Annotated Study Book for Study Design: C4591001

Study Design Version: 16.0

Sponsor: Pfizer

Protocol: C4591001

Sponsor Drug Name: BLINDED THERAPY

C4591001 - COVID19

Generated by Central Designer TM
February 22, 2021 8:10AM

C	C4591001: ADVERSE EVENT REPORT (AE) - Repeating Form														
# (Category	AE Identifier		Start Date		Toxicity Grade	Serious	Is AE a Result of a Medication Error	Relationship to Study Treatment	Action Taken with Study Treatment	Concomitant Medication Given	Non-Drug Treatment Given	Outcome	Caused Study Discontinuation	Serious Adverse Event Number
1															
Ad	verse Ev	ent Report													
1.	Catego [Catego														
2.	AE ID: [AE Ide	ntifier]													
3.	(If poss diagnos individu sympto	ıal													
4.	Start D	ate Time: Date]	~ /		/ V 24-hour clock										
5.	still ong	dverse even joing? Adverse itill Ongoing	NO End [Date Tir	me: / / 24-hour cloc	k									
6.		Grade: y Grade]	1 2 3 4												
7.	serious If Yes, I PFIZER IMMEDI Fatal; L threate Inpatien hospita prolong existing hospita Persiste significa disabilit Congen anomal defect; medical may jee subject require	NOTIFY IATELY. ife- ning; nt lization or at on of lization; ent or ant y/incapacity itial y/birth Important event (i.e. opardize and may //surgical ntion to above es).	Is thi YE NO D d ti YE NO Did ti YE NO Did ti YE NO Is thi YE NO Is thi YE NO NO Is thi	ES O his ser ES O his ser ES O his ser ES O o r med c ES	ous event result ii ous event require	n death? or prolong n persisten stening?	hospitaliz	nomaly or birth defe							
8.	Is this a		O YES												

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9.	event the result of a study Medication Error? If Yes, record the type of med cation error on the Medicat on Error Log. [Is AE a Result of a Medicat on Error] Is this event related to study treatment: [Relationship to Study Treatment]	 NOT RELATED If Not Related to study treatment(s), this event is due to:
		RELATED
10.	Latest Action Taken with Study Treatment: [Action Taken w th Study Treatment]	ORUG WITHDRAWN NOT APPLICABLE
11.	Was a Concomitant Medicat on given? [Concom tant Medicat on Given]	○ YES ○ NO
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	○ YES ○ NO
13.	What was the outcome of this adverse event?: [Outcome]	 ○ FATAL ○ NOT RECOVERED/NOT RESOLVED ○ RECOVERED/RESOLVED ○ RECOVERED/RESOLVED WITH SEQUELAE ○ RECOVERING/RESOLVING ○ UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuat on]	○ YES ○ NO
15.	Serious Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]	
16.	Comparison Term [hidden] [Comparison Term]	
17.	Lowest Level Term [hidden]	

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	[Lowest Level Term]	
18.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	
19.	Dict onary-Derived Term [hidden] [Dict onary-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)							
1	nformed Consent - Booster							
1	Consent Was:	OBTAINED						
	[Consent Was:]	Date Written Consent Obtained						

C4	4591001: INCLUSION/EXCLUSION CRITERIA - BOOSTER (BOOST IE)							
	Criterion Description							
1.								
Inc	lusion Criteria Not Met Entry							
1.1	Description of Inclus on Crterion Not Met [Criter on Description]							
	Criterion Description							
2.								
Exc	clusion Criteria Met Entry							
2.1	Description of Exclusion Cr terion Met [Criter on Description]							

C	C4591001: BOOSTER DOSE TRIGGER FORM (BOOST TRIG)						
В	ooster 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 vis t The participant will NOT return for consent/eligibil ty assessment for the booster dose visit					

C4591001: LABORATORY DATA - HEMATOLOGY (CD4)									
aboratory Data Hematology									
Lab Panel: [Category for Lab Test]	HEMATOLO	OGY							
Laboratory Name and Address [Vendor Name (DERIVED)]									
3. Collect on Date: [Collection Date:]					_				
Specimen Type: [Specimen Type]									
b Result									
Sponsor-Defined Identifier		Test:	Result:	Not Done:	Lab Normal Range				
		CD4_PX4722							
b Result Entry									
Sponsor ID: [Sponsor-Defined Identifier]									
Personal Test: [Test:]	OCD4_PX4	722							
Result:									
Not Done: [hidden] [Not Done:]	O NOT DON	E							
LNMT [Lab Normal Range]	Low	LOW							
	High								
	Unit								
	-	13							
	0%								
	Lab Panel: [Category for Lab Test] Laboratory Name and Address [Vendor Name (DERIVED)] Collect on Date: [Collection Date:] Specimen Type: [Specimen Type] b Result Sponsor-Defined Identifier b Result Entry Sponsor ID: [Sponsor-Defined Identifier] Test: [Test:] Result: [Result:] Not Done: [hidden] [Not Done:]	boratory Data Hematology Lab Panel: [Category for Lab Test] Laboratory Name and Address [Vendor Name (DERIVED)] Collect on Date: [Collection Date:] Specimen Type: [Specimen Type] b Result Sponsor-Defined Identifier b Result Entry Sponsor ID: [Sponsor-Defined Identifier] 7 Test: [Test:] 8 Result: [Result:] Not Done: [hidden] [Not Done:] LINMT [Lab Normal Range] High Unit 0 10^3/mn 0 /uL	boratory Data Hematology Lab Panel: [Category for Lab Test] Laboratory Name and Address [Vendor Name (DERIVED)] Collect on Date: [Collection Date:] Specimen Type: [Specimen Type] b Result Sponsor-Defined Identifier Test: [Col4_PX4722 b Result Entry Sponsor ID: [Sponsor-Defined Identifier] Test: [Test:] Result: [Result:] Not Done: [hidden] [Not Done:] LUMMT [Lab Normal Range] Low High Unit O 10^3/mm3 O /uL	Doratory Data Hematology Lab Panel: [Category for Lab Test] Laboratory Name and Address [Vendor Name (DERIVED)] Collect on Date: [Collection Date:] [Collection Date:] [Specimen Type: [Specimen Type] Defined Identifier Sponsor-Defined Identifier Defined Identifier Test: CD4_PX4722 Defined Identifier Test: Result: Defined Identifier CD4_PX4722 Defined Identifier Test: Result: Defined Identifier Test: Result: Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Noncor ID: [Sponsor-Defined Identifier] Test: [Test:] Defined Identifier Test: Result: Test: Test: Test: Result: Test: Test: Result: Test: Test:	Decretory Data Hematology Lab Panel: [Category for Lab Test] Laboratory Name and Address [Vendor Name (DERIVED)] Collect on Date: [Collection Date:] Specimen Type: [Specimen Type] Decretory Result Sponsor-Defined Identifier Sponsor ID: [Sponsor-Defined Identifier] Test: [Test:] Test: [Test:] Result: [Result:] Not Done: [Inidden] [Not Done: [Inidden] [Not Done:] Low High Lunit Lunit Unit U				

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

C4	591001: CONCOMITAN	591001: CONCOMITANT MEDICATIONS - BASELINE (CONMED BSL) - Repeating Form								
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	
1										
Coı	ncomitant Medications									
1.	What is the med cation dentifier [Sponsor-Defined Identifier]	?								
2.	Category: [Category for Medication]		GENERAL CONCOMITANT MEDICATIONS							
3.	Concomitant Med cat ons Pre-spe [Concom tant Medicat ons Pre-sp		○ NO							
4.	Medicat on: Provide the complete gener c dru where applicable). Where gener full trade or proprietary name. Ir the Medication text (e.g., Ingred formulation). [Name of Medication]	c name is unknown, enter the nclude clarifying information in								
5.	Dose: [Dose Description]									
6.	Dose Unit: [Dose Unit]		<u> </u>							
7.	Dose Frequency: [Dose Frequency]		<u> </u>							
8.	Route: [Route]									
9.	Start Date: [Start Date]									
10.	Comparison Term [hidden] [Comparison Term]									
11.	Standardized Medication Name - [Standardized Medication Name]									
12.	Standardized Medication Code - I [Standardized Medication Code]	Dict onary derived [hidden]								

С	4591001: CONCOMITANT MEDICA					
#	Sponsor-Defined Identifier Catego		ory for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date
1						
Co	oncomitant Medications					
1.	What is the med cation dentifier? [Sponsor-Defined Identifier]					
2.	Category: [Category for Medication]		O VACCINATIONS			
3.	Concomitant Medications Pre-specified: [Concom tant Medicat ons Pre-specified]		ONO			
4.	Medicat on: Provide the complete gener c drug name (includ where applicable). Where gener c name is unknot full trade or proprietary name. Include clarifying the Med cation text (e.g., Ingredient(s), route, uformulation). [Name of Medication]	own, enter the information in				
5.	Date: [Start Date]					
6.	6. Comparison Term [hidden] [Comparison Term]					
7. Standardized Medication Name - D ctionary derived. [hidden] [Standardized Medication Name]						
8.	Standardized Medication Code - Dictionary deriv [Standardized Medication Code]	red [hidden]				

(C4591001: MAIN INFORMED CONSENT (CONSENT)				
I	Informed Consent				
1	. Consent Was: [Consent Was:]	OBTAINED Date Written Consent Obtained			

C	C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)				
Co	ontact Outcome				
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	O CONTACT OUTCOME			
2.	Contact Type: [Type of Contact/Visit]	CLINIC VISIT TELEHEALTH VISIT			
3.	Was contact made? [Was Contact Made]	YES Date of Contact:			
4.	Comments: [Comments/Findings/Details]				

С	24591001: CONTACT OUTCOME - MONTH 6 (CONTACT 6M)				
C	ontact Outcome				
1.	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	OCONTACT OUTCOME			
2.	Contact Type: [Type of Contact/Visit]	CLINIC VISIT TELEHEALTH VISIT			
3.	Was contact made? [Was Contact Made]	○ YES Date of Contact: ○ V ○ V ○ NO If No, why?			
4.	Comments: [Comments/Findings/Details]				

