition - Follow-Up				
1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]				
	Phase of Disposition: [Disposition Phase]	O FOLLOW-UP			
3.	Status: [Status]				
	Specify Status: [Specify Status]				

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

# C4591001: DISPOSITION - SCREENING (DISP SCR)

Di	isposition - Screening				
1.	Date of Complet on/Discontinuation/Death [Date of Completion/Discontinuation/Death]				
	Phase of Disposition: [Disposition Phase]	SCREENING			
3.	Status: [Status]				
	Specify Status: [Specify Status]				

### C4591001: DISPOSITION - TREATMENT (DISP TRT)

D	isposition - Treatment				
1.	Date of Complet on/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]				
2.	Phase of Disposition: [Disposition Phase]	O VACCINATION OPEN LABEL TREATMENT O SUBSTUDY			
3.	Status: [Status]				
4.	Specify Status: [Specify Status]				

С	C4591001: DATE OF VISIT (DOV)			
D	Date of Visit			
1.	Date of Visit [Date of Visit]			
2.	Erroneous Visit [Visit Error]	O ERRONEOUS VISIT		

С	C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)					
Da	ate of Visit					
1.	Date of Visit [Date of Visit]					
2.	Erroneous Visit [Visit Error]	O ERRONEOUS VISIT				
С	COVID-19 Illness Visit					
3.	COVID-19 Illness Visit:     Image: COVID-19 Illness Visit       [COVID-19 Illness Visit]     Image: COVID-19 Illness Visit					

C	C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)				
Da	ite of Visit				
	Date of Visit [Date of Visit]				
2.	Erroneous Visit [Visit Error]	O ERRONEOUS VISIT			
СС	COVID-19 Illness Visit				
3.	COVID-19 Illness Visit: [COVID-19 Illness Vist]				

C	C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV)				
Da	ate of Visit				
1.	Date of Visit [Date of Visit]				
2.	Erroneous Visit [Visit Error]	O ERRONEOUS VISIT			
С	COVID-19 Surveillance Visit				
3.	COVID-19 Surveillance Vist:     Image: Covid and the second				

C	C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)				
Da	ate of Visit				
1.	Date of Visit [Date of Visit]				
2.	Erroneous Visit [Visit Error]	O ERRONEOUS VISIT			
С	COVID-19 Repeat Swab				
3.	COVID-19 Repeat Swab: [COVID-19 Repeat Swab]				

# C4591001: INFORM ENROLLMENT (ENROLL) InForm Enrollment 1. Subject ID [Subject ID]

# C4591001: HIV STATUS (HIV) HIV Status

_ L		
	1. Select appropriate response - What is the subject HIV status? [Trigger Response 2]	<ul> <li>The subject is known to be HIV POSITIVE</li> <li>The subject is NOT known to be HIV POSITIVE</li> </ul>

C	1591001: LAB CHEMISTRY (HIV R	NA)					
La	b Chemistry Details						
1.	Lab Panel: [Category for Lab Test]	OCLINICAL CHEMISTRY					
2.	Laboratory Name and Address [Vendor Name]						
3.	Collection Date: [Collect on Date:]	<b>v</b> / <b>v</b> /					
4.	Specimen Type: [Specimen Type]     BLOOD						
La	b Result						
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:	Lab Normal	Range
5.a	1	HIV RNA (Ultra	asensitive)				
La	b Result Entry						
5.:	Sponsor ID: [Sponsor-Defined Identifier]		]				
5.2	2 Test: [Test:]	O HIV RNA (Ultrasens tive)					
5.3	B Result: [Result:]						
5.4	Not Done: [hidden] [Not Done:]	ONOT DONE					
5.!	5 LNMT [Lab Normal Range]	Low					
		High					
	Un t /mL						
L							

#### C4591001: ELECTRONIC SAMPLE TRACKING - HLA (HLA)

Ele	ectronic Sample Tracking					
1.	Data Origin [Data Origin]	○ SITE				
2.	Sample Type [Sample Type]	O WHOLE_BLOOD				
3.	Sample Collected? [Sample Collected]	NO YES Date of Collect on: ↓ ↓ ↓ ↓				
	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]					
		Sample ID				
5.						
Ali	quot Entry					
Ple	ease enter barcode for each aliquot.					
5.1	Sample ID [Sample ID]					

C4591001: HEALTH CARE UTILIZATION (HLTHCARE)						
Health Care Utilization						
	Evaluation Interval: [hidden] [Evaluation Interval]	○ SINCE THE START OF THE RESPIRATORY ILLNE	SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE			
2.	Disease Name: [hidden] [Disease Name]	© RESPIRATORY ILLNESS				
He	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				
He	alth Care Utilization Entry					
3.1	Pre-Specified: [hidden] [Pre-Specified]	YES				
3.2	Physician or Healthcare Professional: [Type of Practitioner]	<ul> <li>SPECIALIST</li> <li>EMERGENCY ROOM</li> <li>PRIMARY CARE PHYSICIAN</li> <li>URGENT CARE</li> <li>TELEPHONE CONSULTATION</li> <li>OTHER</li> </ul>				
3.3	Occurrence of Visits or Contacts: [Occurrence of Vis ts or Contacts]	VES Number of Vis ts or Contacts:				
He	alth Care Utilization Other					
	Other Type of Pract tioner Specify: [Other Type of Pract t oner Specify]					
He	alth Care Utilization					
	<ul> <li>Has the subject been hospitalized due to potential COVID-19 illness?</li> <li>[Been Hospitalized]</li> <li>YES</li> <li>YES</li> <li>NO</li> <li>NO</li> </ul>					

C	C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form						
#	Hospitalization Category		Hospitalization Term	Admission Date	Ongoing		
1							
Ho	ospitalization Details						
1.	Hosp talization Category: [Hospitalization Category]	OHOSPITALIZATION S	TATUS				
2.	Hosp talization Term: [Hospitalization Term] O ICU HOSPITAL						
3.	Admission Date: [Admission Date]	✓ / ✓ /	~				
4.	Ongoing? [Ongoing]	VES NO Discharge Date:	V				

C4	591001: ILLNESS DET	AILS (ILL POTEN)	
Illr	ess Details		
1.	Category of Clinical Event: [Category of Clin cal Event:]	O POTENTIAL COVID-19 ILLNESS	
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	YES     Respiratory Illness Diagnosis:     Date of Diagnosis:     V	
3.	Toxicity Grade: [Toxicity Grade]	0 1 2 3 4 5	
4.	Comparison Term: [hidden] [Comparison Term]		
5.	Lowest Level Term [hidden] [Lowest Level Term]		
6.	Lowest Level Term Code [hidden] [Lowest Level Term Code]		
7.	D ctionary Derived Term [hidden] [D ctionary Derived Term]		
8.	Preferred Term Code [hidden] [Preferred Term Code]		
9.	High Level Term [hidden] [High Level Term]		
10.	High Level Term Code [hidden] [High Level Term Code]		
11.	High Level Group Term [hidden] [High Level Group Term]		
12.	High Level Group Term Code [hidden] [High Level Group Term Code]		
13.	Primary System Organ Class [hidden] [Primary System Organ Class]		
14.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]		

C4591001:	<b>TILINESS</b>	DETATIS -	SEVERE	(11)	SEVERE)
C4331001.	ILLINL33	DLIAILS -	JEVERE	(	JLVLKL)

C4	591001: ILLNESS DET	AILS - SEVERE (ILL SEVERE)
Illn	ess Details	
1.	Category of Clinical Event: [Category of Clin cal Event:]	SEVERE COVID-19 ILLNESS
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	<ul> <li>SIGNIFICANT ACUTE RENAL DYSFUNCTION</li> <li>SIGNIFICANT ACUTE HEPATIC DYSFUNCTION</li> <li>SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION</li> </ul>
3.	Was a diagnosis obtained? [Diagnosis Obtained]	YES         Diagnosis:         Start Date:         ♥ / ♥ / ♥         Ongoing?:         YES         NO         End Date:         ♥ / ♥ / ♥         ♥ NO         End Date:         ♥ / ♥         ♥ NO
4.	Toxicity Grade: [Toxicity Grade]	01 02 03 04 05
5.	Comparison Term: [hidden] [Comparison Term]	
6.	Lowest Level Term [hidden] [Lowest Level Term]	
7.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	
8.	D ctionary Derived Term [hidden] [D ctionary Derived Term]	
9.	Preferred Term Code [hidden] [Preferred Term Code]	
10.	High Level Term [hidden] [High Level Term]	
11.	High Level Term Code [hidden] [High Level Term Code]	
12.	High Level Group Term [hidden] [High Level Group Term]	
13.	High Level Group Term Code [hidden] [High Level Group Term Code]	
14.	Primary System Organ Class [hidden] [Primary System Organ Class]	
15.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	

C4	591001: ILLNESS DET	AILS - SEV	ERE (ILL	SEVERE) -	Repeatin	g Form			
#	Category of Clinical E		1	ubcategory of			Diagnosis O	btained	Toxicity Grade
1									
Illr	ness Details								
1.	Category of Clinical Event: [Category of Clin cal Event:]	O SEVERE CC	OVID-19 ILLNE	ESS					
2.	Subcategory of Clin cal Event: [Subcategory of Clin cal Event]	SIGNIFICA	NT ACUTE HE	NAL DYSFUNCTI PATIC DYSFUNC UROLOGIC DYSF	CTION				
3.	Was a diagnosis obtained? [Diagnosis Obtained]	VES Diagnosis: Start Date: VI Ongoing?: VES NO End Dat	✓ /						
4.	Toxicity Grade:	● NO	/						
		2 3 4 5							
5.	Comparison Term: [hidden] [Comparison Term]								
6.	Lowest Level Term [hidden] [Lowest Level Term]								
7.	Lowest Level Term Code [hidden] [Lowest Level Term Code]								
8.	D ctionary Derived Term [hidden] [D ctionary Derived Term]								
9.	Preferred Term Code [hidden] [Preferred Term Code]								
10.	High Level Term [hidden] [High Level Term]								
11.	High Level Term Code [hidden] [High Level Term Code]								
12.	High Level Group Term [hidden] [High Level Group Term]								
13.	High Level Group Term Code [hidden] [High Level Group Term Code]								
14.	Primary System Organ Class [hidden] [Primary System Organ Class]								
15.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]								

#### C4591001: IMAGING (IMAGING) - Repeating Form # Date of Assessment Location of Assessment **Imaging Method Overall Assessment** 1 Imaging 1. Date of Assessment: ✓ / **~** / ~ [Date of Assessment] 2. Locat on of Assessment: CHEST [Location of Assessment] OHEAD OTHER If other, specify: 3. Type of Imaging Exam: ○CT SCAN [Imaging Method] OX-RAY OULTRASOUND ○ MRI OTHER If other, specify: OABNORMAL 4. Assessment: [Overall Assessment] If abnormal, specify findings: **INDETERMINATE** NORMAL OUNKNOWN ONOT EVALUABLE

## C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

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

#### Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	01 02 03 04
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

Exc	lusion Criteria				
#	Exclusion Number	•	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1		lical 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		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 allerg c		EX03A00
2.d	4	Receipt of	med cat ons intended to prevent COVID-19		EX04A00
2.e	8		mpromised indiv duals with known or suspected immunodeficiency, as d by history and/or laboratory/phys cal examination		EX08A00
2.f	9		s 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	Women wi	no are pregnant or breastfeeding		EX11A00
2.i	12	Previous v	accinat on with any coronavirus vaccine		EX12A00
2.j	13	Subjects w cort coster	ho receive immunosuppressive therapy, such as cytotox c agents or system c oids		EX13A01
2.k	15		blood/plasma products or immunoglobulin, from 60 days before study n administrat on or planned receipt throughout the study		EX14A01
2.1	16		on in other studies involving study intervention w thin 28 days pr or to study or during study participat on		EX15A01
2.m	17	Previous p nanopart c	articipation in other studies involving study intervent on containing lip d les		EX16A01
2.n	22		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	у			
2.1	Exclusion Number: [Exclusion Number]				
2.2	Cr terion Description [Criter on Descript o				
2.3	Cr terion met? [Criter on met?]		● YES Describe details if relevant		

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

Page 41 of 118

# C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

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

#### Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	●1 ●2 ●3 ●4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Crterion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

**Exclusion Criteria** Criterion met? Criterion ID: (For Pfizer use only) # Exclusion Number **Criterion Description** EX01A00 2.a 1 Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation 2.b 2 Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or EX02A00 hepatitis B virus (HBV) 3 EX03A00 History of severe adverse reaction associated with a vaccine and/or severe allerg c 2.c reaction (eg, anaphylaxis) to any component of the study intervent on(s) 2.d 4 Receipt of med cat ons intended to prevent COVID-19 EX04A00 8 EX08A00 Immunocompromised indiv duals with known or suspected immunodeficiency, as 2.e determined by history and/or laboratory/phys cal examination 2.f 10 Bleeding diathesis or condition associated w th prolonged bleeding that would, in the EX10A00 opinion of the investigator, contraindicate intramuscular inject on EX11A00 Women who are pregnant or breastfeeding 11 2.g 2.h 12 Previous vaccinat on with any coronavirus vaccine EX12A00 2.i 13 EX13A01 Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c cort costeroids 2.j 15 Receipt of blood/plasma products or immunoglobulin, from 60 days before study EX14A01 intervention administrat on or planned receipt throughout the study 2.k 16 Participation in other studies involving study intervention within 28 days pr or to study EX15A01 entry and/or during study participation 2.1 17 Previous part cipation in other studies involving study intervent on containing lip d EX16A01 nanopart cles 2.m 22 Investigator s te staff or Pfizer employees directly involved in the conduct of the study, EX21A01 site staff otherwise supervised by the investigator, and their respective family members **Exclusion Criteria Entry** 2.1 Exclusion Number: ~ Exclusion Number 2.2 Cr terion Description: ~ [Criter on Descript on ○YES 2.3 Cr terion met? Criter on met?] Describe details if relevant ONO

2.4 Cr terion ID: (For Pfizer use

#### FDA-CBER-2022-5812-0228725

file:///C:/Users/zhangd70/AppData/Local/Apps/2.0/7QDN0DKX.747/1YNZC0P6.4RQ/orac..08.0 182cbe9101fd197d 0006.0003 3b03f6c8c5fb... 3/30/2021



Page 43 of 118

## C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)

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

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

#### Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	01 02 03 04
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Crterion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