C	4591001: CONTACT OUTCOME (CONTACT SV)				
С	ontact Outcome				
1	Follow-Up Contact Category [hidden] [Follow Up Contact Category]	OCONTACT OUTCOME			
2	. Contact Type: [Type of Contact/Visit]	O TELEPHONE VISIT			
3	. Was contact made? [Was Contact Made]	YES Date of Contact: V / V / V NO If No, why?			
4	. Comments: [Comments/Findings/Details]				

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

#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	Comments:
1			· · · · · ·			
Microl	biology Specimen					
	tual Date of Collect on: ate of Collect on]					
	ecimen Type: pecimen Type]	SERUM BLOOD PLASMA				
	say Code and Description: ssay Code and Description]	SEVERE ACUTE RESP SYNDROME (CORONAVIRUS 2			
	v ce Type: ev ce Type]	○ SARS-COV-2 DIAGNOSTIC TEST				
	st Result: esult]	O POSITIVE NEGATIVE INDETERMINATE				
	mments/Findings/Details: omments:]					

С	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									
М	icrobiology Specimen								
1.	Actual Date of Collect o [Date of Collect on]	n:							
2.	Specimen Type: [Specimen Type]		SWABBED MATERIAL RESPIRATORY SECRETIONS						
3.	Specimen Collect on Lo [Specimen Collection Lo		NASOPHARYNX LOWER RESPIRATORY SYSTEM THROAT						
4.	Assay Code and Description [Assay Code and Description of the code and Description of		SEVERE ACUTE RESP SYNDROME CO	RONAVIRUS 2					
5.	Dev ce Type: [Dev ce Type]		SARS-COV-2 DIAGNOSTIC TEST						
6.	Trade Name: [Trade Name]		<u> </u>						
7.	Test Result: [Result]		POSITIVE NEGATIVE INDETERMINATE						
8.	Comments/Findings/De [Comments:]	tails:							
9.	Trade Name Other, Spe [Trade Name Other, Sp								

C4:	C4591001: DEATH DETAILS CODED (DEATH DTL)					
Dea	eath Details					
1. [Date of Collection / Notif cation of Death: Date of Collect on / Notif cation of Death]					
	Cause of Death Status Cause of Death					
2.						
Cau	se of Death Entry					
2.1	Cause of Death Status: [Cause of Death Status]	O PRIMARY CAUSE OF DEATH O SECONDARY CAUSE OF DEATH				
2.2	Cause of Death: [Cause of Death]					
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	D ctionary-Derived Term [hidden] [D ctionary-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]					

C	C4591001: DEMOGRAPHY (DEMOG)				
D	Demography				
1	Subject ID [Subject ID]				
2	Birth Date: [Birth Date]				
3	Sex: [Sex]	○ FEMALE ○ MALE			
4	Ethnicity: [Ethnicity]	○ HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN○ NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN○ NOT REPORTED			
5	Race: (Check X all that apply): [Race Of Subject]	BLACK OR AFRICAN AMERICAN AMERICAN INDIAN OR ALASKA NATIVE ASIAN NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WHITE NOT REPORTED			
6	Racial Designation: [Racial Designation]	○ JAPANESE ○ OTHER			

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

C	C4591001: DISPOSITION - FOLLOW-UP (DISP FUP)			
D	sposition - Follow-Up			
1.	Date of Completion/Discontinuation/Death: [Date of Completion/Discontinuat on/Death:]			
2.	Phase of Disposit on: [Disposition Phase]	O FOLLOW-UP		
3.	Status: [Status]			
4.	Specify Status: [Specify Status]			

C	C4591001: DISPOSITION - SCREENING FOR FURTHER VACCINATION (DISP RESCR)				
D	isposition - Screening for Further Vaccination				
	Date of Completion/Discontinuation/Death: [Date of Completion/Discontinuat on/Death:]				
	Phase of Disposit on: [Disposition Phase]	REPEAT SCREENING 1			
3.	Status: [Status]				
4.	Specify Status: [Specify Status]				

C	C4591001: DISPOSITION - SCREENING (DISP SCR)				
D	isposition - Screening				
	1. Date of Completion/Discontinuation/Death [Date of Completion/Discontinuat on/Death]				
	Phase of Disposit on: [Disposition Phase]	SCREENING			
3.	Status: [Status]				
4.	Specify Status: [Specify Status]				

С	C4591001: DISPOSITION - TREATMENT (DISP TRT)				
D	isposition - Treatment				
1. Date of Completion/Discontinuation/Death: [Date of Completion/Discontinuat on/Death:]					
2.	Phase of Disposit on: [Disposition Phase]	○ VACCINATION○ OPEN LABEL TREATMENT○ 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]			
	Erroneous Visit [Vis t Error]	© ERRONEOUS VISIT		

C	C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)				
D	Date of Visit				
	Date of Visit [Date of Visit]				
	Erroneous Visit [Vis t Error]	© ERRONEOUS VISIT			
C	COVID-19 Illness Visit				
	COVID-19 Illness Vis t: [COVID-19 Illness Visit]				

C	C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)				
D	Date of Visit				
	Date of Visit [Date of Visit]				
	Erroneous Visit [Vis t Error]	© ERRONEOUS VISIT			
C	COVID-19 Illness Visit				
	COVID-19 Illness Vis t: [COVID-19 Illness Visit]				

C4591001: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE (DOV SURV)				
Date of Visit				
1. Date of Visit [Date of Visit]				
2. Erroneous Visit [Vis t Error]	© ERRONEOUS VISIT			
COVID-19 Surveillance Visit				
3. COVID-19 Surveillance Vist: [COVID-19 Surveillance Vist]				

C	C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)				
D	Date of Visit				
	Date of Visit [Date of Visit]				
	Erroneous Visit [Vis t Error]	© ERRONEOUS VISIT			
C	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)			
H	HIV Status		
1	. Select appropriate response - What is the subject HIV status? [Trigger Response 2]	The subject is NOT known to be HIV POSITIVE The subject is NOT known to be HIV POSITIVE	

C4	C4591001: LAB CHEMISTRY (HIV RNA)					
Lal	Lab Chemistry Details					
1.	Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY				
2.	Laboratory Name and Address [Vendor Name]					
3.	Collect on Date: [Collection Date:]					
4.	Specimen Type: [Specimen Type]	BLOOD				
Lal	Result					
#		Test:	Result:	Not Done:	Lab Normal Range	
5.a		HIV RNA (Ultrasensitive)				
La	Result Entry					
5.1	Sponsor ID: [Sponsor-Defined Identifier]					
5.2	Test: [Test:]	HIV RNA (Ultrasens tive)				
5.3	Result: [Result:]					
5.4	Not Done: [hidden] [Not Done:]	O NOT DONE				
5.5	LNMT [Lab Normal Range]	Low				
		High				
		Unit				

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C4591001: HEALTH CARE UTILIZATION (HLTHCARE)						
He	Health Care Utilization					
Evaluation Interval: [hidden] [Evaluat on Interval] ()			SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE			
2. Disease Name: [hidden] [Disease Name]			© RESPIRATORY ILLNESS			
He	ealth Care Utilization					
#			Type of Practitioner		Occurrence of Visits or Contacts	
3.8	YES	SPEC	ALIST			
3.t	YES	EMER	GENCY ROOM			
3.0	YES	PRIMA	ARY CARE PHYSICIAN			
3.0	d YES	URGE	NT CARE			
3.6	YES	TELEF	PHONE CONSULTATION			
3.f	YES	OTHE	R			
Не	ealth Care Utilization Entry					
3.:	Pre-Specified: [hidden] [Pre-Specified]		○ YES			
3.2 Phys cian or Healthcare Professional: [Type of Pract toner]			SPECIALIST EMERGENCY ROOM PRIMARY CARE PHYSICIAN URGENT CARE TELEPHONE CONSULTATION OTHER			
[Occurrence of Visits or Contacts]			YES Number of Visits or Contacts: NO			
He	Health Care Utilization Other					
4. Other Type of Practit oner Specify: [Other Type of Practitioner Specify]						
He	Health Care Utilization					
[Been Hospitalized]		to	Has the subject been in intensive care due to potential COVID-19 illnes YES NO	s?		

C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form							
#	# Hospitalization Category		Hospitalization Term	Admission Date	Ongoing		
1							
Hospitalization Details							
1	Hospitalization Category: [Hospitalization Category]	OHOSPITALIZATION STATUS	5				
2	Hospitalization Term: [Hospitalization Term]	O ICU O HOSPITAL					
3	Admission Date: [Admission Date]	V / V / V					
4	Ongoing? [Ongoing]	○ YES ○ NO Discharge Date: ☑ / ☑ / ☑					

C4591001: ILLNESS DETAILS (ILL POTEN)							
Illness Details							
1.	Category of Clinical Event: [Category of Clinical Event:]	POTENTIAL COVID-19 ILLNESS					
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	NO PES Respiratory Illness Diagnosis: Date of Diagnosis:					
3.	Toxicity Grade: [Tox c ty Grade]	0 01 02 03 04 05					
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.	Dict onary Derived Term [hidden] [Dict onary 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]						

C4	C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)				
Illr	ness Details				
1.	Category of Clinical Event: [Category of Clinical Event:]	SEVERE COVID-19 ILLNESS			
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	○ SIGNIFICANT ACUTE RENAL DYSFUNCTION ○ SIGNIFICANT ACUTE HEPATIC DYSFUNCTION ○ SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION			
3.	Was a diagnosis obtained? [Diagnosis Obtained]	YES Diagnosis: Start Date: Ongoing?: YES NO End Date: NO NO			
4.	Toxicity Grade: [Tox c ty 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.	Dict onary Derived Term [hidden] [Dict onary 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]				
	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]

C	C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE) - Repeating Form							
#	Category of Clinical Event	t:	Subcategory of Clinica	Event	Diagnosis Obtained	Toxicity Grade		
1								
Illi	ness Details							
1.	Category of Clinical Event: [Category of Clinical Event:]	SEVERE COVID-19 I	LLNESS					
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	SIGNIFICANT ACUTE	E RENAL DYSFUNCTION E HEPATIC DYSFUNCTION E NEUROLOGIC DYSFUNCTION					
3.	Was a diagnosis obtained? [Diagnosis Obtained]	YES Diagnosis: Start Date: Ongoing?: YES NO End Date: NO						
4.	Toxicity Grade: [Tox c ty Grade]	1 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.	Dict onary Derived Term [hidden] [Dict onary 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]				1			