**Exclusion Criteria** # Exclusion Number Criterion met? Criterion ID: (For Pfizer use only) **Criterion Description** Other medical or psychiatric condition incl. recent (within past year) or active suicidal EX01A00 2.a 1 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 allerg c 2.c reaction (eg, anaphylaxis) to any component of the study intervent on(s) 2.d 4 Receipt of med cat ons intended to prevent COVID-19 EX04A00 8 EX08A00 Immunocompromised indiv duals with known or suspected immunodeficiency, as 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 10 Bleeding diathesis or condition associated w th prolonged bleeding that would, in the EX10A00 2.g opinion of the investigator, contraindicate intramuscular inject on Women who are pregnant or breastfeeding EX11A00 2.h 11 12 Previous vaccinat on with any coronavirus vaccine EX12A00 2.i 2.j 13 Individuals who receive immunosuppressive therapy, such as cytotoxic agents or EX13A00 systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are perm tted 2.k 14 Receipt of blood/plasma products or immunoglobulin, from 60 days before study EX14A00 intervention administrat on or planned receipt throughout the study Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participat on EX15A00 2.1 15 EX16A00 2.m 16 Previous participation in other studies involving study intervent on containing lip d nanopart cles 21 Investigator s te staff or Pfizer employees directly involved in the conduct of the study, EX21A00 2.n site staff otherwise supervised by the investigator, and their respective family members **Exclusion Criteria Entry** 2.1 Exclusion Number: ~ [Exclusion Number] Cr terion Description: ~ 2.2 [Criter on Descript on] ○YES 2.3 Cr terion met? [Criter on met?] Describe details if relevant

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

Page 45 of 118

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)						
		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	Exclusion Criteria Met Entry						
2.1	Description of Exclusion Cr terion Met [Criter on Descript on]						

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

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

Inc	nclusion Criteria					
#	Inclusion Number	Criterion Description	Criterion met? Crite	erion 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)	INOI	1A00		
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures	IN02	2A00		
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	INOS	3A00		
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol	IN04	4A00		

#### Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	●1 ●2 ●3 ●4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Crterion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

090177e196cd54aa\Approved\Approved On: 16-Apr-2021 13:33 (GMT) **Exclusion Criteria** 2.a 1 2.b 2 3 2.c 2.d 4 5 2.e 2.f 8 2.g 2.h 2.i 2.j 2.k 2.1 2.m 17 2.n 22 2.1

# Exclusion Number Criterion met? Criterion ID: (For Pfizer use only) **Criterion Description** Other medical or psychiatric condition incl. recent (within past year) or active suicidal EX01A00 deation/behavior/lab abnormal ty that may increase the risk of study participation Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or EX02A00 hepatitis B virus (HBV) EX03A00 History of severe adverse reaction associated with a vaccine and/or severe allerg c reaction (eg, anaphylaxis) to any component of the study intervent on(s) Receipt of med cat ons intended to prevent COVID-19 EX04A00 EX05A00 Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19 Immunocompromised indiv duals w th known or suspected immunodeficiency, as EX08A00 determined by history and/or laboratory/phys cal examination Bleeding diathesis or condition associated w th prolonged bleeding that would, in the EX10A00 10 opinion of the investigator, contraindicate intramuscular inject on 11 Women who are pregnant or breastfeeding EX11A00 12 Previous vaccinat on with any coronavirus vaccine EX12A00 EX13A01 13 Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c cort costeroids 15 Receipt of blood/plasma products or immunoglobulin, from 60 days before study EX14A01 intervention administrat on or planned receipt throughout the study EX15A01 16 Participation in other studies involving study intervention within 28 days pr or to study entry and/or during study participat on EX16A01 Previous participation in other studies involving study intervent on containing lip d nanopart cles Investigator s te staff or Pfizer employees directly involved in the conduct of the study, EX21A01 site staff otherwise supervised by the investigator, and their respective family members **Exclusion Criteria Entry** Exclusion Number: ~ [Exclusion Number] 2.2 Cr terion Description: ~ [Criter on Descript on] 2.3 Cr terion met? ○YES [Criter on met?] Describe details if relevant ONO



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

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

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

### Inclusion Criteria Entry

. . .

1.1	Inclusion Number: [Inclusion Number]	●1 ●2 ●3 ●4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Crterion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

EXC							
#	Exclusion 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 the shormal 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)		EX02A00		
2.c	3		severe adverse reaction associated with a vaccine and/or severe allerg c g, anaphylaxis) to any component of the study intervent on(s)		EX03A00		
2.d	4	Receipt of	med cat ons intended to prevent COVID-19		EX04A00		
2.e	5	Stages 1 a	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		Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c cort costeroids		EX13A01		
2.1	15		Receipt of blood/plasma products or immunoglobulin, from 60 days before study nervention administrat on or planned receipt throughout the study		EX14A01		
2.m	16		n in other studies involving study intervention within 28 days pr or to study or during study participation		EX15A01		
2.n	.n 17 Previous pranopart		articipation in other studies involving study intervent on containing lip d es		EX16A01		
2.0			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		EX21A01		
Exc	lusion Criteria Entr	у					
2.1	2.1 Exclusion Number: [Exclusion Number]						
2.2	2.2 Cr terion Description: [Criter on Descript on]						
2.3	Cr terion met? [Criter on met?]		O YES Describe details if relevant				

	<sup>◯</sup> NO	
2.4 Cr terion ID: (For only) [Criter on ID: (Fo only)]		

Page 50 of 118

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

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

Inc	nclusion Criteria					
#	Inclusion Number	Criterion Description	Criterion met? Crite	erion 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)	INOI	1A00		
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures	IN02	2A00		
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	INOS	3A00		
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol	IN04	4A00		

### Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	$ \begin{array}{c} 1\\ 2\\ 3\\ 4 \end{array} $	
1.2	Cr terion Description: [Criter on Descript on]		
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant	
1.4	Crterion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>	

Excl	xclusion Criteria						
#	Exclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)				
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00				
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	EX02A00				
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allerg c reaction (eg, anaphylaxis) to any component of the study intervent on(s)	EX03A00				
2.d	4	Receipt of med cat ons intended to prevent COVID-19	EX04A00				
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19	EX05A00				
2.f	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination	EX08A00				
2.g	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention	EX09A00				
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00				
2.i	11	Women who are pregnant or breastfeeding	EX11A00				
2.j	12	Previous vaccinat on with any coronavirus vaccine	EX12A00				
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are perm tted	EX13A00				
2.1	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A00				
2.m	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A00				
2.n	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A00				
2.0	21	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	EX21A00				
Exc	lusion Criteria Entr	/					
2.1 Exclusion Number: [Exclusion Number]							
2.2 Cr terion Description: [Criter on Descript on]							
2.3 Cr terion met? [Criter on met?]		YES Describe details if relevant					

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

Page 52 of 118

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

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

Inc	nclusion Criteria					
#	Inclusion Number	Criterion Description	Criterion met? Crite	erion 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)	INOI	1A00		
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures	IN02	2A00		
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	INOS	3A00		
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol	IN04	4A00		

## Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	□1 □2 □3 □4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

Exc	Exclusion Criteria					
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)		
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation		EX01A00		
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00		
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allerg c reaction (eg, anaphylaxis) to any component of the study intervent on(s)		EX03A00		
2.d	4	Receipt of med cat ons intended to prevent COVID-19		EX04A00		
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19		EX05A00		
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)		EX06A01		
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00		
2.h	8	Immunocompromised indiv duals with known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00		
2.i	9	Sentinel participants in Stage 1 only: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A04		
2.j	10	Bleeding diathesis or condition associated wth prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00		
2.k	11	Women who are pregnant or breastfeeding		EX11A00		
2.1	12	Previous vaccinat on with any coronavirus vaccine		EX12A00		
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c 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 participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01		
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A01		
2.t	20	Sentinel participants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen		EX19A01		

		(HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t			
2.u	21		articipants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 EX20A01		
2.v	22		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	у			
2.1	2.1 Exclusion Number: [Exclusion Number]				
2.2	2.2 Cr terion Description: [Criter on Descript on]				
2.3	2.3 Cr terion met? [Criter on met?]		YES Describe details if relevant NO		
2.4	2.4 Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]				

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

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

Inc	nclusion Criteria					
#	Inclusion Number	Criterion Description	Criterion met? Crite	erion 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)	INOI	1A00		
1.b	2	Participants who are willing and able to comply w th all scheduled visits, vaccination plan, laboratory tests, lifestyle cons derat ons, and other study procedures	IN02	2A00		
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	INOS	3A00		
1.d	4	Capable of giving personal signed informed consent, which includes compliance with the requirements and restr ctions listed in the ICD and in this protocol	IN04	4A00		

#### Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	01 02 03 04
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Crterion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

Exclusion Criteria					
#	Exclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)		
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00		
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	EX02A00		
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allerg c reaction (eg, anaphylaxis) to any component of the study intervent on(s)	EX03A00		
2.d	4	Receipt of med cat 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/phys cal 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 w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on	EX10A00		
2.k	11	Women who are pregnant or breastfeeding	EX11A00		
2.1	12	Previous vaccinat on with any coronavirus vaccine	EX12A00		
2.m	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art cular, intrabursal, or topical cort costeroids are perm tted	EX13A00		
2.n	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administrat on or planned receipt throughout the study	EX14A00		
2.0	15	Participation in other studies involving study intervention w thin 28 days pr or to study entry and/or during study participation	EX15A00		
2.p	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles	EX16A00		
2.q	17	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit	EX17A00		
2.r	18	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator	EX18A00		
2.s	19	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening vis t	EX19A00		

2.t	20	EX20A00	
2.u	21	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	EX21A00
Exc	lusion Criteria Entr	/	
2.1	Exclusion Number: [Exclusion Number]		
2.2	Cr terion Description [Criter on Descript or		
2.3	Cr terion met? [Criter on met?]	VES Describe details if relevant	
2.4	Cr terion ID: (For Pfi only) [Criter on ID: (For Pf only)]		

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

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

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

#### Inclusion Criteria Entry

**Exclusion Criteria** 

1.1	Inclusion Number: [Inclusion Number]	□1 □2 □3 □4
1.2	Cr terion Description: [Criter on Descript on]	
1.3	Cr terion met? [Criter on met?]	VES NO Describe details if relevant
1.4	Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	<ul> <li>IN01A00</li> <li>IN02A00</li> <li>IN03A00</li> <li>IN04A00</li> </ul>

#	Exclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation	EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allerg c reaction (eg, anaphylaxis) to any component of the study intervent on(s)	EX03A00
2.d	4	Receipt of med cat ons intended to prevent COVID-19	EX04A00
2.e	5	Stages 1 and 2 only: Prev ous clinical or microbiolog cal diagnosis of COVID-19	EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)	EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)	EX07A00
2.h	8	Immunocompromised indiv duals with known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal 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 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 system c 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 participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit	EX17A01
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator	EX18A01
2.t	20	Sentinel participants in Stage 1 only: Positive test for HIV, hepat tis B surface antigen	EX19A01

		(HBsAg), hepat at screening vis	tis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs)	
2.u	21		ceipt of study intervention EX	(20A01
2.v	22		e staff or Pfizer employees directly involved in the conduct of the study, vise supervised by the investigator, and their respective family members	(21A01
Exc	lusion Criteria Entr	/		
2.1	2.1 Exclusion Number: [Exclusion Number]			
2.2	2.2 Cr terion Description: [Criter on Descript on]			
2.3	2.3 Cr terion met? [Criter on met?]		rES Describe details if relevant	
2.4	2.4 Cr terion ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]			

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#### C4591001: CASEBOOK SIGNATURE FORM (INVSIG)

Lasebook Signature Form				
1. Casebook Signature [Casebook Signature]	Click Here to Enable			

C4	591001: CENTRAL LAB SAMPL	E COLLECTION (LAB)			
Cer	ntral Lab Sample Collection				
	Collection Date: [Collect on Date:]				
2. Specimen Type: OBLOOD					
Lab	) Test				
#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected		
3.a	CLINICAL CHEMISTRY	BLOOD CHEMISTRY			
3.b	HEMATOLOGY	DIFFERENTIAL	DIFFERENTIAL		
Lat	o Test Entry				
3.1	Lab Panel: [Category for Lab Test]	<ul> <li>HEMATOLOGY</li> <li>CLINICAL CHEMISTRY</li> </ul>			
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	O DIFFERENTIAL BLOOD CHEMISTRY			
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	VES NO			

#### C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)

C4	C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)						
Cen	tral Lab Sample Collection						
1.	Collection Date: [Collect on Date:]						
	Specimen Type: [Specimen Type]	OBLOOD					
Lab	Test						
#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected				
3.a	CLINICAL CHEMISTRY	BLOOD CHEMISTRY					
3.b	CLINICAL CHEMISTRY	VIROLOGY					
3.c	HEMATOLOGY	DIFFERENTIAL					
Lab	Test Entry						
3.1	Lab Panel:     OHEMATOLOGY       [Category for Lab Test]     OLINICAL CHEMISTRY						
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	O DIFFERENTIAL O BLOOD CHEMISTRY O VIROLOGY					
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	● YES ● NO					

C4	C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form									
#	Category for Lab Test	Vendor Name	Collection Da	te:	Specimen T	уре	Lab Result			
1										
Lal	b Chemistry Details									
1.	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY								
	Laboratory Name and Address [Vendor Name]									
3.	Collection Date: [Collect on Date:]									
4.	Specimen Type: [Specimen Type]	OBLOOD								
Lal	o Result									
# •	Sponsor-Defined Identifier	Te	st:	Result:	Not Done:	Lab N	ormal Range			
5.a		C Reactive Protein_PX3	329							
La	b Result Entry									
5.1	Sponsor ID: [Sponsor-Defined Identifier]									
5.2	Test: [Test:]	C Reactive Protein_PX	329							
5.3	Result: [Result:]									
5.4	Not Done: [hidden] [Not Done:]	O NOT DONE								
5.5	LNMT [Lab Normal Range]	Low High Un t								

C4	591001: LOCAL LABORATORY	DATA - REPEATING C	HEMISTRY (LAB CH	IEM) - Re	epeating Form	n
#	Category for Lab Test	Vendor Name	Collection Date:		Specimen Type	Lab Result
1						
Lab	Chemistry Details					
	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY				
	Laboratory Name and Address [Vendor Name]					
	Collection Date: [Collect on Date:]					
	Specimen Type: [Specimen Type]	OBLOOD				
Lab	Result					
# ✓	Sponsor-Defined Identifier	Tes	st:	Result:	Not Done:	Lab Normal Range
5.a		C Reactive Protein_PX329				
5.b		Alanine Aminotransferase_F	YX30			
5.c		Aspartate Aminotransferase	e_PX28			
5.d		Alkaline Phosphatase_PX35				
5.e		Bilirubin_PX21				
5.f		Blood Urea Nitrogen_PX47				
5.g		Creatinine_PX48				
Lab	Result Entry					
5.1	Sponsor ID: [Sponsor-Defined Identifier]					
5.2	Test: [Test:]					
5.3	Result: [Result:]					
5.4	Not Done: [Not Done:]	O NOT DONE				
5.5	LNMT [Lab Normal Range]	Low				
		High				
		Un t				

C4	591001: LOCAL LABORATO	RY DATA ·	- REPEATING Hematol	logy (LAB HEM)	<ul> <li>Repeating Fo</li> </ul>	rm	
#	Category for Lab Test	Category for Lab Test Vendor Name (DERIVED) Collection		Collection Date	ction Date: Specimen Type		Lab Result
1							
Lal	poratory Data Hematology						
	Lab Panel: [Category for Lab Test]	Он	EMATOLOGY				
2.	Laboratory Name and Address [Vendor Name (DERIVED)]						
3.	Collection Date: [Collect on Date:]		v / v / v				
4.	Specimen Type: [Specimen Type]	ОВ	LOOD				
Lal	Result						
# ✓	Sponsor-Defined Identifi	er	Test:	Result:	Not Done:	Lab No	rmal Range
5.a			Hemoglobin_PX1				
5.b			Hematocr t_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				
La	b Result Entry						
5.1	Sponsor ID: [Sponsor-Defined Identifier]						
5.2	Test: [Test:]		~				
5.3	Result: [Result:]						
5.4	Not Done: [Not Done:]	0	NOT DONE				
5.5	LNMT [Lab Normal Range]	Lov	h				

C4591001: CENTRAL LAB SAMPLE COLLECTION - HLA (LAB HLA)							
Cen	tral Lab Sample Collection						
	Collection Date: [Collect on Date:]						
	Specimen Type: [Specimen Type]	OBLOOD					
Lab	Test						
#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected				
3.a	HEMATOLOGY	IMMUNOLOGY					
Lab	Test Entry						
3.1	Lab Panel: [Category for Lab Test]	O HEMATOLOGY					
3.2	Lab Sub-Panel: [Subcategory for Lab Test]						
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	VES NO					

C4	591001: CENTRAL LAB SAMPLE CO	DLLECTION - PBMC (LAB PBMC)					
Cen	tral Lab Sample Collection						
	Collection Date: [Collect on Date:]						
	Specimen Type: [Specimen Type]	OBLOOD					
Lab	Test						
#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected				
3.a	HEMATOLOGY	IMMUNOLOGY					
Lab	Test Entry						
3.1	Lab Panel: [Category for Lab Test]	O HEMATOLOGY					
3.2	Lab Sub-Panel: [Subcategory for Lab Test]						
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	VES NO					

C4	C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)								
La	Lab Urinalysis								
1.	Lab Panel: [Category for Lab Test]	OURINALYSIS							
2.	Lab Sub-Panel: [Subcategory for Lab Test]	OPREGNA	ANCY						
3.	Collection Date: [Collect on Date:]	✓ /	<b>v</b> /						
4.	Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]								
5.	Specimen Type: [Specimen Type]	OURINE							
La	b Result								
#	Sponsor-Defined Identifier			Test:	Result:	Not Done:			
6.a	1		Chor ogonadotropin Beta_PX113						
La	b Result Entry								
6.1	Sponsor ID: [Sponsor-Defined Identifier]			]					
6.2	2 Test: OChor of [Test:]		gonado	tropin Beta_PX113					
6.3	5.3 Result: [Result:] ONEGA								
6.4	Not Done: [Not Done:]		ONE						

C4	59100	1: MEDIC	ATI	0	N ERROR (MED	) ERROR) - F	Repeating Form	า			
		Medication Error		rt	Is the medication error Still Ongoing		Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	
1					<u>j</u>						
Me	dication	Error				1					
1.	Categor [Catego		(	ОМ	EDICATION ERROR						
2.	of Medic	on Error (Type ation Error): t on Error]	•								
3.	error, re incorrect number dispense to the su	a dispensing cord the t container that was cd/administere ubject: [hidder ct package ID]	n]								
4.	Start Da [Start D				• / • / •						
5.	still ong	ned cat on erro	2			<b>v</b>					
6.	with Stu	ction Taken dy Treatment: 1edication ct on]			O ACTION TAKEN ERMANENTLY DISCO	NTINUED					
7.	Med cati [Concon	oncomitant on given? n tant on Given]		) YI ) N							
8.		on-Drug nt given? ug Treatment	1	) YI							
9.	cause th	Medication Err le subject to b nued from the Study nuat on]	e   🧞	) N							
10.	error as any adv	medication sociated with erse events?	(	)YI A	ES E ID:						
		ed With AE]		А	E ID:						
				A	E ID:						
				A	E ID:						
				A	E ID:						
			0		0						
11.	Ser ous	Adverse Event		_							
	Number Only	: For Pfizer Us Adverse Even	e								
12.	[hidden]	son Term / rison Term]									
13.	[hidden]	Level Term Level Term]								]	
14.	Lowest I Code [hi	_evel Term									
15.	Term [h	ry-Derived idden] ary-Derived									

16.	Preferred Term Code [hidden] [Preferred Term Code]	
17.	High Level Term <i>[hidden]</i> [High Level Term]	
18.	High Level Term Code [hidden] [High Level Term Code]	
19.	High Level Group Term <i>[hidden]</i> [High Level Group Term]	
20.	High Level Group Term Code [hidden] [High Level Group Term Code]	
21.	Primary System Organ Class [hidden] [Primary System Organ Class]	
22.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	

C45	C4591001: GENERAL MEDICAL HISTORY (MEDHX)								
	Line/MH Number		Medical History Term	Start Date	Ongoing				
1.									
Med	ical History Details Entry								
1.1	Line/MH Number: [Line/MH Number]								
1.2	Disease/Syndrome/Surgery/Non- Drug Allergies/Drug Allergies: [Medical History Term]								
1.3	Start Date: [Start Date]	<b>v</b> /							
1.4	Ongoing: [Ongoing]	YES NO End Date:							
1.5	Comparison Term [hidden] [Comparison Term]								
1.6	Lowest Level Term [hidden] [Lowest Level Term]								
1.7	Lowest Level Term Code [hidden] [Lowest Level Term Code]								
1.8	Dict onary Derived Term [hidden] [Dictionary Derived Term]								
1.9	Preferred Term Code [hidden] [Preferred Term Code]								
1.10	High Level Term [hidden] [High Level Term]								
1.11	High Level Term Code [hidden] [High Level Term Code]								
1.12	High Level Group Term [hidden] [High Level Group Term]								
1.13	High Level Group Term Code [hidden] [High Level Group Term Code]								
1.14	Primary System Organ Class [hidden] [Primary System Organ Class]								
1.15	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]								

C	C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form									
#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)							
1										
03	Dxygenation Parameters									
1.	Date Time of Assessment:       Image: Assessment in the									
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]									
3.	FiO2 (Fract on of Inhaled         Oxygen):         [FiO2 (Fraction of Inhaled         Oxygen)]									

# C4591001: PBMC/HLA BLOOD SAMPLE TRIGGER FORM (PBMC TRIG)

#### PBMC/HLA Blood Sample Trigger Form

1.	Select appropriate response - Is the participant part of the group
	collecting blood samples for
	PBMC isolation and HLA typing
	(select sites only)?
	[Trigger Response 15]

Yes, the participant is part of the group collecting blood samples for PBMC isolat on and HLA typing
 No, the part cipant is NOT part of the group collecting blood samples for PBMC isolat on and HLA typing

C4	C4591001: PHYSICAL EXAMINATION (PHYS EXAM)						
Phy	sical Examination						
	Exam Date: [Exam Date]						
Phy	sical Examination Result						
#		Body System Examined	Result				
2.a	GENERAL APPEARANCE						
2.b	SKIN						
2.c	HEAD						
2.d	EYES						
2.e	EARS						
2.f	NOSE						
2.g	THROAT						
2.h	HEART						
2.i	LUNGS						
2.j	ABDOMEN						
2.k	MUSCULOSKELETAL						
2.1	EXTREMITIES						
2.m	NEUROLOGICAL						
2.n	LYMPH NODES						
Phy	sical Examination Result Entr	у					
2.1	Body System Examined: [Body System Examined]						
2.2	Result: [Result]	<ul> <li>NORMAL</li> <li>ABNORMAL</li> <li>If abnormal findings, specify: (If clinically significant, record on the Medical History or Advers</li> <li>Are there clinically signif cant findings?</li> <li>YES</li> <li>NO</li> <li>NOT DONE</li> </ul>	e Event CRF as appropriate).				

C	4591001: ELECTRONIC	SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19)
Ele	ectronic Sample Tracking	
1.	Data Origin [Data Origin]	OSITE
2.	Sample Type [Sample Type]	SERUM
3.	Sample Collected? [Sample Collected]	NO 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]	
		Sample ID
5.		
AI	iquot Entry	
Ple	ease enter barcode for each aliquo	t.
5.	1 Sample ID [Sample ID]	

C4	591001: CONCO	OMITANT MED	ICAT	IONS - PROHIBITED	O (PROHIB	CM) - Repeat	ing Fo	rm			
#	Sponsor-Defined Identifier	Category for Medication	Cone	comitant Medications Pre- specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing
1											
Cor	comitant Medication	าร									
1.	What is the medication [Sponsor-Defined Ide										
2.	Category: [Category for Medicat	: on]		CONCOMITANT IMMUNOS CORTICOSTEROIDS IMMUNOGLOBULINS	SUPPRESSIVE TH	IERAPY					
3.	Concomitant Medicati [Concom tant Medicat			<b>○</b> NO							
4.	Med cation:										
	Prov de the complete (including salt form, v generic name is unkn proprietary name. Ind in the Med cat on text route, use, formulatic [Name of Medication]	where applicable). W own, enter the full tr clude clarifying inforr : (e.g., Ingredient(s) n).	ade or nation								
5.	Dose: [Dose Description]										
6.	Dose Unit: [Dose Unit]										
7.	Dose Frequency: [Dose Frequency]										
8.	Route: [Route]										
9.	Start Date: [Start Date]										
10.	Ongoing? [Ongoing]			○ YES           ○ NO           End Date:           ○ / ○ / ○	]						
11.	Comparison Term [hi [Comparison Term]	dden]									
12.	Standardized Med cat derived. [hidden] [Standardized Med ca		у								
13.	Standardized Med cat derived [hidden] [Standardized Med ca		/								

C4	591001:	RADIATION TREATMENT	(PROHIB ND) - Repeating Form			
#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?
1						
Rad	diation Treat	ment				
1.	Category: [Category]		ORADIATION THERAPY			
2.	What is the t [Treatment I	reatment Identifier? dentifier]				
3.		Non-drug Treatment Pre-specified: ug Treatments Pre-specified]	OYES			
4.	Treatment: [Treatment]					
5.	Start Date: [Start Date]					
6.	Ongoing? [Ongoing?]		YES     NO     End Date:			
7.	7. Comparison Term [hidden] [Comparison Term]					
8.	Lowest Level	Term [hidden] I Term]				
9.	Lowest Level	Term Code [hidden] I Term Code]				
10.		erived Term [hidden] erived Term]				
11.	Preferred Ter [Preferred Te	r <b>m Code <i>[hidden]</i></b> rrm Code]				
12.	High Level Te [High Level T	erm [hidden] [erm]				
13.	I3. High Level Term Code [hidden] [High Level Term Code]					
14.	4. High Level Group Term [hidden] [High Level Group Term]					
15.	High Level G [High Level C	roup Term Code [hidden] Group Term Code]				
16.	Primary Syst [Primary Sys	em Organ Class [hidden] tem Organ Class]				
17.	Primary Syst [Primary Sys	em Organ Class Code [hidden] tem Organ Class Code]				

C4	591001: VITAL SIGNS - PULSE OX ROOM AIR (PULSE OX) - Repeating Form						
#	Date:		Vital Signs Details				
1							
Vit	/ital Signs						
1.	Date:]						
Vit	Vital Signs Details						
#	Re	cord Identifier:	Oxygen Saturation				
L							
2.a	1						
Vit	al Signs Details Entry						
2.1	Record Identifier: ( [Record Identifier:]	1					
2.2	P     SPO2 Pulse Oximetry %       [Oxygen Saturation]						

C	C4591001: RANDOMIZATION (RAND)					
Di	Disposition					
1.	Randomizat on Date : [Randomization Date :]					
2.	Randomizat on Number: [Randomization Number]					
3.	Randomizat on Group: [Randomization Group]					

C	C4591001: RANDOMIZATION - BOOSTER (RAND BOOST)						
Di	Disposition						
1.	Randomizat on Date : [Randomization Date :]						
	Randomizat on Number: [Randomization Number]						
3.	Rerandomization SSID: [Rerandomizat on SSID]						

# C4591001: REACTOGENICITY DIARY (REAC DIARY)

Reactogenicity Diary							
1. Select appropriate response - Reactogen c ty diary collection [Trigger Response 9]	<ul> <li>○ YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT</li> <li>○ NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</li> </ul>						

C4	4591001: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT (REACTION)						
Unj	planned Assessment Of Local	Reaction					
	SR Category [hidden] OUNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT						
	Date of Assessment: [Date of Assessment]						
	Injection Site Location [Injection S te Location]	O DELTOID MUSCLE					
	Injection Site Body S de: [Injection S te Body Side]	OLEFT ORIGHT					
Rea	action						
#	Reac	tion:	R	eaction Present:			
5.a	REDNESS						
5.b	SWELLING						
Rea	action Entry		·				
5.1	Reaction: [React on:]	OREDNESS SWELLING					
5.2	Reaction Present: [React on Present:]	<ul> <li>YES</li> <li>Maximum Diameter (cm):</li> <li>Minimum Diameter (cm):</li> <li>Meets Grade 4 Reaction Cr teria:</li> <li>YES</li> <li>NO</li> <li>NO</li> </ul>					
Syr	nptom	1					
#		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	PAIN					
6.g	NEW OR WORSENED JOINT PA	IN					
6.h	CHILLS						
Syr	mptom Entry						
6.1	Symptom: [Symptom:]						
6.2	Symptom Present: [Symptom Present:]	YES Symptom Grade: 1 2 3 4 Event related to Study Tr YES NO NO	eament?				