	[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]	<u>•</u> /	▽ / ▽				
2. Location of Assessment: [Location of Assessment]	CHEST HEAD OTHER If other,	specify:				
3. Type of Imaging Exam: [Imaging Method]	CT SCAN X-RAY ULTRASC MRI OTHER If other,	DUND				
4. Assessment: [Overall Assessment]	ABNORMA If abnorm INDETER NORMAL UNKNOW NOT EVA	nal, specify findings: MINATE				

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)					
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).						
Incl	usion Criteria					
#	Inclusion Number			Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Male or female part cipa randomization (depende		between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at upon study stage)		IN01A00
1.b	2	Participants who are wil study procedures	ling	and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other		INO2A00
1.c	3	Healthy participants who inclus on in the study	o ar	re determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for		IN03A00
1.d	4	Capable of giving persor	nal :	signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in		IN04A00
Inc	lusion Criteria Entr	у				
1.1	Inclusion Number: [Inclus on Number]		0000	2 3		
1.2	Criter on Description [Criter on Description					
1.3 Criter on met? [Criter on met?]			Ŏ	YES NO Describe details if relevant		
1.4 Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]			○ IN01A00 ○ IN02A00 ○ IN03A00 ○ IN04A00			
Exc	lusion Criteria					
#	Exclusion Number	•		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psych risk of study participati		ic condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the		EX01A00
2.b	2	Known infect on with h	uma	an immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adver intervention(s)	rse i	reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study		EX03A00
2.d	4	Receipt of medications	inte	ended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination				EX08A00
2.f	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention			EX09A00	
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscula injection				EX10A00
2.h	11	Women who are pregna	Vomen who are pregnant or breastfeeding EX11A00			
2.i	12		rev ous vaccinat on with any coronavirus vaccine EX12A00			
2.j	13			 imunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, costeroids are permitted		EX13A00
2.k	14			roducts or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EX14A00

2.1	15	Participation in other s	articipation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on EX15A00					
2.m	16	Prev ous participation	n other studies involving study intervention containing lipid nanoparticles	EX16A00				
2.n	21	Investigator site staff their respective family	or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and members	EX21A00				
Exc	Exclusion Criteria Entry							
2.1 Exclusion Number: [Exclusion Number]								
2.2	2.2 Criter on Description: [Criter on Description]							
2.3 Criter on met? [Criter on met?]			YES Describe details if relevant NO					
2.4	Criter on ID: (For Pfi [Criter on ID: (For Pfi							

C 4	591001: INCL	USION/EXCLUSI	ON CRITERIA (IN EX STG3)				
Stu	Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).						
Inc	lusion Criteria						
#	Inclusion Number		Criterion met? Criterion ID: (For Pfizer use only)				
1.a	1	Male or female part cipa randomization (depende	ints between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at ent upon study stage)	IN01A00			
1.b	2	Participants who are wil study procedures	ling and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other	IN02A00			
1.0	3	Healthy participants wh inclus on in the study	o are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for	IN03A00			
1.d	4	Capable of giving perso this protocol	nal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in	IN04A00			
Inc	lusion Criteria Entr	·v		'			
1.1	I.1 Inclusion Number: [Inclus on Number]		○1 ○2 ○3 ○4				
1.2	Criter on Description [Criter on Description						
1.3	Criter on met? [Criter on met?]		YES NO Describe details if relevant				
1.4	Criter on ID: (For Pf [Criter on ID: (For F		○ IN01A00○ IN02A00○ IN03A00○ IN04A00				
Exc	lusion Criteria						
_	Exclusion Number	•	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)			
2.a	1	Other medical or psychrisk of study participati	iatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the on	EX01A00			
2.b	2	Known infect on with h	uman immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	EX02A00			
2.c	3	History of severe adversintervention(s)	rse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study	EX03A00			
2.d	4	Receipt of medications	intended to prevent COVID-19	EX04A00			
2.e	8	8 Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination EX08A00					
2.f	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection					
2.g	11 Women who are pregnant or breastfeeding EX11A00						
_	12 Prev ous vaccinat on with any coronavirus vaccine EX12A00						
2.i	· · · · · · · · · · · · · · · · · · ·						
2.j		Receipt of blood/plasm study	a products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the	EX14A01			
2.k	16	· ·	tudies involving study intervention within 28 days prior to study entry and/or during study participat on	EX15A01			
2.1	17	EX16A01					

2.m		nvestigator site staff or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and neir respective family members		EX21A01				
Exc	cclusion Criteria Entry							
	Exclusion Number: [Exclusion Number]							
	Criter on Description: [Criter on Description]							
	Criter on met? [Criter on met?]	O YES Describe details if relevant NO						
	Criter on ID: (For Pfize [Criter on ID: (For Pfize							

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)								
Stu	dy eligibility requires	subjects to meet all inclu	lusion	criteria (YES) and Not meet exclus on criteria (NO).					
Inc	Inclusion Criteria								
#	Inclusion Number			Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)			
1.a	1	Male or female part cipa randomization (depende		etween the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at con study stage)		IN01A00			
1.b	2	Participants who are wil study procedures	illing a	and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other		IN02A00			
1.c	3	Healthy participants who inclus on in the study	ho are	determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for		IN03A00			
1.d	4	Capable of giving persor	onal si	gned informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in	n	IN04A00			
Inc	lusion Criteria Enti	ry							
1.1	Inclusion Number: [Inclus on Number]		01 02 03 04						
1.2	Criter on Description [Criter on Description			▼					
1.3	Criter on met? [Criter on met?] NO Describe details if relevant								
1.4		Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)] IN01A00 IN02A00 IN03A00 IN04A00							
Exc	lusion Criteria								
#	Exclusion Numbe	r		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)			
2.a	1	Other medical or psych risk of study participati		condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase t	he	EX01A00			
2.b	2	Known infect on with h	human	n immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00			
2.c	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)				EX03A00				
2.d	4 Receipt of medications intended to prevent COVID-19				EX04A00				
2.e	8 Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination EX08A00					EX08A00			
2.f	9 Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention					EX09A00			
2.g	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection				ar	EX10A00			
2.h	11 Women who are pregnant or breastfeeding EX11A00								
2.i	12	Prev ous vaccinat on wi	vith an	y coronavirus vaccine		EX12A00			
2.j	13	Subjects who receive in	immur	nosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01			
-	15			ducts or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout t	he	EX14A01			
2.1	16	Participation in other st	studies	s involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01			

2.m	17	Prev ous participation in		EX16A01			
2.n		Investigator site staff or their respective family r	igator, and	EX21A01			
Excl	usion Criteria Entry	1					
2.1	Exclusion Number: [Exclusion Number]						
2.2	2.2 Criter on Description: [Criter on Description]						
2.3 Criter on met? [Criter on met?]			YES Describe details if relevant NO				
	Criter on ID: (For Pfiz [Criter on ID: (For Pf						

C4	A591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)					
	Criterion Description					
1.						
Inc	Inclusion Criteria Not Met Entry					
1.1	Description of Inclus on Cr terion Not Met [Criter on Description]					
		Criterion Description				
2.						
Ex	Exclusion Criteria Met Entry					
2.1	Description of Exclusion Cr terion Met [Criter on Description]					

2.1 16

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)							
Stu	Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).							
Inc	Inclusion Criteria							
#	Inclusion Number			Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)		
1.a	1	Male or female part cipa randomization (depende		between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at pon study stage)		IN01A00		
1.b	2	Participants who are wil study procedures	lling	and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other		IN02A00		
1.c	3	Healthy participants who	io are	e determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for		IN03A00		
1.d	4	Capable of giving persor this protocol	nal s	igned informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in		IN04A00		
Inc	lusion Criteria Ent	ry						
	1.1 Inclusion Number: [Inclus on Number] 0 1 0 2 0 3 0 4							
1.2	Criter on Descriptio							
1.3	Criter on met? [Criter on met?]		010					
1.4	Criter on ID: (For P [Criter on ID: (For I		OI	N01A00 N02A00 N03A00 N04A00				
	lusion Criteria							
\vdash	Exclusion Numbe			Criterion Description		Criterion ID: (For Pfizer use only)		
2.a	1	Other medical or psych risk of study participati		c condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase th	е	EX01A00		
2.b	2	Known infect on with h	numa	n immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00		
2.c	3	History of severe adversintervention(s)	rse r	eaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study		EX03A00		
2.d	4	Receipt of medications	inte	nded to prevent COVID-19		EX04A00		
2.e	5	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19 EX05A00				EX05A00		
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination				EX08A00		
2.g	10	Bleeding diathesis or co	ondit	ion associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular		EX10A00		
2.h	11	Women who are pregn	ant c	or breastfeeding		EX11A00		
2.i	12	Prev ous vaccinat on w	ith a	ny coronavirus vaccine		EX12A00		
2.j	13	Subjects who receive in	mmu	nosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01		
2.k	15	Receipt of blood/plasm study	na pro	oducts or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout th	е	EX14A01		

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EX15A01

Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on

2.m	17	Prev ous participation in other studies ir	rev ous participation in other studies involving study intervention containing lipid nanoparticles EX16A01						
2.n	22	Investigator site staff or Pfizer employed their respective family members	es directly involved in the conduct of the study, s te staff otherwise supervised by the investigat	r, and	EX21A01				
Exc	Exclusion Criteria Entry								
2.1	Exclusion Number: [Exclusion Number]								
2.2	Criter on Description [Criter on Description								
2.3	Criter on met? [Criter on met?]	YES Describe deta	ails if relevant						
2.4	Criter on ID: (For Pfi [Criter on ID: (For Pfi								

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)					
Stu	dy eligibility requires	subjects to meet all incl	usi	ion criteria (YES) and Not meet exclus on criteria (NO).		
Inc	clusion Criteria					
#	Inclusion Number			Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a		Male or female part cipa randomization (depende		ts between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at t upon study stage)		IN01A00
1.b		Participants who are wil study procedures	llin	ng and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other		IN02A00
1.c		Healthy participants who inclus on in the study	10 a	are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for		IN03A00
1.d		Capable of giving persor this protocol	na	Il signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in		IN04A00
Inc	lusion Criteria Entr	у				
1.1	Inclusion Number: [Inclus on Number])1)2)3)4		
1.2	Criter on Description [Criter on Description					
1.3	1.3 Criter on met? [Criter on met?]			YES NO Describe details if relevant		
1.4	Criter on ID: (For Pfi [Criter on ID: (For P			IN01A00 IN02A00 IN03A00 IN04A00		
Exc	lusion Criteria					
	Exclusion Number			Criterion Description		Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psych risk of study participati		tric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the 1		EX01A00
2.b	2	Known infect on with h	ıun	man immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adver	rse	e reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study		EX03A00
2.d	4	Receipt of medications	Receipt of medications intended to prevent COVID-19 EX04A00			
2.e	5	Stages 1 and 2 only: P	rev	vious clin cal or microb olog cal diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised i examination	ind	dividuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical		EX08A00
2.g	9	Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention				EX09A00
2.h	10	Bleeding diathesis or co	one	dition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular		EX10A00
2.i	11	Women who are pregn	an	nt or breastfeeding		EX11A00
2.j	12	Prev ous vaccinat on w	ith	any coronavirus vaccine		EX12A00
2.k	13	Subjects who receive in	mr	munosuppressive therapy, such as cytotox c agents or system c corticosteroids		EX13A01
2.1	15	Receipt of blood/plasm study	na p	products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EX14A01

١.	1	I		l -					
2.m	16	Participation in other s	ticipation in other studies involving study intervention within 28 days prior to study entry and/or during study participat on EX15A01						
2.n	17	Prev ous participation i	n other studies involving study intervention containing lipid nanoparticles	EX16A01					
2.0	22	Investigator site staff of their respective family	or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and members	EX21A01					
Exc	Exclusion Criteria Entry								
2.1	2.1 Exclusion Number: [Exclusion Number]								
2.2	2.2 Criter on Description: [Criter on Description]								
2.3	2.3 Criter on met? [Criter on met?]		YES Describe details if relevant NO						
2.4	Criter on ID: (For Pfi [Criter on ID: (For P								

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC NS)								
Stu	Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).								
Inc	nclusion Criteria								
#	Inclusion Number		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)				
1.a	1	Male or female part cipa randomization (dependent	ints between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at ent upon study stage)		IN01A00				
1.b	2	Participants who are will study procedures	ling and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other		INO2A00				
1.c	3	Healthy participants wh inclus on in the study	o are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for		IN03A00				
1.d	4	Capable of giving perso this protocol	nal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in		IN04A00				
Inc	lusion Criteria Ent	ry							
1.1	Inclusion Number: [Inclus on Number]		①1 ②2 ③3 ③4						
1.2	Criter on Descriptio								
1.3	Criter on met? [Criter on met?]		YES NO Describe details if relevant						
1.4	Criter on ID: (For P [Criter on ID: (For I		○ IN01A00○ IN02A00○ IN03A00○ IN04A00						
Exc	lusion Criteria								
#	Exclusion Numbe	r	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)				
2.a	1	Other medical or psychrisk of study participat	iatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the on		EX01A00				
2.b	2	Known infect on with h	uman immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00				
2.c	3	History of severe adve	rse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study		EX03A00				
2.d	4	Receipt of medications	intended to prevent COVID-19		EX04A00				
2.e	5	Stages 1 and 2 only: P	revious clin cal or microb olog cal diagnosis of COVID-19		EX05A00				
2.f	2.f 8 Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination EX08A00				EX08A00				
2.g	g 9 Indiv duals with a history of autoimmune disease or an active autoimmune disease requiring therapeut c intervention EX09A00				EX09A00				
	10	Bleeding diathesis or c injection	ondition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular		EX10A00				
2.i	11	Women who are pregn	ant or breastfeeding		EX11A00				
2.j	12	Prev ous vaccinat on w	ith any coronavirus vaccine		EX12A00				
2.k	13		e immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, corticosteroids are permitted		EX13A00				
21	1.4	Receipt of blood/place	a products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EY14A00				

	study							
2.m	15	Participation in other s	tudies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A00			
2.n	16	Prev ous participation i	n other studies involving study intervention containing lipid nanoparticles		EX16A00			
2.0	21		eir respective family members EX21A00					
Exc	Exclusion Criteria Entry							
2.1	2.1 Exclusion Number: [Exclusion Number]							
2.2	Criter on Description: [Criter on Description]							
2.3	Criter on met? [Criter on met?]		YES Describe details if relevant NO					
2.4	Criter on ID: (For Pfi [Criter on ID: (For Pfi							

2.k 11

Women who are pregnant or breastfeeding

C4	591001: INCL	USION/EXCLUSI	ON CRITERIA (INC EXC S)					
Stu	Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).							
Inc	Inclusion Criteria							
#	Inclusion Number		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)			
1.a	1	Male or female part cipa randomization (depende	ints between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at ent upon study stage)		IN01A00			
1.b	2	Participants who are wil study procedures	ling and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other		IN02A00			
1.c	3	Healthy participants wh inclus on in the study	o are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for		IN03A00			
1.d	4	Capable of giving perso this protocol	nal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in	1	IN04A00			
Inc	lusion Criteria Entr	у						
1.1	Inclusion Number: [Inclus on Number]		○1 ○2 ○3 ○4					
1.2	Criter on Description [Criter on Description							
1.3 Criter on met? [Criter on met?]			YES NO Describe details if relevant					
1.4 Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]			○ IN01A00○ IN02A00○ IN03A00○ IN04A00					
Exc	lusion Criteria							
-	Exclusion Number		Criterion Description		Criterion ID: (For Pfizer use only)			
2.a	1	Other medical or psychrisk of study participation	iatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase t on	ne	EX01A00			
2.b	2	Known infect on with h	uman immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00			
2.c	3	History of severe adversintervention(s)	rse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study	,	EX03A00			
2.d	4	Receipt of medications intended to prevent COVID-19			EX04A00			
2.e	5	Stages 1 and 2 only: P	revious clin cal or microb olog cal diagnosis of COVID-19		EX05A00			
2.f	6	Sentinel participants in	Stage 1 only: Indiv duals at high risk for severe COVID-19 (full details in protocol)		EX06A01			
2.g	7	Sentinel participants in worker, emergency res	Stage 1 only: Indiv duals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare ponse personnel)		EX07A00			
2.h	8	Immunocompromised examination	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination					
2.i	9	Sentinel participants in intervention	Stage 1 only: Indiv duals w th a history of autoimmune disease or an active autoimmune disease requiring therapeur	ic	EX09A04			
2.j	10	Bleeding diathesis or coinjection	ondition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscula	r	EX10A00			

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EX11A00

2.1	12	Prev ous vaccinat on w	Prev ous vaccinat on with any coronavirus vaccine					
2.m	13	Subjects who receive i	ubjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids EX13A01					
2.n	14	Sentinel participants in	Stage 1 only: Regular receipt of inhaled/nebulized cort costeroids		EX22A01			
2.0	15	Receipt of blood/plasm study	a products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EX14A01			
2.p	16	Participation in other s	tudies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01			
2.q	17	Prev ous participation i	n other studies involving study intervention containing lipid nanoparticles		EX16A01			
2.r	18	Sentinel participants in	Stage 1 only: Pos tive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01			
2.s	19		Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormal ty. Except Bilirubin, other stable may be considered eligible by Investigator		EX18A01			
2.t	20		Stage 1 only: Pos tive test for HIV, hepat tis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or dies (HCV Abs) at screening vis t		EX19A01			
2.u	21	Sentinel participants in	Stage 1 only: SARS-CoV-2 NAAT-pos tive nasal swab w thin 24 hours before receipt of study intervent on		EX20A01			
2.v	22	Investigator site staff of their respective family	or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and members		EX21A01			
Exc	lusion Criteria Entr	у						
2.1	Exclusion Number: [Exclusion Number]							
2.2	Criter on Description [Criter on Description							
	2.3 Criter on met? [Criter on met?]		YES Describe details if relevant NO					
2.4	Criter on ID: (For Pfi							

2.1 12

Prev ous vaccinat on with any coronavirus vaccine

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)							
Stu	Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).							
Inc	Inclusion Criteria							
#	Inclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)					
1.a		pants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at ident upon study stage)	IN01A00					
1.b	2 Participants who are study procedures	willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other	IN02A00					
1.c	3 Healthy participants vinclus on in the study	who are determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for	IN03A00					
1.d	4 Capable of giving per this protocol	sonal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in	IN04A00					
Inc	lusion Criteria Entry							
1.1	Inclusion Number: [Inclus on Number]	○1 ○2 ○3 ○4						
1.2	Criter on Description: [Criter on Description]							
1.3	Criter on met? [Criter on met?]	○ YES ○ NO Describe details if relevant						
1.4	Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]	○ IN01A00○ IN02A00○ IN03A00○ IN04A00						
Exc	lusion Criteria							
#	Exclusion Number	Criterion Description	Criterion met? Criterion ID: (For Pfizer use only)					
2.a	1 Other medical or psy risk of study particip	chiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase the ation	EX01A00					
2.b	2 Known infect on with	human immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	EX02A00					
2.c	History of severe addintervention(s)	verse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study	EX03A00					
2.d	4 Receipt of medicatio	ns intended to prevent COVID-19	EX04A00					
2.e	5 Stages 1 and 2 onlys	Previous clin cal or microb olog cal diagnosis of COVID-19	EX05A00					
2.f	6 Sentinel participants	in Stage 1 only: Indiv duals at high risk for severe COVID-19	EX06A00					
2.g	7 Sentinel participants worker, emergency is	in Stage 1 only: Indiv duals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare response personnel)	EX07A00					
2.h	8 Immunocompromise examination	d individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical	EX08A00					
2.i	9 Indiv duals with a his	story of autoimmune disease or an active autoimmune disease requiring therapeut c intervention	EX09A00					
2.j	Bleeding diathesis or injection	condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular	EX10A00					
2.k	k 11 Women who are pregnant or breastfeeding EX11A00							