C4	4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form								
#	Treatment Identifier	Con N	lon-Drug Treatm	ents Pre-specified	Treatment	Treatment	Start Date	Ongoing?	
1									
Res	piratory Treatment								
1.	What is the treatment Identifier? [Treatment Identifier]	<b>)</b>							
2.	Concomitant Non-drug Treatment [Con Non-Drug Treatments Pre-s		<b>○</b> YES						
3.	B. Treatment: [Treatment]		<ul> <li>INTUBATION</li> <li>NON-INVASIV</li> <li>CPAP</li> <li>OXYGEN THER</li> </ul>	E POSITIVE PRESSURE V APY	ENTILATION				
4.	Treatment: [Treatment]								
5.	Start Date: [Start Date]								
6.	5. Ongoing? [Ongoing?]		YES NO End Date:	♥/					
7.	7. Comparison Term [hidden] [Comparison Term]								
8.	Lowest Level Term [hidden] [Lowest Level Term]								
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	]		]					
10.	D ctionary Derived Term [hidden] [D ctionary Derived Term]	]							
11.	Preferred Term Code [hidden] [Preferred Term Code]			]					
12.	2. High Level Term [hidden] [High Level Term]								
13.	High Level Term Code [hidden] [High Level Term Code]								
14.	High Level Group Term [hidden] [High Level Group Term]								
15.	High Level Group Term Code [hid [High Level Group Term Code]	dden]							
16.	Primary System Organ Class [hid [Primary System Organ Class]	lden]							
17.	Primary System Organ Class Cod [Primary System Organ Class Co								

C4	4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form								
#	Treatment Identifier	Con N	on-Drug Treatn	nents Pre-specifi	ed	Treatment	Treatment	Start Date	Ongoing?
1									
Res	piratory Treatment								
1.	What is the treatment Identifier? [Treatment Identifier]								
2.	Concomitant Non-drug Treatment Pre- [Con Non-Drug Treatments Pre-specifie		<b>○</b> YES						
3.	B. Treatment: [Treatment]		CPAP MECHANICAL EXTRACORPO	VE POSITIVE PRES VENTILATION DREAL MEMBRANE DXYGEN THERAPY					
4.	Treatment: [Treatment]								
5.	Start Date: [Start Date]		V / V	/					
6.	Ongoing? [Ongoing?]		YES NO End Date:	✓ /					
7.	Comparison Term [hidden] [Comparison Term]								
8.	Lowest Level Term [hidden] [Lowest Level Term]								
9.	Lowest Level Term Code [hidden] [Lowest Level Term Code]								
10.	D ctionary Derived Term [hidden] [D ctionary Derived Term]								
11.	Preferred Term Code [hidden] [Preferred Term Code]								
12.	High Level Term [hidden] [High Level Term]								
13.	High Level Term Code [hidden] [High Level Term Code]								
14.	High Level Group Term [hidden] [High Level Group Term]								
15.	High Level Group Term Code [hidden] [High Level Group Term Code]								
16.	Primary System Organ Class [hidden] [Primary System Organ Class]								
17.	Primary System Organ Class Code [hid [Primary System Organ Class Code]	lden]							

# C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF)

Fu	urther Vaccination Confirmation							
1.	Select appropriate response - Is part cipant willing to return for Vaccination 3? [Trigger Response 1]	<ul> <li>Participant is willing to return for Vaccinat on 3 Participant is:</li> <li>eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</li> <li>eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2</li> <li>eligible and NOT confirmed to have received only placebo at Vaccination 1/2</li> <li>Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible</li> </ul>						

## C4591001: INFORMED CONSENT - FURTHER VACCINATION (REVAX CONS)

I	nformed Consent - Further Vaccination			
1	. Consent Was:	OBTAINED		
	[Consent Was:]	Date Written Consent Obtained		

<b>C</b> 4	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.					
Ex	Exclusion Criteria Met Entry				
2.1	Description of Exclusion Cr terion Met [Criter on Descript on]				

### C4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB)

Ele	Electronic Sample Tracking						
1.	Data Origin [Data Origin]	○ SITE					
2.	Sample Type [Sample Type]	○NASAL_SWAB ○NASAL_SWAB_SELF					
3.	Sample Collected? [Sample Collected]	NO         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]						
		Sample ID					
5.							
Ali	Aliquot Entry						
Ple	ease enter barcode for each aliquot	t.					
5.1	1 Sample ID [Sample ID]						

C	C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK)					
E	Electronic Sample Tracking					
1.	Data Origin [Data Origin]	○ SITE				
2.	Sample Type [Sample Type]	SERUM				
3.	Sample Collected? [Sample Collected]	NO 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]					
	Sample ID					
5						
A	Aliquot Entry					
Р	ease enter barcode for each aliquo	t.				
5	5.1 Sample ID [Sample ID]					

С	C4591001: INFORM SCREENING (SCREEN)				
In	InForm Screening				
1.	InForm Initials [hidden] [InForm Initials]				
2.	Birth Date: [Birth Year]				

Page 89

CAEDIADA ELECTRONIC		ACAL CWAR CELE	
C4591001: ELECTRONIC	SAMPLE IRACKING - P	NASAL SWAB SELF (	SELF SWAB)

<u> </u>						
Ele	ectronic Sample Tracking					
1.	Data Origin [Data Origin]	OSITE				
2.	Sample Type [Sample Type]	○ NASAL_SWAB_SELF				
3.	Sample Collected? [Sample Collected]	NO 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]					
		Sample ID				
5.						
Ali	Aliquot Entry					
Ple	Please enter barcode for each aliquot.					
5.1	1 Sample ID [Sample ID]					

C45	591001: SIGNS AND S	YMPTOMS OF POTENTIAL COVID-19 (SOD)			
Sign	gns and Symptoms				
	Pate of Assessment: Date of assessment]				
	eate of First Symptom Started: First Symptom Started Date]				
	ymptoms Ongoing? OYES Symptoms Ongoing] ONO				
		Date of Last Symptom Resolved:			
Sym	ptoms				
#	Event Pre-specified	Symptoms	Symptom Present		
✓ 4.a	YES	FEVER			
	YES	LOSS OF TASTE/SMELL			
4.c	YES	NEW OR INCREASED COUGH			
4.d	YES	NEW OR INCREASED NASAL CONGESTION			
4.e	YES	NEW OR INCREASED NASAL DISCHARGE			
4.f	YES	NEW OR INCREASED SHORTNESS OF BREATH			
4.g	YES	NEW OR INCREASED SORE THROAT			
	YES	NEW OR INCREASED SPUTUM PRODUCTION			
	YES	NEW OR INCREASED WHEEZING			
<u> </u>	ptoms Entry				
	Event Pre-specified: [hidden] [Event Pre-specified]	O YES			
	Symptoms: [Symptoms]				
	Was symptom present? [Symptom Present]	O YES ○NO			
		Symptoms - Other			
5. V					
	ptoms - Other Entry				
5.1	Symptoms - Other Text: [Symptoms - Other]				
5.2	Comparison Term: [hidden]				
	[Comparison Term]				
5.3	Lowest Level Term [hidden]				
5.4	Lowest Level Term Code				
J.4	[hidden] [Lowest Level Term Code]				
5.5	Dict onary Derived Term				
	[hidden] [Dictionary Derived Term]	L			
5.6	Preferred Term Code [hidden] [Preferred Term Code]				
5.7	High Level Term [hidden] [High Level Term]				
5.8	High Level Term Code [hidden]				
	[High Level Term Code]				
5.9	High Level Group Term [hidden] [High Level Group Term]				
5.10	High Level Group Term Code [hidden]				
	[High Level Group Term Code]				
5.11	Primary System Organ Class [hidden]				
5 10	[Primary System Organ Class] Primary System Organ Class				
5.12	Code [hidden] [Primary System Organ Class				
		I			

Code]

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C4!	591001: SIGNS AND S	YMPTOMS	OF	POTENTIAL COVID-19 (SOD)	
Sign	is and Symptoms				
	Date of Assessment: Date of assessment]	<ul><li>✓ /</li></ul>	- /	Y	
	Date of First Symptom Started: First Symptom Started Date]	✓ /	- /	Y	
	Symptoms Ongoing? Symptoms Ongoing]	● YES ● NO Date of Last	: Sym	nptom Resolved:	
Sym	ptoms				
#	Event Pre-specified			Symptoms	Symptom Present
<ul><li>✓</li><li>4.a</li></ul>	YES	FEVER			
4.b	YES		NCRE	ASED COUGH	
4.c	YES			ASED SHORTNESS OF BREATH	
4.d	YES	CHILLS			
4.e	YES	NEW OR I	NCRE	ASED MUSCLE PAIN	
4.f	YES	NEW LOSS	OF	TASTE OR SMELL	
4.g	YES	NEW OR I	NCRE	ASED SORE THROAT	
4.h	YES	DIARRHEA	1		
4.i	YES	VOMITING	i		
Sym	ptoms Entry				
4.1	Event Pre-specified: [hidden] [Event Pre-specified]	<b>○</b> YES			
	Symptoms: [Symptoms]	*			
4.3	Was symptom present? [Symptom Present]	OYES ONO			
				Symptoms - Other	
5. ✔					
	ptoms - Other Entry				
5.1	Symptoms - Other Text:				 1
	[Symptoms - Other]				 
5.2	Comparison Term: [hidden] [Comparison Term]				
5.2					]
5.3	Lowest Level Term [hidden] [Lowest Level Term]				
5.4	Lowest Level Term Code [hidden] [Lowest Level Term Code]				
5.5	Dict onary Derived Term				]
	[hidden] [Dictionary Derived Term]				
5.6	Preferred Term Code [hidden] [Preferred Term Code]				 7
5.7	High Level Term [hidden] [High Level Term]				
5.8	High Level Term Code <i>[hidden]</i> [High Level Term Code]				
5.9	High Level Group Term [hidden] [High Level Group Term]				
5.10	High Level Group Term Code [hidden] [High Level Group Term Code]				
5.11	Primary System Organ Class [hidden]				
	[Primary System Organ Class]				1
5.12	Primary System Organ Class Code [hidden] [Primary System Organ Class				
1		1			

file:///C:/Users/zhangd70/AppData/Local/Apps/2.0/7QDN0DKX.747/1YNZC0P6.4RQ/orac..08.0 182cbe9101fd197d 0006.0003 3b03f6c8c5fb... 3/30/2021

Code]

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# C4591001: STRATIFICATION (STRAT)

SI	Stratification				
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]				
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	<ul> <li>○ Age 18 to 55</li> <li>○ Age 65 to 85</li> </ul>			
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	<ul> <li>10 mcg</li> <li>20 mcg</li> <li>30 mcg</li> </ul>			
4.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	021 Day 060 Day			
5.	Select appropriate response - BNT Number [Trigger Response 7]	O(BNT162b1 or PBO)         O(BNT162b2 or PBO)         O(BNT162b3 or PBO)			

### C4591001: STRATIFICATION (STRAT)

_		
SI	tratification	
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	O Stage 1 O Stage 2
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	<ul> <li>Age 18 to 55</li> <li>Age 56 to 85</li> <li>Age 65 to 85</li> </ul>
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	<ul> <li>Low dose level (3mcg)</li> <li>Medium dose level (10mcg)</li> <li>High dose level (30mcg)</li> <li>Low dose level (10mcg)</li> <li>Medium dose level (30mcg)</li> <li>High dose level (100mcg)</li> <li>Low dose level (0.1mcg)</li> <li>Medium dose level (0.3mcg)</li> <li>High dose level (1mcg)</li> <li>Medium dose level (1mcg)</li> <li>Mid-High dose level (50mcg)</li> <li>Low-Mid dose level (20mcg)</li> </ul>
4.	Select appropriate response - Randomizat on Dose Group [hidden] [Trigger Response 6]	<ul> <li>21 Day 2-dose group</li> <li>60 Day 2-dose group</li> <li>1-dose group</li> </ul>
5.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	021 Day 60 Day
6.	Select appropriate response - BNT Number [Trigger Response 7]	<ul> <li>(BNT162a1 or PBO)</li> <li>(BNT162b1 or PBO)</li> <li>(BNT162b2 or PBO)</li> <li>(BNT162c2 or PBO)</li> <li>(BNT162b3 or PBO)</li> </ul>

### C4591001: STRATIFICATION (STRAT)

s	Stratification				
1	Select appropriate response - Randomizat on Stage [Trigger Response 3]	O Stage 2			
2	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	O Age 18 to 55 Age 56 to 85			
3	Select appropriate response - Randomizat on Dose [Trigger Response 5]	<ul> <li>10 mcg</li> <li>20 mcg</li> <li>30 mcg</li> </ul>			
4	Select appropriate response - BNT Number [Trigger Response 7]	<ul> <li>(BNT162b1 or PBO)</li> <li>(BNT162b2 or PBO)</li> <li>(BNT162b3 or PBO)</li> </ul>			

С	4591001: SUBJECT STA	TUS (SUB STATU)
S	ubject Status	
1.	Subject Status [Subject Status]	
2.	Subject Status Date [Status Date]	

### C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS)

I	Informed Consent - Asymptomatic Surveillance				
1	Consent Was: [Consent Was:]	OBTAINED			
		Date Written Consent Obtained			

C4591001: ELECTRONIC	SAMPLE TRACKING -	NASAL SWAR	(SWAR PFF)
CTJJIOOI. LLLCIKOMIC	SAFIFEL INACKING -	MASAL SWAD	(SWADFIL)

Ele	ectronic Sample Tracking	
1.	Data Origin [Data Origin]	OSITE
2.	Sample Type [Sample Type]	○NASAL_SWAB
3.	Sample Collected? [Sample Collected]	NO YES Date of Collect on: ↓ ↓ ↓ ↓
	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
		Sample ID
5.		
Ali	iquot Entry	
Ple	ease enter barcode for each aliquot	
5.1	I Sample ID [Sample ID]	

04504

#	Date of Collection	Specimen Ty	oe Specimen	<b>Collection Location</b>	Assay Code and Description	Device Type	Trade Name	Result	Comments:
1									
Mi	crobiology Specimer	ı							
1.	Actual Date of Collect [Date of Collect on]	ion:	✓ /	~					
2.	Specimen Type: [Specimen Type]	0	SWABBED MATE	RIAL					
3.	Specimen Collection L [Specimen Collection		NASAL CAVITY						
4.	Assay Code and Desc [Assay Code and Desc		SEVERE ACUTE F	ESP SYNDROME CORO	NAVIRUS 2				
5.	Device Type: [Device Type]	0	SARS-COV-2 DIA	GNOSTIC TEST					
6.	Trade Name: [Trade Name]	0	CEPHEID XPERT	XPRESS SARS-COV-2 T	EST				
7.	Test Result: [Result]	ŏ	POSITIVE NEGATIVE INDETERMINATE						
8.	Comments/Findings/E [Comments:]	Details:							