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EX12A00

2.m	13		ndiv duals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, atrabursal, or topical corticosteroids are permitted				
2.n	14	Receipt of blood/plasm study	na products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EX14A00		
2.0	15	Participation in other s	studies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A00		
2.p	16	Prev ous participation	in other studies involving study intervention containing lipid nanoparticles		EX16A00		
2.q	17	Sentinel participants in	n Stage 1 only: Pos tive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A00		
2.r	18		n Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormal ty. Except Bilirubin, other stable may be considered eligible by Investigator		EX18A00		
2.s	19		n Stage 1 only: Pos tive test for HIV, hepat tis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or odies (HCV Abs) at screening vis t		EX19A00		
2.t	20	Sentinel participants in	n Stage 1 only: SARS-CoV-2 NAAT-pos tive nasal swab w thin 24 hours before receipt of study intervent on		EX20A00		
2.u	21	Investigator site staff of their respective family	or Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and members		EX21A00		
Exc	usion Criteria Entr	у					
2.1	Exclusion Number: [Exclusion Number]						
2.2	Criter on Description [Criter on Description						
2.3	Criter on met? [Criter on met?]		YES Describe details if relevant				
			○ NO				
2.4	Criter on ID: (For Pfi [Criter on ID: (For Pfi						

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Prev ous vaccinat on with any coronavirus vaccine

C4	C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC S)							
Stu	Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclus on criteria (NO).							
Inc	clusion Criteria							
#	Inclusion Number	•		Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)		
1.a	1	Male or female part cipa randomization (depende		between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at upon study stage)		IN01A00		
1.b	2	Participants who are wil study procedures	illing	and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other		IN02A00		
1.c	3	Healthy participants wh inclus on in the study	no are	e determined by medical history, physical examination, and clin cal judgment of the investigator to be eligible for		IN03A00		
1.d	4	Capable of giving perso this protocol	nal s	signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and i	n	IN04A00		
Inc	lusion Criteria Ent	ry						
	Inclusion Number: [Inclus on Number]		0000	2 3 4				
1.2	Criter on Descriptio							
1.3	Criter on met? [Criter on met?]		Ŏ	YES NO Describe details if relevant				
1.4	Criter on ID: (For P [Criter on ID: (For I		0	IN01A00 IN02A00 IN03A00 IN04A00				
Exc	lusion Criteria							
\vdash	Exclusion Numbe			Criterion Description		Criterion ID: (For Pfizer use only)		
2.a	1	Other medical or psychrisk of study participati		ic condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormality that may increase t	he	EX01A00		
2.b	2	Known infect on with h	numa	in immunodef ciency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00		
2.c	3	History of severe adversintervention(s)	erse r	reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the stud	/	EX03A00		
2.d	4	Receipt of medications	inte	ended to prevent COVID-19		EX04A00		
2.e	Stages 1 and 2 only: Previous clin cal or microb olog cal diagnosis of COVID-19 EX05A00				EX05A00			
2.f	6	Sentinel participants in	n Sta	ge 1 only: Indiv duals at high risk for severe COVID-19 (full details in protocol)		EX06A01		
2.g	7	Sentinel participants in worker, emergency res		ge 1 only: Indiv duals currently working in occupat ons with high risk of exposure to SARS-CoV-2 (eg, healthcare se personnel)		EX07A00		
2.h	8	Immunocompromised examination	indiv	viduals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical		EX08A00		
2.i	9	Indiv duals with a histo	ory o	f autoimmune disease or an active autoimmune disease requiring therapeut c intervention		EX09A00		
2.j	10	Bleeding diathesis or co	condi	tion associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscula	ır	EX10A00		
2.k	11	11 Women who are pregnant or breastfeeding EX11A00						

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EX12A00

2.m	13	Subjects who receive immunosuppressive therapy, such as cytotox c agents or system c corticosteroids EX13A01					
2.n	14	Sentinel participants in	Stage 1 only: Regular receipt of inhaled/nebulized cort costeroids		EX22A01		
2.0	15	Receipt of blood/plasm study	a products or immunoglobulin, from 60 days before study intervent on administration or planned receipt throughout the		EX14A01		
2.p	16	Participation in other s	cudies involving study intervention within 28 days prior to study entry and/or during study participat on		EX15A01		
2.q	17	Prev ous participation i	n other studies involving study intervention containing lipid nanoparticles		EX16A01		
2.r	18	Sentinel participants in	Stage 1 only: Pos tive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01		
2.s	19		Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormal ty. Except Bilirubin, other stable nay be considered eligible by Investigator		EX18A01		
2.t	20		Stage 1 only: Pos tive test for HIV, hepat tis B surface antigen (HBsAg), hepat tis B core antibodies (HBc Abs), or dies (HCV Abs) at screening vis t		EX19A01		
2.u	21	Sentinel participants in	Stage 1 only: SARS-CoV-2 NAAT-pos tive nasal swab w thin 24 hours before receipt of study intervent on		EX20A01		
2.v	22	Investigator site staff of their respective family	r Pfizer employees directly involved in the conduct of the study, s te staff otherwise supervised by the investigator, and members		EX21A01		
Exc	lusion Criteria Entr	у					
2.1	Exclusion Number: [Exclusion Number]						
2.2	Criter on Description [Criter on Description						
2.3	Criter on met? [Criter on met?]		O YES Describe details if relevant NO				
2.4 Criter on ID: (For Pfizer use only) [Criter on ID: (For Pfizer use only)]							

C	C4591001: CASEBOOK SIGNATURE FORM (INVSIG)					
C	Casebook Signature Form					
1	. Casebook Signature [Casebook Signature]	Click Here to Enable				

C4	C4591001: CENTRAL LAB SAMPLE COLLECTION (LAB)							
Cer	Central Lab Sample Collection							
	Collect on Date: [Collection Date:]							
	Specimen Type: [Specimen Type]	BLOOD						
Lab	Test							
#	Category for Lab Test	Subcategory for Lab Test	Lab Sub-Panel Collected					
3.a	CLINICAL CHEMISTRY	BLOOD CHEMISTRY						
3.b	HEMATOLOGY	DIFFERENTIAL						
Lat	Test Entry							
3.1	Lab Panel: [Category for Lab Test]	○ HEMATOLOGY○ CLINICAL CHEMISTRY						
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	O DIFFERENTIAL O BLOOD CHEMISTRY						
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	YES NO						

C4	C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)							
Cer	Central Lab Sample Collection							
	Collect on Date: [Collection Date:]							
	Specimen Type: [Specimen Type]	BLOOD						
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						
Lat	Test Entry							
3.1	Lab Panel: [Category for Lab Test]	O HEMATOLOGY O CLINICAL CHEMISTRY						
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	○ DIFFERENTIAL ○ BLOOD CHEMISTRY ○ VIROLOGY						
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	○ YES ○ NO						

Category for Lab Test	Vendor Name	Collection Date:		Specimen Type	Lab Result	
ab Chemistry Details			-		'	
. Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY					
. Laboratory Name and Address [Vendor Name]						
. Collect on Date: [Collection Date:]						
. Specimen Type: [Specimen Type]	OBLOOD					
ab Result						
# Sponsor-Defined Identifier	Test	:	Result:	Not Done:	Lab Normal Range	
.a	C Reactive Protein_PX329					
.b	Alanine Aminotransferase_PX30					
.c	Aspartate Aminotransferase_PX28					
.d	Alkaline Phosphatase_PX35					
.e	Bilirubin_PX21					
.f	Blood Urea Nitrogen_PX47					
.g	Creatinine_PX48					
ab Result Entry				·		
.1 Sponsor ID: [Sponsor-Defined Identifier]						
.2 Test: [Test:]	✓					
.3 Result: [Result:]						
.4 Not Done: [Not Done:]	O NOT DONE	○ NOT DONE				
.5 LNMT [Lab Normal Range]	Low	Low				
	High					
	Unit					

Category for Lab Test	Vendor Name	Collection Date	Collection Date:		/pe	Lab Result
b Chemistry Details						
Lab Panel: [Category for Lab Test]	CLINICAL CHEMISTRY	OCLINICAL CHEMISTRY				
Laboratory Name and Address [Vendor Name]						
Collect on Date: [Collection Date:]						
Specimen Type: [Specimen Type]	BLOOD					
b Result						
Sponsor-Defined Identifier		Test:	Result:	Not Done:	Lab Normal	Range
	C Reactive Protein_PX329					
b Result Entry						
Sponsor ID: [Sponsor-Defined Identifier]						
Prest: [Test:]	C Reactive Protein_PX329					
Result:						
Not Done: [hidden] [Not Done:]	O NOT DONE	O NOT DONE				
LNMT [Lab Normal Range]	Low					
	High					
	Unit					

C4 :	4591001: LOCAL LABORATORY DATA - REPEATING Hematology (LAB HEM) - Repeating Form							
#	Category for Lab Test	V	endor Name (DERIVED)	Collection Date:	Spe	ecimen Type	Lab Result	
1								
Lab	oratory Data Hematology							
1. L	ab Panel: Category for Lab Test]	OHE	HEMATOLOGY					
2. L	.aboratory Name and Address Vendor Name (DERIVED)]							
	Collect on Date: Collection Date:]							
4. 5	Specimen Type: Specimen Type]	OBL	OOD					
Lab	Result							
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:	Lab N	Normal Range	
5.a			Hemoglobin_PX1					
5.b			Hematocrit_PX2					
5.c			Erythrocytes_PX3					
5.d			Platelets_PX5					
5.e			Leukocytes_PX7					
5.f			Neutrophils_PX608					
5.g			Eosinophils_PX609					
5.h			Monocytes_PX612					
5.i			Basophils_PX610					
5.j			Lymphocytes_PX611					
Lab	Result Entry							
5.1	Sponsor ID: [Sponsor-Defined Identifier]							
5.2	Test: [Test:]		v					
5.3	Result: [Result:]							
5.4	Not Done: [Not Done:]	○ N	O NOT DONE					
5.5	LNMT [Lab Normal Range]	Range] Low						
		High						
		Unit	v					