C4	591001: VACCINATIO	N SYMP	TOMS DIAR	Y - SYMPTOM RESOLVED DATES (SYMPRDATE)
Va	ccination Symptoms Diary - Sy	mptom Re	solved Dates	
1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed? [Fever/Pain Medication on Last Diary Day]	YES Ongoin YES NO Stop		
#	Symptom:		Were	fever or systemic symptoms present on the last day the Subject Diary was completed?
2.a	FEVER			
2.t	FATIGUE			
2.0	HEADACHE			
2.0	CHILLS			
2.6	VOMITING			
2.f	DIARRHEA			
2.0	NEW OR WORSENED MUSCLE P	PAIN		
2.h	NEW OR WORSENED JOINT PAI	[N		
2.1	Symptom: [Symptom:]	~		
2.2	Were fever or system c symptoms present on the last day the Subject Diary was completed? [Were fever or systemic symptoms present on the last day the Subject Diary was completed?]	YES Ongoin YES NO Stop		
3.	Injection Site Location: [Injection S te Location:]	O DELTO	ID MUSCLE	
4.	Injection Site Body S de: [Injection S te Body Side:]	OLEFT ORIGHT		
#	Injection Site Reaction:		Were i	njection site reactions present on the last day the Subject Diary was completed?
5.a				
5.t				
5.0	PAIN AT INJECTION SITE			
5.1	Injection Site React on: [Injection Site Reaction:]	OREDNE		E
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 Ongoin YES NO Stop		

Page 102

C	C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form		
#	Tra	nsfusion Type Date of Transfusion	
1			
1.	Transfus on Type: [Transfus on Type]	<ul> <li>PACKED RBC</li> <li>PLATELETS</li> <li>WHOLE BLOOD</li> <li>PLASMA</li> <li>OTHER Specify:</li> </ul>	
2.	Date of Transfus on: [Date of Transfusion]		

# CHARTMENT UNBLINDED (TRN UNBLN) Treatment Unblinded : 1. Date Treatment Unblinded : Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">SUBJECT SAFETY CONCERN 2. Primary Reason for Unblinding: Image: Colspan="2">OTHER If other, specify: Image: Colspan="2">OTHER If other, specify: Image: Colspan="2">ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

C	C4591001: TREATMENT UNBLINDED - BOOSTER (TRN UNBLNB)				
Tr	eatment Unblinded - Booster				
1.	Date Treatment Unblinded : [Date Treatment Unblinded :]				
2.	Primary Reason for Unblinding: [Primary Reason for Unblinding]	OSUBJECT SAFETY CONCERN OTHER If other, specify:			

C	4591001: UNPLANNED	VISIT (UNPL)
Un	planned Assessments	
1.	Assessments [Assessments]	CONTACT OUTCOME

### C4591001: VACCINATION (VACIN TRT)

Vac		
	cination	
1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	YES         Date of First Delay:         ✓       ✓         Reason(s) for Temporary Delay of Vaccination         FEVER OR ACUTE ILLNESS         RECENT SYSTEMIC CORTICOSTEROID TREATMENT         RECENT NON-STUDY VACCINATION         ANTICIPATED NON-STUDY VACCINATION         NO
2.	Treatment Name [Treatment Name]	
3.	Formulat on: [Formulat on:]	O INJECTION
4.	Dose Date Time: [Dose Date Time:]	▼ /         ▼ /         ▼           ▼ :         ▼ 24-hour clock
5.	Anatomical Locat on: [Anatomical Locat on:]	O DELTOID MUSCLE
6.	Body Side: [Body S de:]	O LEFT O RIGHT
7.	Route: [Route:]	○ INTRAMUSCULAR
8.	Planned Dose: [Planned Dose]	
9.	Planned Dose Unit: [Planned Dose Unit]	© ug
10.	Actual Dose: [Actual Dose:]	
11.	Unit: [Unit:]	O ug
12.	Was the Actual Dose adjusted from planned? [Dose Adjusted From Planned]	<ul> <li>YES</li> <li>What was the reason the dose was adjusted?</li> <li>ADVERSE EVENT(S)</li> <li>INSUFFICIENT CLINICAL RESPONSE</li> <li>OTHER SPECIFY</li> <li>If other, specify:</li> <li>NO</li> </ul>
13.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
14.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	VES NO If No, specify reason:
15.	Comparison Term [hidden] [Comparison Term]	
16.	Standardized Med cation Name -	

Page 107

D ctionary Derived. [hidden] [Standardiz Med cation Name]
Standardize Med cation Code - D ctionary Derived [hidden] [Standardiz Med cation Code]

C4E01001.	VACCINATION	
C4391001:	VACCINATION	(VACIN IKI)

	cination	
1.	Was there a temporary delay of vaccinat on? [Temporary Delay of Vaccination]	YES         Date of First Delay:         Image: Provide the state of the stat
2.	Treatment Name [Treatment Name]	
3.	Formulat on: [Formulat on:]	○ INJECTION
4.	Dose Date Time: [Dose Date Time:]	▼ /         ▼ /         ▼           ▼ :         ▼ 24-hour clock
5.	Anatomical Locat on: [Anatomical Locat on:]	O DELTOID MUSCLE
6.	Body Side: [Body S de:]	O LEFT O RIGHT
7.	Route: [Route:]	OINTRAMUSCULAR
8.	Container Number: [hidden] [PAC / K t Number:]	
9.	Actual Dose: [Actual Dose:]	
10.	Unit: [Unit:]	© mL ⊙ ug
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	<ul> <li>○ THE PROTOCOL SPECIFIED OBSERVATION PERIOD</li> <li>○ 30 MINUTES</li> </ul>
12.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	VES NO If No, specify reason:
13.	Comparison Term [hidden] [Comparison Term]	
14.	Standardized Med cation Name - D ctionary Derived. [hidden] [Standardized Med cation Name]	
15.	Standardized Med cation Code - D ctionary Derived [hidden]	

### Page 109

[Standardized
Med cation
Codel

C	4591001: CONCOMITAN	T MEDICA	TIONS - VA	SOPRESSORS (VASOPRESS) - Re	peating Form		
#	Sponsor-Defined Identifier	Category fo	or Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Ongoing
1							
Co	ncomitant Medications						
1.	What is the medication identifier? [Sponsor-Defined Identifier]						
2.	Category: [Category for Med cat on]		O GENERAL CC	NCOMITANT MEDICATIONS			
3.	Concomitant Medications Pre-spec [Concomitant Medications Pre-specent		ONO				
4.	Medication: Provide the complete gener c drug (including salt form, where applica generic name is unknown, enter th or proprietary name. Include clarif information in the Med cat on text Ingredient(s), route, use, formulat [Name of Medication]	able). Where ne full trade ying (e.g.,					
5.	Start Date: [Start Date]		✓ / ✓				
6.	Ongoing? [Ongoing]		● YES ● NO End Date: ● ✓ /				
7.	Comparison Term [hidden] [Comparison Term]						
8.	Standardized Medication Name - D derived. [hidden] [Standardized Med cat on Name]	Dict onary					
9.	Standardized Medicat on Code - Di derived [hidden] [Standardized Med cat on Code]	ictionary					

### C4591001: VACCINATION 4 TRIGGER FORM (VAX4 TRIG)

١	accination 4 Trigger Form	
1	. Select appropriate response - Has the part cipant been selected to receive an add tional (4th) dose of BNT162b2SA? [Trigger Response 14]	<ul> <li>○ Yes, the participant has been selected to receive an add t onal (4th) dose of BNT162b2SA</li> <li>○ No, the part cipant has NOT been selected to receive an add t onal (4th) dose of BNT162b2SA</li> </ul>

Vita	al Signs			
1.	Date: [Date:]			
Vita	al Signs Details			
#	Record Identifier	r: Temperature	Temperature Unit	Temperature Location:
2.a	1			
Vita	al Signs Details Entry			
2.1	Record Identifier: [Record Identifier:]	01		
2.2	Temperature: [Temperature]			
2.3	Unit: [Temperature Unit]	OF OC		
2.4	Temperature Location: [Temperature Location:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD		

C4	591001: VITAL SIG	NS - BASELIN	E (VITALS BSL)								
Vit	al Signs										
	Date: [Date:]	✓ /	/ 🗸								
	Weight: [Weight]										
	<b>Un t:</b> [Weight Unit]	Okg OLB									
	Height: [Height]										
5.	Un t: [Height Un t] orm in										
	Body Mass Index: [Body Mass Index]										
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:]	01									
7.2	Temperature: [Temperature]										
7.3	Unit: [Temperature Unit]	C F									
7.4	Temperature Location: [Temperature Location:]	ORAL CAVIT EAR RECTUM AXILLA FOREHEAD	ΓY								
7.5	Systol c: [Systolic:]										
7.6	Diastol c: [Diastol c:]										
7.7	BP Posit on: [BP Position]	SITTING									
7.8	Pulse: [Pulse:]										

C4	591001: VITAL SIGNS	- BASE	LINE (VITALS BSL)								
Vita	al Signs										
	Date: [Date:]	✓ /	♥ / ♥								
	Weight: [Weight]										
	<b>Un t:</b> [Weight Unit]	Okg OLB									
	Height: [Height]										
	. Un t: [Height Un t] Ocm in										
	Body Mass Index: [Body Mass Index]										
Vita	al Signs Details										
#	Record Identifier:		Temperature	Temperature Unit	Temperature Location:						
7.a	1										
Vita	Vital Signs Details Entry										
	al Signs Details Entry										
7.1	al Signs Details Entry Record Identifier: [Record Identifier:]	01									
	Record Identifier:										
7.2	Record Identifier: [Record Identifier:] Temperature:	01 0C 0F									

C4	591001: VITAL SIGN	s - covi	D (VITALS O	COV) - Repeating Form	
#	Date:			Vital Signs Details	
1					
Vita	al Signs				
	Date: [Date:]	<b>~</b> /	✓ /		
Vita	al Signs Details				
# ✔	Record Identifier:	Systolic:	Diastolic:	Respiratory Rate in respirations/minute	Heart Rate in beats/minute
2.a	1				
Vit	al Signs Details Entry				
2.1	Record Identifier: [Record Identifier:]	01			
2.2	Systol c: [Systolic:]				
2.3	Diastol c: [Diastol c:]				
2.4	Respiratory Rate in respirations/minute: [Respiratory Rate in respirations/minute]				
2.5	Heart Rate in beats/minute: [Heart Rate in beats/minute]				

### C4591001: VITAL SIGNS (VITALS FUP) Vital Signs 1. Date: ✓ / **v** / ~ [Date:] Vital Signs Details **Record Identifier:** Diastolic: **BP** Position # Temperature Temperature Unit **Temperature Location:** Systolic: Pulse: 2.a 1 SITTING Vital Signs Details Entry 2.1 Record Identifier: [Record Identifier:] $\bigcirc 1$ 2.2 Temperature: [Temperature] 2.3 Unit: OF [Temperature Unit] ОС 2.4 Temperature Location: [Temperature Location:] ORAL CAVITY EAR ○ RECTUM AXILLA **FOREHEAD** 2.5 Systol c: [Systolic:] 2.6 Diastol c: [Diastol c:] BP Posit on: ○ SITTING 2.7 [BP Position] 2.8 Pulse: [Pulse:]

C4591001: WITHDRAWAL OF CONSENT (WOC)									
W	ithdrawal Of Consent								
1.	Withdrawal of Consent Date : [Withdrawal of Consent Date :]		<b>v</b> /	<b>v</b> /					

# A-1426-0086 / C4591001-Post-12-July-2020 App Subject Facing Screen Report

Localized texts are displayed in English (US).

### Contents

1 Notifications / Subject card	2
2 Common	5
3 Form: Vaccination Diary	22
4 Form: COVID-19 Illness Diary	37
5 Form: Patient main menu	40
6 Form: Subject training diary	47
7 Form: Settings	54
8 Form: Security question	55

Localized months and days of the week will display throughtout the app.

Month	Janua	iry	February	March	April	May	June	July	August	September	October	Novembe	r December
Abbr.	Jan		Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Days	Monday Tuesday			Wednesday T			sday	Friday	Satu	rday	Sunday		
Abbr.	Μ	lon	Tue Wed		Thu	hu Fri				Sun			

**Note**: Text below the screens/messages is for information purposes only and gives instruction on when particular wording on a screen/message may display or what a computed value may display

# 1 Notifications / Subject card

### Email notification/Subject card to provisioned device subjects:

Welcome to the C4591001-Post-12-July-2020 study!

### Email notification only: [Hello, ]

The information below will guide you on how to start using the TrialMax App.

On the phone provided to you by the study clinic, open the TrialMax App and type in the following code to activate it: [Activation Code]

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

During your study clinic visit, the study personnel will help you with any questions related to the TrialMax App activation.

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the activation, contact your study clinic or the Helpdesk.

If you contact your study clinic or the Helpdesk, you may need to give the following information:

Subject card only: [ Participant number: XXXXXXXX ]

Subject card only: [ Site number: XXXX ]

Trial ID: C4591001-Post-12-July-2020

### Email notification only: [ ------

This is an automatic e-mail message sent by Signant Health, an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdes k. ]

### SMS Body for Provisioned Devices:

Welcome to the C4591001-Post-12-July-2020 Study! Activate the TrialMax App with code:

[Activation Code]

### Email notification/Subject card to BYOD subjects:

Welcome to the C4591001-Post-12-July-2020 study!

### Email notification only: [Hello, ]

The information below will guide you on how to install the TrialMaxApp onto your cell phone and how to start using the TrialMax App after the installation.

Email notification only: [To install the TrialMax App, tap the link below and follow the on-screen instructions.

Subject card only: [To install the TrialMax App, tap the link in the installation text message (SMS) or email you will receive in a few minutes, and follow the on-screen instructions.

If you have not received the text message or email, enter the following internet address into the web browser of your device: ]

[Link]

After the installation has completed, open the TrialMax App and type in the following code to activate it: [Activation Code]

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

During your study clinic visit, the study clinic personnel will help you with any questions related to the TrialMax App installation.

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the installation, contact your study clinic or the Helpdesk.

If you contact your study clinic or the Helpdesk, you may need to give the following information:

Subject card only: [Participant number: XXXXXXXX ]

Subject card only: [ Site number: XXXX ]

Trial ID: C4591001-Post-12-July-2020

### Email notification only: [ ------

This is an automatic e-mail message sent by Signant Health, an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review,

use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdesk. ]

### SMS Body for BYOD subjects:

Welcome to the C4591001-Post-12-July-2020 Study! To install the TrialMax App, select the link: [Link] Activate the TrialMax App with code: [Activation Code]

### App notification:

Please fill in your diary!

Email notification subject : COVID-19 Illness Diary Reminder

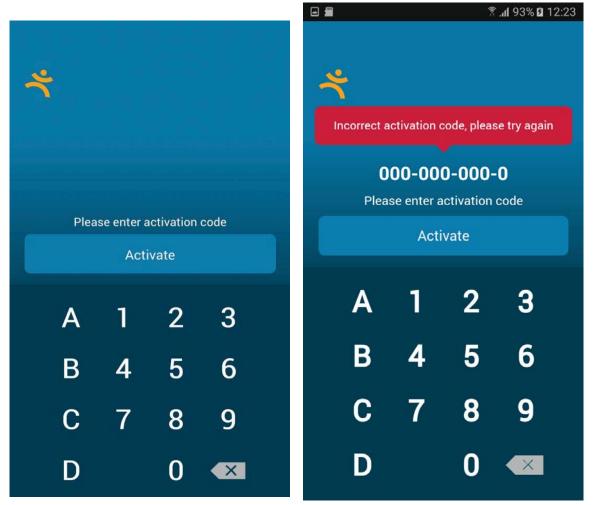
### Email and SMS Body for COVID-19 Illness Diary Reminder:

Please continue to complete the illness diary weekly or if you experience COVID-19 symptoms or have a COVID-19 diagnosis. Contact your study doctor with any suspected COVID-19 symptoms.

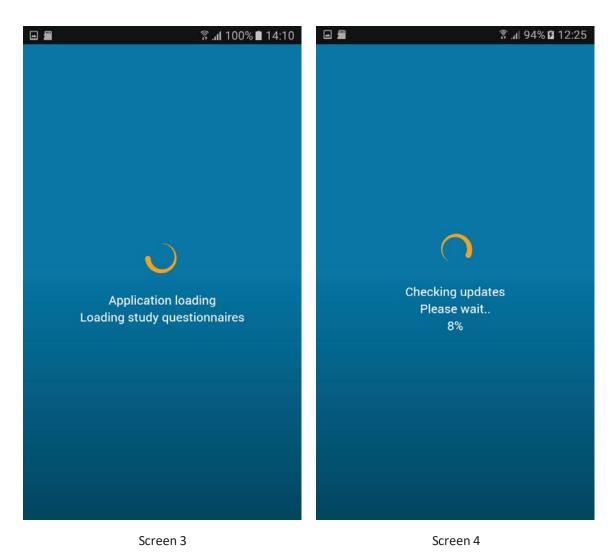
### Email notification only: [ ------

This is an automatic e-mail message sent by Signant Health, an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdesk. ]

## 2 Common



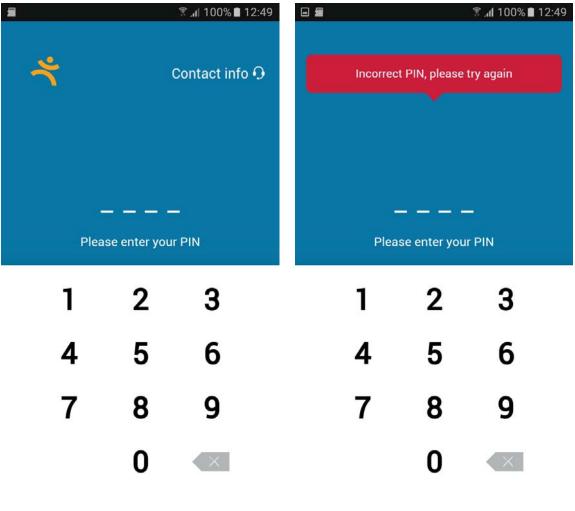
Screen 1



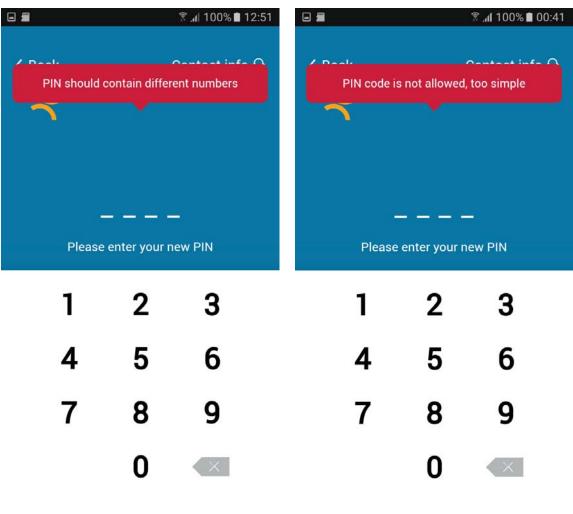
090177e198823706\Approved\Approved On: 04-Nov-2021 12:49 (GMT)

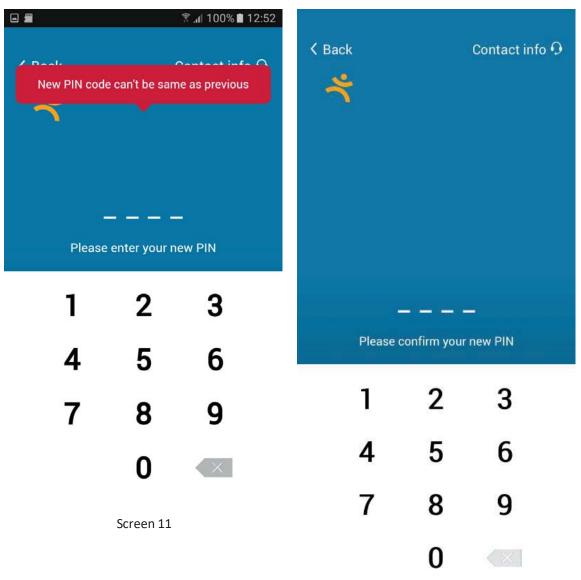
Page 6 of 57

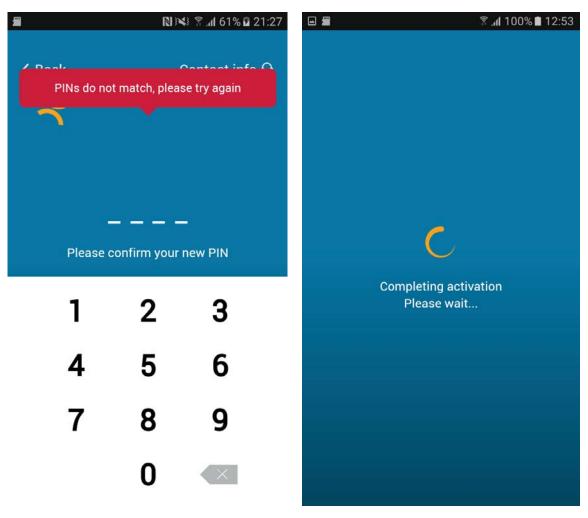
A-1426-0086 /	App Subject Facing Screen Report	26-OCT-2020
C4591001-Post-12-July-2020	English (USA) enUS	Version 4

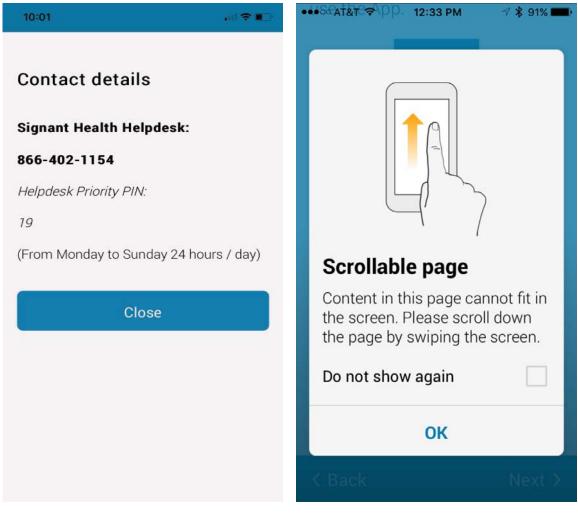


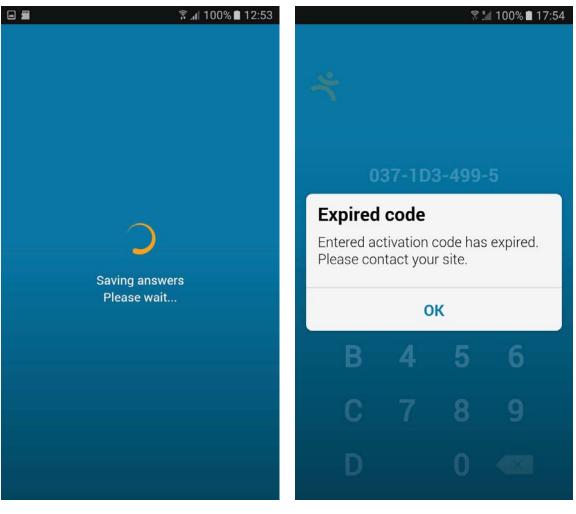
িয়া 100% ∎ 16:23 New PIN required	< Back			Contact info $\Theta$
You are required to choose a new memorable PIN. Your new PIN must be 4 characters.				
PINs that consist of characters following each other, like 1234 or 9876, or repeat the same character, like 1111 or 9999, are not accepted.				
Old PINs cannot be reused.	Please enter your new PIN			
Create a new PIN		1	2	3
		4	5	6
		7	8	9
Screen 7			<b>O</b> Screen 8	×

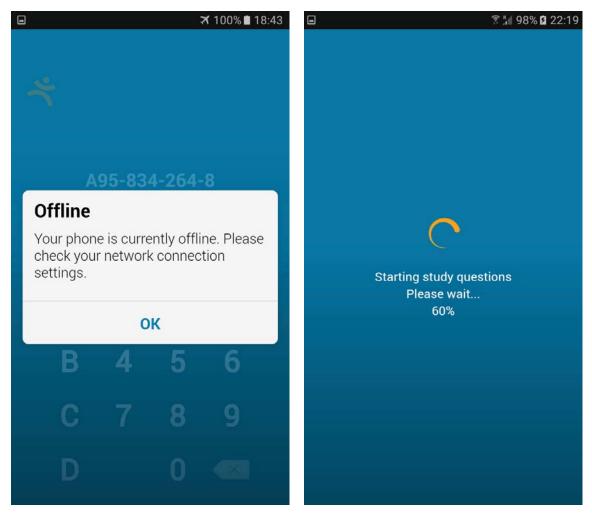


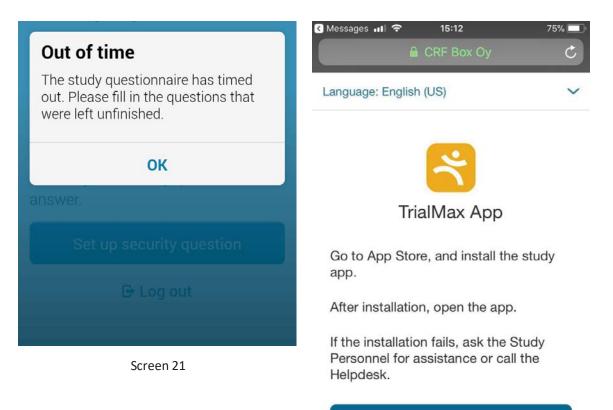








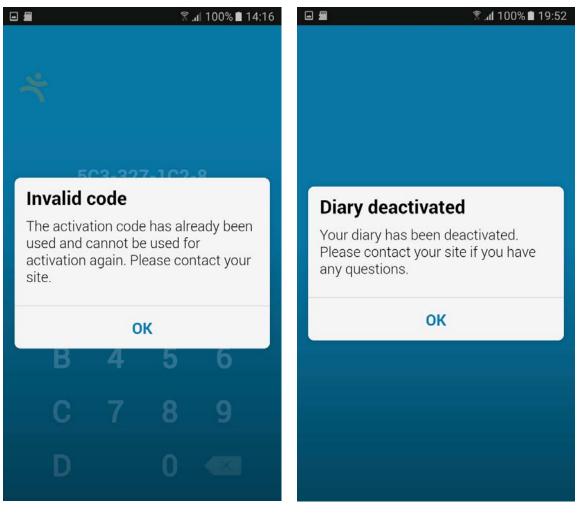


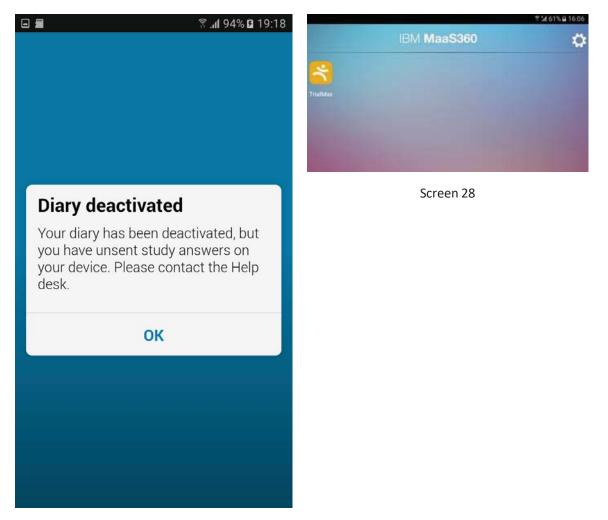


Go to App Store



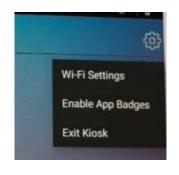
A-1426-0086 / C4591001-Post-12-July-2020	App Subject Facing So English (USA)	-	26-OCT-2020 Version 4
CRF Box Oy		■ = ↑	≅.al 100%∎ 14:18 n.net/; 1 :
Language: English (Master)	~	Language: English (US)	
TrialMax Ap Unfortunately this device can		TrialMax A	App
study app.			
Please inform the Study Pers your site.	ionnel / contact	Go to Play Store, and ins app.	stall the study
		After installation, open t	he app.
		If the installation fails, a Personnel for assistance Helpdesk.	
		Go to Play St	ore
< > 1			
Screen 23		Screen 24	



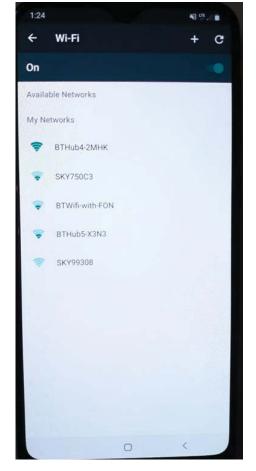


Screen 27

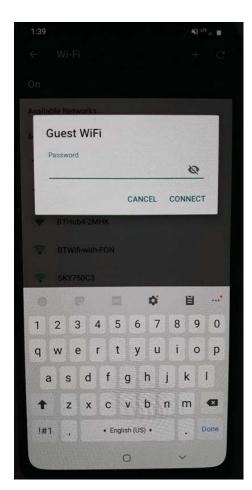
### App Subject Facing Screen Report English (USA) enUS



Screen 29



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



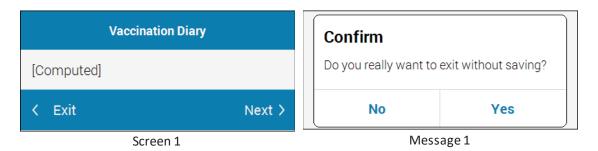
Screen 31



Screen 32

	Note: Other messages that could appear on the device include:
	'Invalid PIN'
	'Installing study questions'
	'Securing study questions'
	'Unsent answers'
Diary deactivated Your diary has been deactivated. Please contact your site if you have any questions.	'There are a lot of unsent study answers. Please make sure your device is connected to the Internet.'
ОК	'The limit of unsent study answers has been reached. Please connect your device to the Internet to fill in the diary again.'
	'Oops!'
	'Something went wrong, please try again or contact the Help desk.'
	'Unsuccessful sending'
	'Cannot safely send the study answers, please contact the Help desk.'
Message 1	'Study ended'
	'You no longer need to fill in the diary. Thank you for your help.'
	'Updating'
	'System is updating, please try again later.'
	'Connection error'
	'No Internet connection. Please check your Internet connection and try again.'
	'Time out'
	'Please check your Internet connection and try again.'
	'Low storage space'
	'Your device is running out of available storage. Please free some storage space and try again.'
	'Error'
	'Something went wrong, please contact the Help desk or click OK to try again.'