C 4	C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)						
Lal	b Urinalysis						
1.	Lab Panel: [Category for Lab Test]	OURINALYS	OURINALYSIS				
2.	Lab Sub-Panel: [Subcategory for Lab Test]	O PREGNANC	CY				
3.	Collect on Date: [Collection Date:]						
	Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]						
5.	Specimen Type: [Specimen Type]	OURINE					
Lal	Result						
#	Sponsor-Defined Identifier		Test:	Result:	Not Done:		
6.a			Choriogonadotropin Beta_PX113				
Lal	Result Entry						
6.1	Sponsor ID: [Sponsor-Defined Identifier]						
6.2	Test: [Test:]	○ Chor ogonadotropin Beta_PX113					
6.3	Result: [Result:]	○ NEGATIVE ○ POSITIVE					
6.4	Not Done: [Not Done:]	O NOT DON	E				

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C45	4591001: MEDICATION ERROR (MED ERROR) - Repeating Form									
	tegory	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	Serious Adverse Event Number
1										
_	ication I Category		O MED	DICATION ERROR						
1.	[Category	y]	OMED	JICATION LIKKOK						
	of Med ca	on Error (Type ation Error):								
	error, re- incorrect number dispense to the su	a dispensing cord the container that was definitional definition of the container that was defined abject: [hidden] of package ID]								
	Start Da [Start Da		~	/						
	still ongo	ned cation error	LIIU	Date: / /						
	with Stu	ction Taken dy Treatment: ledication ction]	_	ACTION TAKEN MANENTLY DISCONTINUED						
	Medicat of [Concom	oncomitant on given? n tant on Given]	O YES O NO							
		on-Drug nt given? ug Treatment	O YES O NO							
	cause th		YES							
	error ass any adve	medicat on sociated with erse events?	YES AE I							
		ed With AE]	AE I	D:						
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11.	Serious /	Adverse Event								

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	Number: For Pfizer Use Only [Serious Adverse Event Number]	
12.	Comparison Term [hidden] [Comparison Term]	
13.	Lowest Level Term [hidden] [Lowest Level Term]	
14.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	
	Dict onary-Derived Term [hidden] [Dict onary-Derived Term]	
	Preferred Term Code [hidden] [Preferred Term Code]	
	High Level Term [hidden] [High Level Term]	
	High Level Term Code [hidden] [High Level Term Code]	
	High Level Group Term [hidden] [High Level Group Term]	
	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 Nւ	ımber	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]								
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	D ctionary Derived Term [hidden] [D ctionary Derived Term]								
1.9	Preferred Term Code [hidden] [Preferred Term Code]								
1.10	High Level Term [hidden] [High Level Term]								
	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 Assessmen	nt	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)					
1									
О	xygenation Parameters								
1.	Date Time of Assessment: [Date Time of Assessment]		-hour clock						
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]								
3.	FiO2 (Fract on of Inhaled Oxygen): [FiO2 (Fract on of Inhaled Oxygen)]								

C4591001: PHYSICAL EXAMINATION (PHYS EXAM)			
Physical Examination			
	Exam Date: [Exam Date]		
Physical Examination Result			
#		Body System Examined	Result
-	GENERAL APPEARANCE		
_	SKIN		
-	HEAD		
	EYES		
_	EARS		
_	NOSE		
_	THROAT		
-	HEART		
2.i			
2.j			
2.k	MUSCULOSKELETAL		
2.1	EXTREMITIES		
_	NEUROLOGICAL		
2.n	LYMPH NODES		
Physical Examination Result Entry			
2.1	Body System Examined: [Body System Examined]		
2.2	Result: [Result]	NORMAL ABNORMAL If abnormal findings, specify: (If clin cally signif cant, record on the Medical History or Adverse Event CRF as appropriate). Are there clinically significant findings? YES NO NOT DONE	

C	4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19)						
Ele	ectronic Sample Tracking	tronic 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 prov de reason: [Reason sample not collected]						
		Sample ID					
5.							
AI	Aliquot Entry						
Ple	ease enter barcode for each aliquot.						
5.	Sample ID [Sample ID]						

C	C4591001: CONCOMITANT MEDICATIONS - PROHIBITED (PROHIB CM) - Repeating Form											
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing		
1												
Co	ncomitant Medications											
1.	What is the med cation dentifi [Sponsor-Defined Identifier]	er?										
2.	2. Category: [Category for Medication]		○ CONCOMITANT IMMUNOSUPPRESSIVE T ○ CORTICOSTEROIDS ○ IMMUNOGLOBULINS									
3.	Concomitant Med cat ons Pre-s [Concom tant Medicat ons Pre-		○ NO									
4.	Medicat on:											
	Provide the complete gener c drug name (including salt form, where applicable). Where gener c name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]		e									
5.	Dose: [Dose Description]											
6.	Dose Unit: [Dose Unit]											
7.	Dose Frequency: [Dose Frequency]											
8.	Route: [Route]											
9.	Start Date: [Start Date]											
10	10. Ongoing? [Ongoing]		YES NO End Date:									
11	11. Comparison Term [hidden] [Comparison Term]											
12	Standardized Medication Name [Standardized Medication Name											
13	Standardized Medication Code [Standardized Medication Code											

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C4	591001: RAI	DIATION TREATMENT (PROH	IB ND) - Repeating Form								
#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?					
1											
Ra	diation Treatmen	t									
1.	Category: [Category]		O RADIATION THERAPY	RADIATION THERAPY							
2.	What is the treati [Treatment Ident										
3.	Concomitant Non [Con Non-Drug T	-drug Treatment Pre-specified: reatments Pre-specified]	YES								
4.	Treatment: [Treatment]										
5.	Start Date: [Start Date]										
6.	Ongoing? [Ongoing?]										
7.	7. Comparison Term [hidden] [Comparison Term]										
8.	Lowest Level Terr [Lowest Level Ter										
9.	Lowest Level Terr [Lowest Level Ter										
10.	Dict onary Derive [Dict onary Derive	d Term [hidden] ed Term]									
11.	Preferred Term C [Preferred Term C	ode [hidden] Code]									
12.	High Level Term (High Level Term										
13.	High Level Term	Code <i>[hidden]</i> Code]									
14.	14. High Level Group Term [hidden] [High Level Group Term]										
15.	High Level Group [High Level Group	Term Code [hidden] Term Code]									
16.	16. Primary System Organ Class [hidden] [Primary System Organ Class]										
17.	Primary System ([Primary System	Organ Class Code [hidden] Organ Class Code]									

C	4591001: VITAL SIGNS - PULSE	OX ROOM AIR (PULSE OX) - Repeating Fo	rm			
#	Date:		Vital Signs Details			
1						
Vit	tal Signs					
	. Date: [Date:]					
Vit	Vital Signs Details					
#		Record Identifier:	Oxygen Saturation			
_						
2.8	a 1					
Vit	tal Signs Details Entry					
2.1	Record Identifier: [Record Identifier:]	O 1				
2.2	SPO2 Pulse Oximetry % [Oxygen Saturat on]					

С	24591001: RANDOMIZATION (RAND)				
Di	sposition				
	Randomizat on Date: [Randomizat on Date:]				
	Randomizat on Number: [Randomizat on Number]				
3.	Randomizat on Group: [Randomizat on Group]				

	C4591001: REACTOGENICITY DIARY (REAC DIARY)		
ı	Reactogenicity Diary		
1	Select appropriate response - Reactogen c ty diary collection [Trigger Response 9]	○ YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT ○ NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	

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C4591001: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT (REACTION)					
Unplanned Assessment Of Local Reaction					
1. CISR Category [hidden] [CISR Category]	OUNPLANNED ASSESSMENT OF LOC	CAL REACTION/SYSTEMIC EVENT			
2. Date of Assessment: [Date of Assessment]					
3. Inject on S te Location [Inject on S te Locat on]	O DELTOID MUSCLE	TOID MUSCLE			
4. Inject on Site Body Side: [Inject on S te Body Side]					
Reaction					
# Reacti	Reaction: Reaction Present:				
5.a REDNESS					
5.b SWELLING					
Reaction Entry					
5.1 React on: [Reaction:]	○ REDNESS ○ SWELLING				
5.2 React on Present: [Reaction Present:]	YES Maximum Diameter (cm): Minimum Diameter (cm): Meets Grade 4 Reaction Criteria: YES NO NO				
Symptom					
#	Symptom:		Symptom Present:		
6.a PAIN AT INJECTION SITE					
6.b FATIGUE/TIREDNESS					
6.c HEADACHE					
6.d VOMITING					
6.e DIARRHEA					
6.f NEW OR WORSENED MUSCLE PAIN					
6.g NEW OR WORSENED JOINT PAIN					
6.h CHILLS					
Symptom Entry					
6.1 Symptom: [Symptom:]					
6.2 Symptom Present: [Symptom Present:] YES Symptom Grade: 1 2 3 4 Event related to Study Treament? YES					

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O NO O NO

C4	4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form										
#	Treatment Identifier		Con Non-Drug Tre	eatments Pre-specifi	ed	Treatment	Treatment	Start Date	Ongoing?		
1											
Re	spiratory Treatment										
1.	What is the treatment Identifier? [Treatment Identifier]										
2.	Concomitant Non-drug Treatment Pre-spec [Con Non-Drug Treatments Pre-specified]	cified:	YES								
3.	B. Treatment: [Treatment]		 ○ INTUBATION ○ NON-INVASIVE POSITIVE PRESSURE VENTILATION ○ CPAP ○ OXYGEN THERAPY 								
4.	Treatment: [Treatment]										
5.	Start Date: [Start Date]		<u> </u> <u> </u> / <u> </u> /	/ <u>•</u>							
6.	6. Ongoing? [Ongoing?]		YES NO End Date:	V / V							
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.	Dict onary Derived Term [hidden] [Dict onary Derived Term]										
11.	Preferred Term Code [hidden] [Preferred Term Code]										
12.	High Level Term [hidden] [High Level Term]										
13.	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 [hidden [Primary System Organ Class Code]]									