# 3 Form: Vaccination Diary

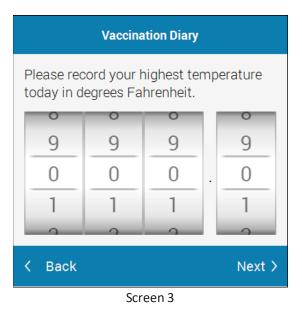


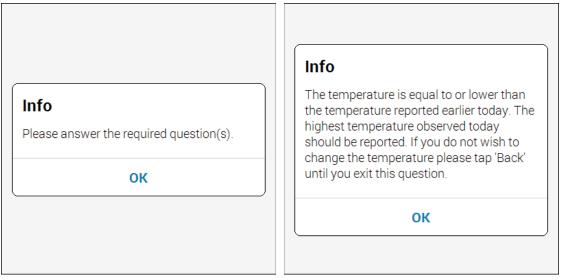
[Computed] Text will display "Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on {1}. You will answer these questions for {2} day(s)."

{1} Will display a date

{2} Will display a number of days.

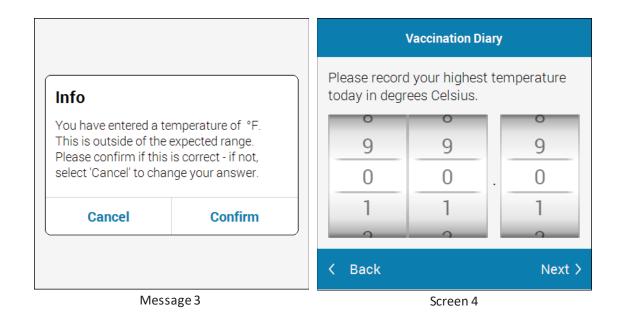
Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 day(s).





Message 1

Message 2

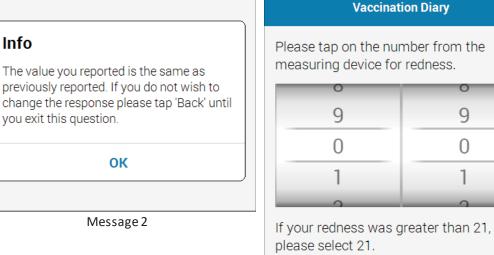


			Vacci	nation Diary
Info			Please confirm yo today:	ur highest temperature
You have entered a temperature of °C. This is outside of the expected range. Please confirm if this is correct - if not, select 'Cancel' to change your answer.			[Computed]	
			< Back	Next >
			S	creen 5
Cancel	Confirm	[Computed] will display the tempera selected on Screen 3 or Screen 4		

Message 3

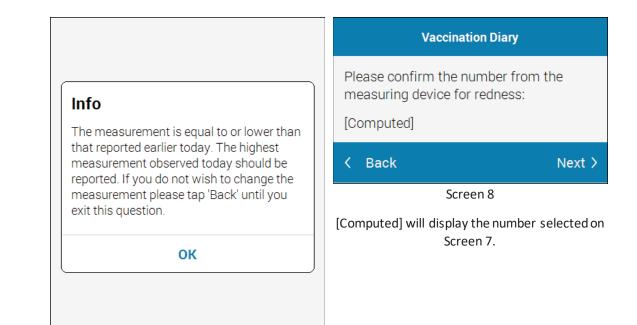
# Info Please contact your study doctor as soon as possible. OK Message 1 X Back Next > Screen 6

090177e198823706\Approved\Approved On: 04-Nov-2021 12:49 (GMT)



✓ Back Next >

Screen 7



Message 2

Vaccination Diary		Vaccinat	tion Diary
Today, have you had any swelling at the injection site?		Please select the number from the measuring device for swelling.	
Хар	0	0	0
Yes	0	9	9
No	$\bigcirc$	0	0
		1	1
< Back	Next >	0	2
Screen 9		If your swelling was please select 21.	greater than 21,
		< Back	Next >

Screen 10

Vaccination Diary	Vaccination Diary	
Please confirm the number from the measuring device for swelling:	Today, have you had any pain at the injection site?	
[Computed]	Yes	
< Back Next >	No	
Screen 11		
[Computed] will display the number selected on Screen 10.	✓ Back Next >	

Vaccination Diary	Vaccination Diary	
Pain at the injection site definitions: Mild = Does not interfere with activity	Please indicate whether the pain at the injection site was:	
Moderate = Interferes with activity	Mild	
Severe = Prevents daily activity	Moderate O	
< Back Next >	Severe	
Screen 13		
	< Back Next >	

Info		Info The severity is equal to or lower than the
	daily activity. If this is go forward or 'No' to er.	severity reported earlier today. The most severe symptom observed today should be reported. If you do not wish to change the severity please tap 'Back' until you exit this question.
No	Yes	ОК
Me	ssage 2	Message 4

Vaccination Diary		Vaccination Diary
Did you go to the ER or were you hospitalized for this reaction?		Today, have you experienced fatigue (tiredness)?
Yes	$\bigcirc$	Yes
No	0	No
< Back	Next >	< Back Next >

Screen 16

Vaccination Diary	Vaccination Diary
Fatigue (tiredness) definitions: Mild = Does not interfere with activity	Please indicate whether the fatigue (tiredness) was:
Moderate = Some interference with	Mild
activity Severe = Prevents daily routine activity	Moderate O
K Back Next >	Severe O
Screen 17	≺ Back Next >

		Vaccination Diary	
Info Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.		Did you go to the ER or were you hospitalized for this reaction?	l
		Yes	0
		No	0
No	Yes		
		< Back	Next >
		Screen 19	

Message 2

Vaccination Diary		Vaccinati	on Diary
Today, have you experienced headache?		Headache definition	IS:
Yes	0	Mild = Does not interf	ere with activity
		Moderate = Some inte	erference with
No	0	activity	
		Severe = Prevents dai	ly routine activity
< Back	Next >	< Back	Next >
Screen 20			
		Scree	n 21

Vaccination Diary	Vaccination Diary
Please indicate whether the headache was:	Did you go to the ER or were you hospitalized for this reaction?
Mild	Yes
Moderate O	No
Severe O	< Back Next >
< Back Next >	Screen 23

Vaccination Diary	Vaccination Diary	
Today, have you experienced vomiting?	Vomiting definitions:	
Yes	Mild = 1 to 2 times in 24 hours Moderate = More than twice in 24 hours	
No	Severe = Requires intravenous hydration	
< Back Next >	< Back Next >	
Screen 24	Screen 25	

Vaccination Diary	
Please indicate whether the vomiting was:	
Mild	0
Moderate	$\bigcirc$
Severe	$\bigcirc$
< Back Ne:	xt >
	XI 7

Message 2

Vaccination Diary		Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?		Today, have you experienced dia	rrhea?
		Yes	$\bigcirc$
Yes	0	Νο	$\bigcirc$
No	$\bigcirc$		0
		< Back	Next >
< Back	Next >	Screen 28	

Vaccination Diary	Vaccination Diary
Diarrhea definitions:	Please indicate whether the diarrhea was:
Mild = 2 to 3 loose stools in 24 hours	Mild
Moderate = 4 to 5 loose stools in 24 hours	Moderate O
Severe = 6 or more loose stools in 24 hours	Severe
≺ Back Next >	< Back Next >
Screen 29	Screen 30

		Vaccination Diary	
Info Severe = 6 or more loose stools in 24 hours. If this is correct tap 'Yes' to go forward or 'No' to change your answer.		Did you go to the ER or were you hospitalized for this reaction?	
		Yes	0
		No	0
No	Yes		
		< Back	Next >
		Screen 31	
Mes	sage 2		

Vaccination Diary	Vaccination Diary	
Today, have you experienced chills?	Chills definitions:	
Yes	Mild = Does not interfere with activity	
No	Moderate = Some interference with activity	
	Severe = Prevents daily routine activity	
✓ Back Next >	✓ Back Next >	
Screen 32		

Vaccination Diary	Vaccination Diary	
Please indicate whether the chills were:	Did you go to the ER or were you hospitalized for this reaction?	
Mild		
	Yes	
Moderate O		
	No	
Severe		
	✓ Back Next >	
< Back Next >	Screen 35	
	561001155	

Vaccination Diary	Vaccination Diary	
Today, have you had new or worsened muscle pain (other than at the injection site)?	Muscle pain definitions: Mild = No interference with activity	
Yes	Moderate = Some interference with activity	
No	Severe = Prevents daily routine activity	
	< Back Next >	
K Back Next >	Screen 37	

-	•••	-	-	•••	-	•	

Vaccination Diary		Vaccination Diary	
Please indicate whether the new or worsened muscle pain was:		Did you go to the ER or were you hospitalized for this reaction?	
Mild	$\bigcirc$	Yes	0
Moderate	$\bigcirc$	No	0
Severe	0	< Back	Next >
K Back	Next >	Screen 39	
Screen 38			

Vaccination Diary		Vaccination Diary
Today, have you had any new or worsened joint pain?		Joint pain definitions: Mild = No interference with activity
Yes	$\bigcirc$	Moderate = Some interference with activity
No	0	Severe = Prevents daily routine activity
K Back N	ext >	✓ Back Next >

Screen 41

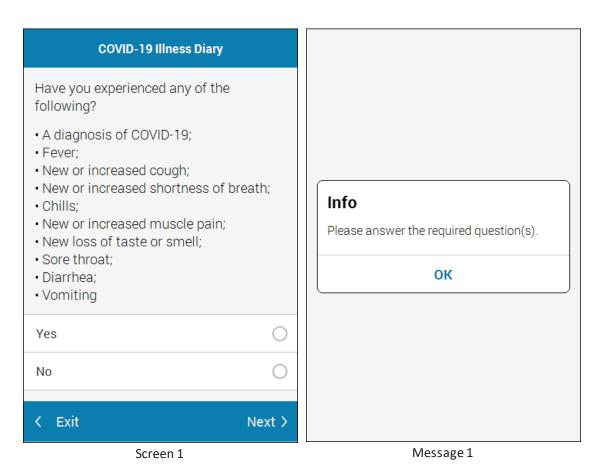
Vaccination Diary	Vaccination Diary
Please indicate whether the new or worsened joint pain was:	Did you go to the ER or were you hospitalized for this reaction?
Mild	Yes
Moderate O	No
Severe O	< Back Next >
< Back Next >	Screen 43

Vaccination	n Diary		
Today, have you taken treat fever or pain?	any medication to	Info	
Yes	0		taking medication to Is your answer correct?
No	0	No	Yes
< Back	Next >		
Screen	44	Me	essage 2

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

for the next 4 day(s).

### 4 Form: COVID-19 Illness Diary



Info You have reported a o COVID-19, or new or i Is this correct?		Confirm Do you really want to No	exit without saving? Yes
No	Yes		
Mess	age 2	Mess	sage 3
COVID-19	llness Diary		
Thank you! You have COVID-19 illness dial answers by selecting to change your answ	ry. Please save your J <b>'Save</b> '. If you wish	An unscheduled illnes your study team is rea contact your study te	quired. Please
Sa	/e	С	к
< Back			
Scre	en 2	Mess	age 1

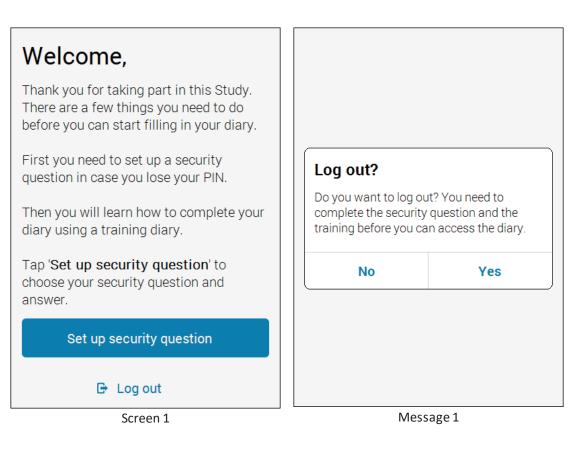
#### Info

Thank you for completing COVID-19 Illness Diary. If you become ill, please complete illness diary. If you remain well, your next check-in is required in 7 days.

ОК

Message 2

### 5 Form: Patient main menu



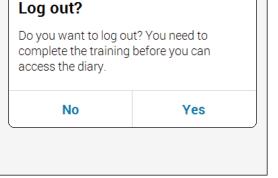
## Thank you,

Your security question and answer have been saved.

Next, tap '**Go to training diary**' to learn how to complete your diary.

Go to training diary

🕒 Log out



Screen 2

Message 1

# Reminder time changed

The reminder time of your study diary has been changed by the study personnel.

[Computed]

[Computed]

If the new reminder time is incorrect, please contact your site.

Tap 'OK' to continue to the main menu of the diary.

#### ОК

#### Screen 3

First [Computed] will show 'Old reminder time: {1}' where {1} will be the old reminder time

Second [Computed] will show 'New reminder time: {1}' where {1} will be the new reminder time

# Hello,

# [Computed]

[Computed]

[Computed]

Report Medication Taken to treat Fever or Pain

Please fill in your COVID-19 Illness Diary if you are diagnosed with COVID-19 or you have possible new or increased symptoms, and when you receive a reminder, at least weekly.