C4	4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form							
#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?		
1								
Res	spiratory Treatment							
1.	What is the treatment Identifier? [Treatment Identifier]							
2.	Concomitant Non-drug Treatment Pre-specifie [Con Non-Drug Treatments Pre-specified]	d: OYES						
3.	Treatment: [Treatment]	 ○ NON-INVASIVE POSITIVE PRESSURE VENTILATION ○ CPAP ○ MECHANICAL VENTILATION ○ EXTRACORPOREAL MEMBRANE OXYGENATION ○ HIGH FLOW OXYGEN THERAPY 	○ CPAP ○ MECHANICAL VENTILATION ○ EXTRACORPOREAL MEMBRANE OXYGENATION					
4.	Treatment: [Treatment]							
5.	Start Date: [Start Date]							
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.	Dict onary Derived Term [hidden] [Dict onary 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 [hidden] [Primary System Organ Class Code]							

(C4591001: FURTHER VACCINATION CONFIRMATION (REVAX CONF)				
F	Further Vaccination Confirmation				
1	. Select appropriate response - Is part cipant willing to return for Vaccination 3? [Trigger Response 1]	Participant is willing to return for Vaccination 3 Participant is: eligible per local/nat onal recommendat ons and confirmed to have received only placebo at Vaccination 1/2 eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccinat on 1/2 eligible and NOT confirmed to have received only placebo at Vaccination 1/2 Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible			

•	C4591001: INFORMED CONSENT - FURTHER VACCINATION (REVAX CONS)		
1	Informed Consent - Further Vaccination		
-	L. Consent Was:	OBTAINED	
	[Consent Was:]	Date Written Consent Obtained	

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C4	C4591001: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION (REVAX IE)		
		Criterion Description	
1.			
Inc	clusion Criteria Not Met Entry		
1.1	Description of Inclus on Cr terion Not Met [Criter on Description]		
		Criterion Description	
2.			
Ex	Exclusion Criteria Met Entry		
2.1	Description of Exclusion Cr terion Met [Criter on Description]		

C	C4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB)		
EI	ectronic 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 prov de reason: [Reason sample not collected]		
		Sample ID	
5.			
Al	Aliquot Entry		
PI	Please enter barcode for each aliquot.		
5.	1 Sample ID [Sample ID]		

С	C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK)		
EI	ectronic 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 prov de reason: [Reason sample not collected]		
		Sample ID	
5.			
A	Aliquot Entry		
PI	Please enter barcode for each aliquot.		
5.	1 Sample ID [Sample ID]		

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

C	C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB)		
-	Electronic Sample Tracking		
	Data Origin [Data Origin]	OSITE	
2.	Sample Type [Sample Type]	O NASAL_SWAB_SELF	
3.	Sample Collected? [Sample Collected]	NO YES Date of Collect on: V / V / V	
4.	If no sample was collected or sample was not collected according to protocol, please prov de reason: [Reason sample not collected]		
		Sample ID	
5.			
Al	Aliquot Entry		
PI	Please enter barcode for each aliquot.		
5.	1 Sample ID [Sample ID]		

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C4	C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)				
Sig	Signs and Symptoms				
	Date of Assessment: [Date of assessment]				
2.	Date of First Symptom Started: [First Symptom Started Date]				
3.	Symptoms Ongoing? [Symptoms Ongoing]	○ YES ○ NO Date of Last Symptom Resolved: ▼ / ▼ / ▼			
Syr	nptoms				
#	Event Pre-specified	Symptoms	Symptom Present		
-	YES	FEVER			
4.b	YES	NEW OR INCREASED COUGH			
4.c	YES	NEW OR INCREASED SHORTNESS OF BREATH			
4.d	YES	CHILLS			
4.e	YES	NEW OR INCREASED MUSCLE PAIN			
4.f	YES	NEW LOSS OF TASTE OR SMELL			
4.g	YES	NEW OR INCREASED SORE THROAT			
4.h	YES	DIARRHEA			
4.i	YES	VOMITING			
Syı	nptoms Entry				
4.1	Event Pre-specified: [hidden] [Event Pre-specified]	○ YES			
4.2	Symptoms: [Symptoms]				
4.3	Was symptom present? [Symptom Present]	○ YES ○ NO			
		Symptoms - Other			
5.					
<u></u>					
	nptoms - Other Entry				
5.1	Symptoms - Other Text: [Symptoms - Other]				
5.2	Comparison Term: [hidden] [Comparison Term]				
5.3	Lowest Level Term [hidden] [Lowest Level Term]				
5.4	[Lowest Level Term Code]				
5.5	D ctionary Derived Term [hidden] [D ctionary Derived Term]				

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5.6	Preferred Term Code [hidden] [Preferred Term Code]	
	High Level Term [hidden] [High Level Term]	
5.8	High Level Term Code [hidden] [High Level Term Code]	
	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]	
5.12	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	

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C4	C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)		
Signs and Symptoms			
	Date of Assessment: [Date of assessment]		
2.	Date of First Symptom Started: [First Symptom Started Date]		
3.	Symptoms Ongoing? Symptoms Ongoing]	○ YES ○ NO Date of Last Symptom Resolved: ▼ / ▼ / ▼	
Syr	nptoms		
#	Event Pre-specified	Symptoms Symptom Present	
4.a	YES	FEVER	
4.b	YES	LOSS OF TASTE/SMELL	
4.c	YES	NEW OR INCREASED COUGH	
4.d	YES	NEW OR INCREASED NASAL CONGESTION	
4.e	YES	NEW OR INCREASED NASAL DISCHARGE	
4.f	YES	NEW OR INCREASED SHORTNESS OF BREATH	
4.g	YES	NEW OR INCREASED SORE THROAT	
4.h	YES	NEW OR INCREASED SPUTUM PRODUCTION	
4.i	YES	NEW OR INCREASED WHEEZING	
Syı	nptoms Entry		
4.1	Event Pre-specified: [hidden] [Event Pre-specified]	○YES	
4.2	Symptoms: [Symptoms]		
4.3	Was symptom present? [Symptom Present]	○ YES ○ NO	
		Symptoms - Other	
5. ✓			
Syı	nptoms - Other Entry		
5.1	Symptoms - Other Text: [Symptoms - Other]		
5.2	Comparison Term: [hidden] [Comparison Term]		
5.3	Lowest Level Term [hidden] [Lowest Level Term]		
5.4	Lowest Level Term Code [hidden] [Lowest Level Term Code]		
5.5	D ctionary Derived Term [hidden] [D ctionary Derived Term]		

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5.6	Preferred Term Code [hidden] [Preferred Term Code]	
	High Level Term [hidden] [High Level Term]	
5.8	High Level Term Code [hidden] [High Level Term Code]	
	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]	
5.12	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	

C	4591001: STRATIFICATION (STRAT)			
S	ratification			
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	Non-Sentinel Stage 1		
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	△ Age 18 to 55 △ Age 65 to 85		
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	○ 10 mcg ○ 20 mcg ○ 30 mcg		
4.	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	0 21 Day 0 60 Day		
5.	Select appropriate response - BNT Number [Trigger Response 7]	○ (BNT162b1 or PBO) ○ (BNT162b2 or PBO) ○ (BNT162b3 or PBO)		

C	4591001: STRATIFICATION (STRAT)			
S	tratification			
1.	Select appropriate response - Randomizat on Stage [Trigger Response 3]	Stage 2		
2.	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	△ Age 18 to 55 △ Age 56 to 85		
3.	Select appropriate response - Randomizat on Dose [Trigger Response 5]	○ 10 mcg ○ 20 mcg ○ 30 mcg		
4.	Select appropriate response - BNT Number [Trigger Response 7]	○ (BNT162b1 or PBO) ○ (BNT162b2 or PBO) ○ (BNT162b3 or PBO)		

C	C4591001: STRATIFICATION (STRAT)			
Stratification				
1	Select appropriate response - Randomizat on Stage [Trigger Response 3]	Stage 1 Stage 2		
2	Select appropriate response - Randomizat on Age Group [Trigger Response 4]	Age 18 to 55Age 56 to 85Age 65 to 85		
3	Select appropriate response - Randomizat on Dose [Trigger Response 5]	 Low dose level (3mcg) Medium dose level (10mcg) High dose level (30mcg) Low dose level (30mcg) Medium dose level (30mcg) High dose level (100mcg) Low dose level (0.1mcg) Medium dose level (0.3mcg) High dose level (1mcg) Migh dose level (50mcg) Migh-High dose level (50mcg) Low-M d dose level (20mcg) 		
4	Select appropriate response - Randomizat on Dose Group [hidden] [Trigger Response 6]	21 Day 2-dose group 60 Day 2-dose group 1-dose group		
5	Select appropriate response - Randomizat on Dose Group [Trigger Response 8]	021 Day 060 Day		
6	Select appropriate response - BNT Number [Trigger Response 7]	○ (BNT162a1 or PBO) ○ (BNT162b1 or PBO) ○ (BNT162b2 or PBO) ○ (BNT162c2 or PBO) ○ (BNT162b3 or PBO)		

С	C4591001: SUBJECT STATUS (SUB STATU)			
Sı	Subject Status			
1.	Subject Status [Subject Status]			
2.	Subject Status Date [Status Date]			

	C4591001: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE (SURV CONS)		
1	Informed Consent - Asymptomatic Surveillance		
-	. Consent Was:	OBTAINED	
	[Consent Was:]	Date Written Consent Obtained	

C	C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE)				
Ele	ctronic Sample Tracking				
1.	Data Origin [Data Origin]	SITE			
2.	Sample Type [Sample Type]	NASAL_SWAB			
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 prov de reason: [Reason sample not collected]				
		Sample ID			
5.					
Al	Aliquot Entry				
Ple	ease enter barcode for each aliquot.				
5.	Sample ID [Sample ID]				