#### COVID-19 Illness Diary

(Symptoms of COVID-19 include; fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea and vomiting)

Training review
 Settings

Screen 4

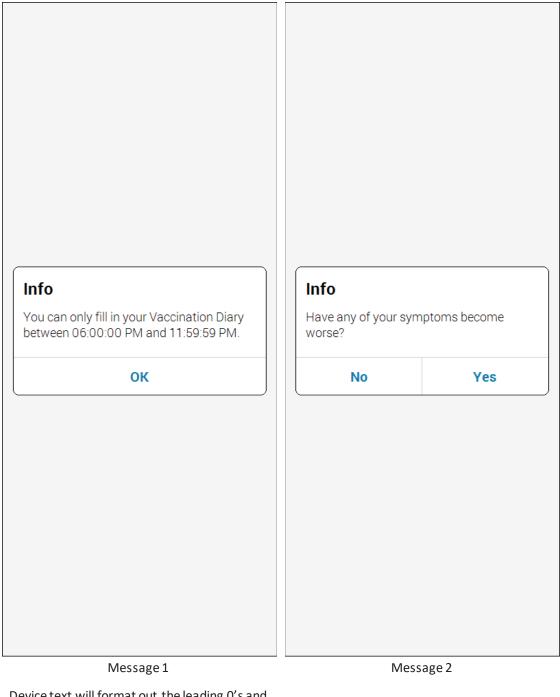
🕒 Log out

First [Computed] text below Hello, will either display: "<b>You are being reminded to complete your weekly COVID-19 Illness Diary.</b>" or "<b>You are being reminded to complete your daily <u>Vaccination Diary</u>.</b>"

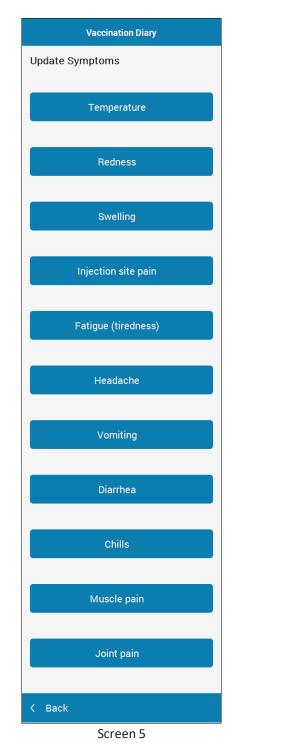
090177e198823706\Approved\Approved On: 04-Nov-2021 12:49 (GMT)

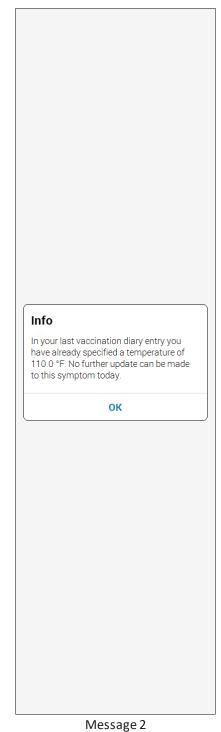
Second [Computed] text below Hello, will either display: "You have completed today's Vaccination Diary.", "You have completed today's Vaccination Diary. Please remember to log in again tomorrow." or "Please fill in your daily Vaccination Diary before midnight."

[Computed] text within the button will read: "Update Symptoms" or "<b>Vaccination Diary</b>"

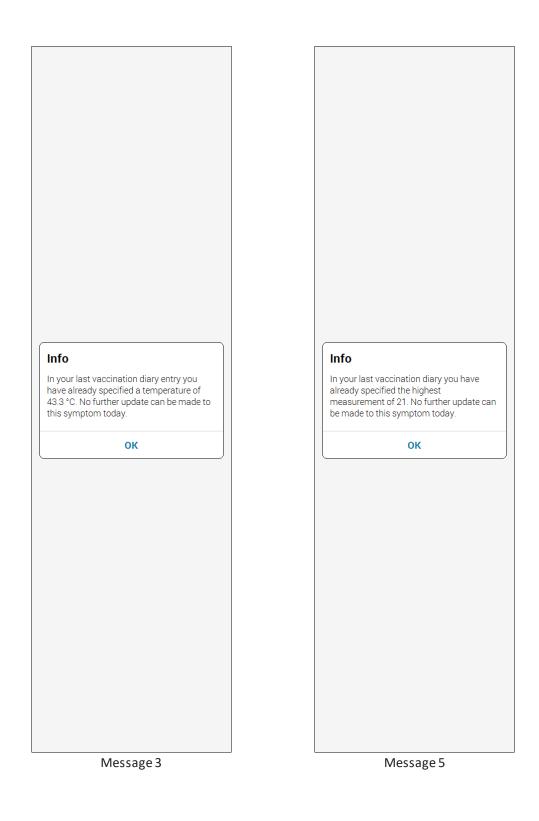


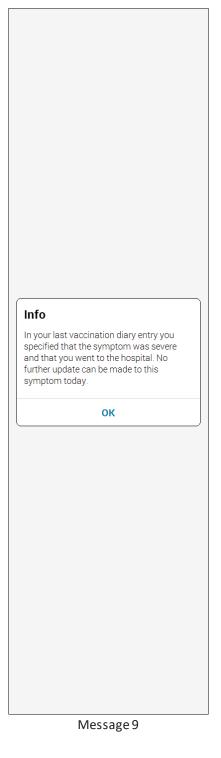
Device text will format out the leading O's and seconds. Actual popup will read "6:00 PM and 11:59 PM"





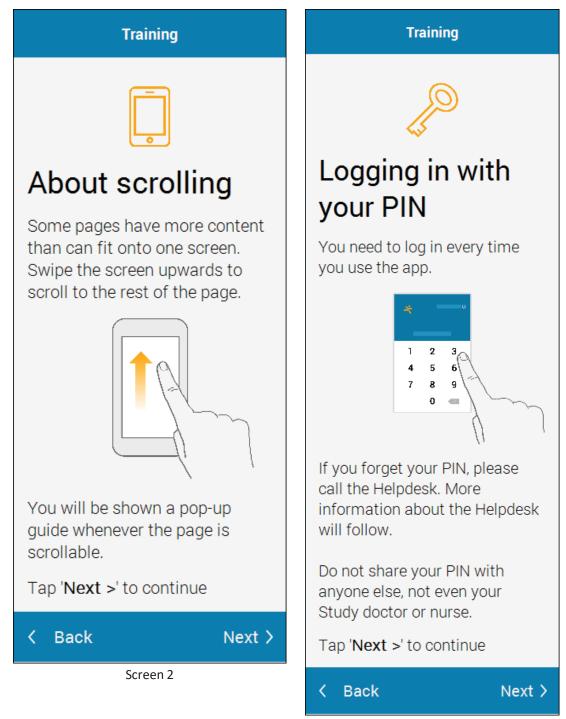


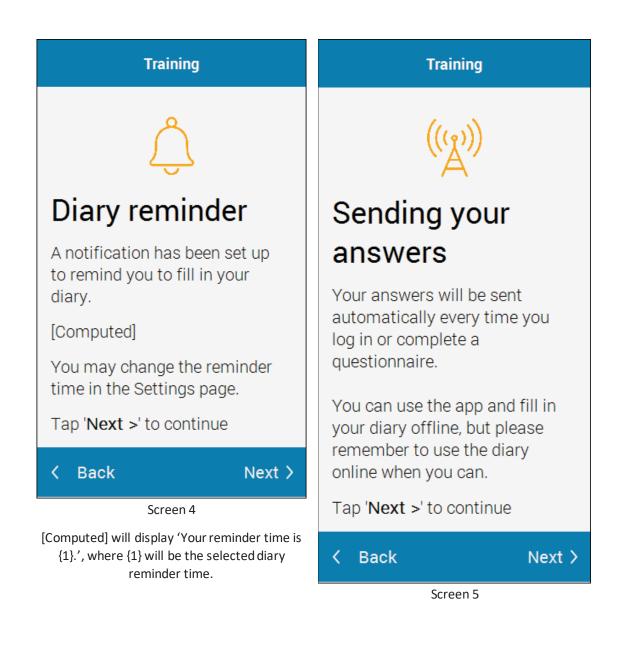




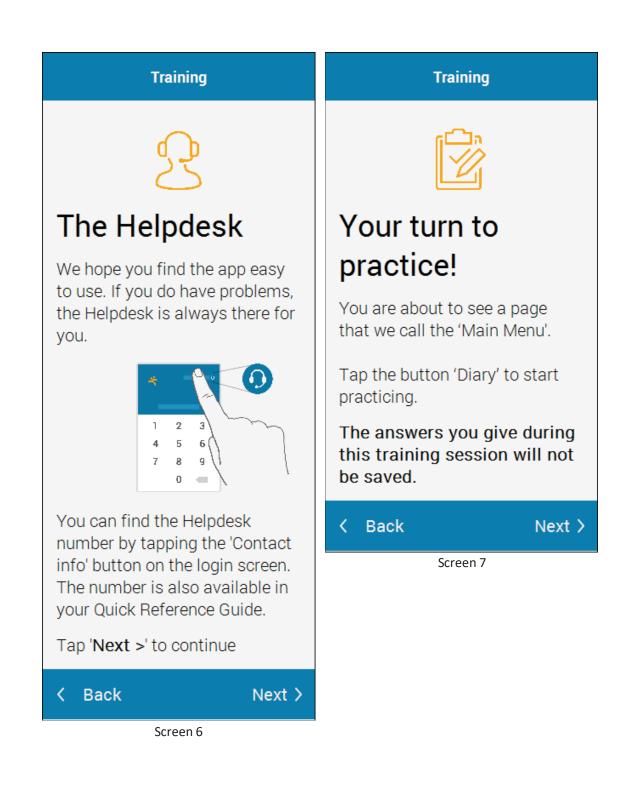
### 6 Form: Subject training diary

Training			
<b>D</b> Welcome to	the	Confirm	
Training!		Do you want to l	-
Here you will learn:		need to complet before you can a	-
- About the app			
- How to fill in your di	ary	No	Yes
Use the ' <b>Next &gt;'</b> butto move through the Tra the ' <b>&lt; Back</b> ' button to	nining. Use		
Let's get started!			
< Back	Next >		
Screen 1		Mess	sage 1

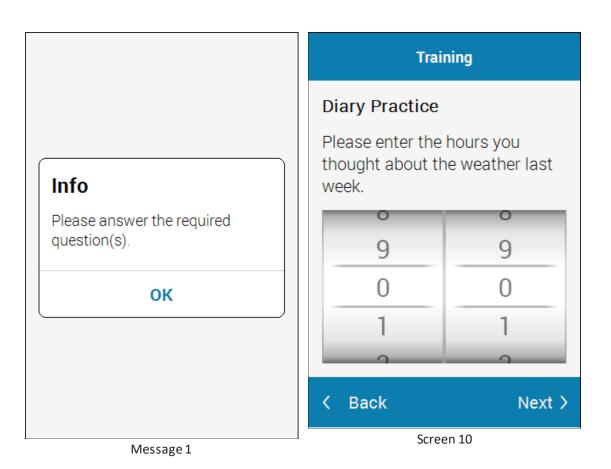




Page 49 of 57



Training	Training
Diary Practice	Diary Practice
Main Menu	Please tap the option that best describes the weather.
Tap the button 'Diary' to begin	Sunny
Diary	Cloudy
< Back	Raining
Screen 8	Snowing O
	く Back Next >



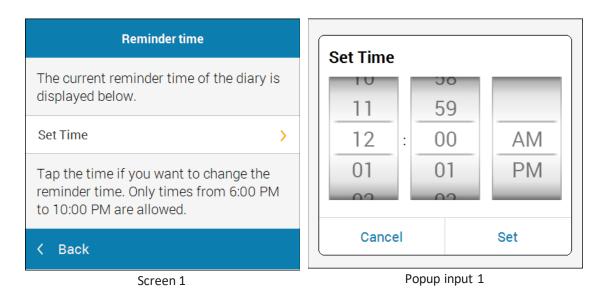
Next >

Training	Training		
Diary Practice When completing your diary, you will be asked to save your answers at the end. If you exit without selecting save, your answers will not be saved. Please press the 'Save' button below to continue.	Well done! Thank you for completing the Training		
Save	diary. Now you are ready to start using your App.		
K Back Screen 11	If you would like to repeat the Training later, just tap the 'Training review' button in the Main Menu.		
	Tap ' <b>Next &gt;</b> ' to continue to the 'Main menu'.		

Back

<

## 7 Form: Settings



### 8 Form: Security question

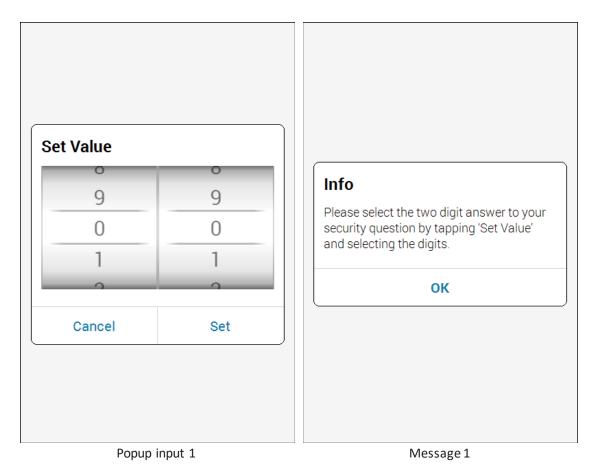
Security question	
Choose your security question. T answer should have only two dig question and answer will be need you forget your PIN.	gits. Your
[Computed]	$\bigcirc$
[Computed]	0
[Computed]	0
Then tap the ' <b>Next &gt;</b> ' button	
< Back	Next >
Screen 1	

Screen 1

[Computed] will show one of the following:

'Your oldest sibling's birth year (YY)' 'Your mother's birth year (YY)' 'Last two digits of your childhood phone number' 'Day of the month of your father's birthday' 'Day of the month of your mother's birthday' 'Childhood home door number (2 digits only)' 'How old were you when you passed your driving test?' 'The year you got married (YY)'

		Security question		
		[Computed]		
		Tap below to select the two digit a to your question:	nswer	
		Set Value	>	
Log out? Do you want to log out? You need to complete the security question and the training before you can access the diary.		After successfully selecting the digits, you can see them above.		
		If you want to change your security question, tap the '< <b>Back</b> ' button of lower left corner to go back.		
No	Yes	Please save your question and ans tapping the ' <b>Save</b> ' button. Once say you will not be able to come back t change your selections.	ved,	
		< Back	Save	
		Screen 2		
		[Computed] will display		
		'Your question:    i>{1}/b>'		
Message 2		{1} will show the question selected on Screen 1		



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# MASTER SUBJECT SCREEN REPORT APPROVAL

Content for Approval					
Language	English for United States				
Subject screen report	A-1426-0086-5270SR-enUS	Version	4	Date	26-Oct-2020

## CUSTOMER

Approval				
Name and Title: Kimberly Rarrick		Signature: DocuSigned by:		
			Kimberly Rarrick	
Company: Pfizer	Role: Study Manager	Date:	26-Oct-2020   16:47 EDT	

## SIGNANT HEALTH

Approval	
Name: Brittany Hayes	Signature: DocuSigned by:
	Brittany Hayes
Title: Project Manager III	Date: 26-Oct-2020   15:29 EDT