С	C4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form								
#	Date of Collection	Specimen Type	e	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:
1									
М	icrobiology Specimen								
1.	Actual Date of Collect on: [Date of Collect on]		~ /						
2.	Specimen Type: [Specimen Type]	0	SWAB	BED MATERIAL					
3.	Specimen Collect on Location [Specimen Collection Location		NASAL	_ CAVITY					
4.	Assay Code and Description: [Assay Code and Description]		SEVER	RE ACUTE RESP SYNDROME CORONAVIRUS 2					
5.	Dev ce Type: [Dev ce Type]	0	SARS-	COV-2 DIAGNOSTIC TEST					
6.	Trade Name: [Trade Name]	0	CEPHE	EID XPERT XPRESS SARS-COV-2 TEST					
7.	Test Result: [Result]	ŏ	POSIT NEGAT INDET						
8.	Comments/Findings/Details: [Comments:]								

C	C4591001: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE)					
Va	accination Symptoms Diary - Symptom Resolved 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]					
#		Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
2.8	FEVER					
2.t	FATIGUE					
2.0	HEADACHE					
2.0	CHILLS					
2.6	VOMITING					
2.f	DIARRHEA					
2.9	NEW OR WORSENED MUSCLE PAIN					
2.1	NEW OR WORSENED JOINT PAIN					
2.:	Symptom: [Symptom:]					
2.2	Were fever or systemic symptoms present on the last day the Subject Diary was completed? [Were fever or systemic symptoms present on the last day the Subject Diary was completed?]					
3.	Inject on S te Location: [Inject on S te Locat on:]	O DELTOID MUSCLE				
4.	Inject on Site Body Side: [Inject on S te Body Side:]	○LEFT ○RIGHT				
#	-	Were injection site reactions present on the last day the Subject Diary was completed?				
\vdash	REDNESS					
\vdash	SWELLING					
\vdash	PAIN AT INJECTION SITE					
5.:	I Injection Site Reaction: [Injection Site Reaction:]	REDNESSSWELLINGPAIN AT INJECTION SITE				
5.2	Were injection site 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 Ongoing? YES NO Stop Date: NO NO NO				

C4591001: TRANSFUSI	ONS (TRANSFUSE) - Repeating Form	
#	Transfusion Type	Date of Transfusion
1		
1. Transfusion Type: [Transfusion Type]	PACKED RBC PLATELETS WHOLE BLOOD PLASMA OTHER Specify:	
2. Date of Transfusion: [Date of Transfus on]		

C4591001: TREATMENT UNBLINDED (TRN UNBLN)			
Freatment Unblinded			
1. Date Treatment Unblinded : [Date Treatment Unblinded :]			
2. Primary Reason for Unblinding: [Primary Reason for Unblinding]	OSUBJECT SAFETY CONCERN OTHER If other, specify: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION		

C4591001: UNPLANNED VISIT (UNPL)			
Unplanned Assessments			
1.	Assessments [Assessments]	CONTACT OUTCOME	

C 4	591001: VACCI	NATION (VACIN TRT)		
Va	/accination			
1.	Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	O YES Date of First Delay: O Y O O O O O O O O O O O O O O O O O		
2.	Treatment Name [Treatment Name]			
3.	Formulat on: [Formulat on:]	○ INJECTION		
4.	Dose Date Time: [Dose Date Time:]			
5.	Anatomical Locat on: [Anatom cal Location:]	O DELTOID MUSCLE		
6.	Body S de: [Body S de:]	○LEFT ○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:]	○ ug		
12.	Was the Actual Dose adjusted from planned? [Dose Adjusted From Planned]	YES What was the reason the dose was adjusted? ADVERSE EVENT(S) INSUFFICIENT CLINICAL RESPONSE OTHER SPECIFY If other, specify:		
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	○ YES ○ NO If No, specify reason:		

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	administration? [Observed Post Dose For Specified Time]	
15.	Comparison Term [hidden] [Comparison Term]	
16.	Standardized Medicat on Name - Dict onary Derived. [hidden] [Standardized Medicat on Name]	
17.	Standardized Medicat on Code - Dict onary Derived [hidden] [Standardized Medicat on Code]	

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C4	C4591001: VACCINATION (VACIN TRT)				
Vaccination					
1.	Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	O YES Date of First Delay: O V O V O V O V O V O V O V O V O V O			
2.	Treatment Name [Treatment Name]				
3.	Formulat on: [Formulat on:]	O INJECTION			
4.	Dose Date Time: [Dose Date Time:]				
5.	Anatomical Locat on: [Anatom cal Location:]	O DELTOID MUSCLE			
6.	Body S de: [Body S de:]	○LEFT ○RIGHT			
7.	Route: [Route:]	○ INTRAMUSCULAR			
8.	Container Number: [hidden] [PAC / Kit Number:]				
9.	Actual Dose: [Actual Dose:]				
10.	Unit: [Unit:]	mL ug			
11.	Timeframe Subject Was Observed [Timeframe Subject Was Observed]	○ THE PROTOCOL SPECIFIED OBSERVATION PERIOD ○ 30 MINUTES			
12.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	○ YES ○ NO If No, specify reason:			
13.	Comparison Term [hidden] [Comparison Term]				
14.	Standardized				

С	4591001: CONCOMITANT MEDI	CATIONS - VA	ASOPRESSORS	(VASOPRESS) - R	epeating Form						
#	Sponsor-Defined Identifier	Category fo	or Medication	Concomitan	Medications Pre-specified	Name o	f Medication	Start Date	Ongoing		
1											
C	oncomitant Medications										
1.	What is the med cation dentifier? [Sponsor-Defined Identifier]										
2.	Category: [Category for Medication]		GENERAL CONCO	DMITANT MEDICATIONS							
3.	Concomitant Medications Pre-specified: [Concom tant Medicat ons Pre-specified]		ONO								
4.	Medicat on: Provide the complete gener c drug name (incl where applicable). Where gener c name is uni full trade or proprietary name. Include clarify the Med cation text (e.g., Ingredient(s), route formulation). [Name of Medication]	known, enter the ing information in									
5.	Start Date: [Start Date]										
6.	Ongoing? [Ongoing]		YES NO End Date:	/							
7.	Comparison Term [hidden] [Comparison Term]										
8.	Standardized Medication Name - D ctionary de [Standardized Medication Name]	erived. [hidden]									
9.	Standardized Medication Code - Dictionary de [Standardized Medication Code]	rived [hidden]									

C4	4591001: VITAL SIGNS - TEMP (VITAL TEMP)									
Vit	al Signs									
	Date: [Date:]	<u>~</u> /	<u> </u>							
Vit	al Signs Details									
#	Record Identifier:		Temperature	Temperature Unit	Temperature Location:					
2.a	1									
Vit	al Signs Details Entry									
2.1	Record Identifier: [Record Identifier:]	01								
2.2	Temperature: [Temperature]									
2.3	Un t: [Temperature Unit]	OF OC								
2.4	Temperature Location: [Temperature Locat on:]	ORAL CENTRE OF CORRECTED OF COR	MI A							

C 4	C4591001: VITAL SIGNS - BASELINE (VITALS BSL)										
Vit	al Signs										
	Date: [Date:]	<u>•</u> /	<u> </u>								
2.	Weight: [Weight]										
3.	Unit: [Weight Unit]	○kg ○LB									
4.	Height: [Height]										
5.	Unit: Com										
6.	Body Mass Index: [Body Mass Index]										
	al Signs Details										
#			Temperature	Temperature Unit	Temperature Location:						
7.a	•										
Vit	al Signs Details Entry										
7.1	Record Identifier: [Record Identifier:]	O 1									
7.2	Temperature: [Temperature]										
7.3	Un t: [Temperature Unit]	rature Unit] OC F									
7.4	Temperature Location: [Temperature Locat on:]	ORAL CENTER OF CORRECTED AXILLA	M								

C4591001: VITAL SIGNS - BA	ASELINE (VITALS	BSL)								
Vital Signs										
1. Date: [Date:]	•/	V								
2. Weight: [Weight]										
3. Unit: [Weight Unit]	⊜kg ⊝LB									
4. Height: [Height]										
5. Unit: [Height Un t]	Unit:									
5. Body Mass Index: [Body Mass Index]										
Vital Signs Details										
# Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:			
7.a 1						SITTING				
Vital Signs Details Entry										
7.1 Record Identifier: [Record Identifier:]	O1									
7.2 Temperature: [Temperature]										
7.3 Un t: [Temperature Unit]	OC OF									
7.4 Temperature Location: [Temperature Locat on:]	ocation: ocation: ORAL CAVITY OCATION: ORAC CAVITY ORA									
7.5 Systolic: [Systolic:]										
7.6 Diastol c: [Diastolic:]										
7.7 BP Position: [BP Position]	SITTING									
7.8 Pulse:										

C4	4591001: VITAL SIGNS - COVID (VITALS COV) - Repeating Form											
#	Date:	_		Vital Signs Details								
1												
Vita	ıl Signs											
	Date: [Date:]		<u> </u>									
Vita	ıl Signs Details	•										
#	Record Identifier:	Systolic:	Diastolic:	Respiratory Rate in respirations/minute	Heart Rate in beats/minute							
2.a	1											
Vit	al Signs Details Entry											
2.1	Record Identifier: [Record Identifier:]	O 1										
2.2	Systolic: [Systolic:]											
2.3	Diastol c: [Diastolic:]											
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)										
Vit	al Signs									
1.	Date: [Date:]	•/	<u>~</u>							
Vit	Vital Signs Details									
#		Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position	Pulse:		
2.a	1						SITTING			
Vit	al Signs Details Entry									
2.1	Record Identifier: [Record Identifier:]	O1								
2.2	Temperature: [Temperature]									
2.3	Unt: [Temperature Unit]	O F O C								
2.4	Temperature Location: [Temperature Locat on:]	ORAL CAVITY EAR RECTUM AXILLA FOREHEAD								
2.5	Systolic: [Systolic:]									
2.6	Diastol c: [Diastolic:]									
2.7	BP Position: [BP Position]	SITTING								
2.8	Pulse: [Pulse:]									

C	4591001: WITHDRAWAL OF CONSENT (WOC)			
٧	/ithdrawal Of Consent			
1	. W thdrawal of Consent Date : [Withdrawal of Consent Date :]	~ /	~ /	/

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

Month	Ja	nuary	February	March	April	May	June	July	August	September	ŏ	ctober	Novembe	r December
Abbr.	Ja	n	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Ŏ	ct	Nov	Dec
Days		Mond	ay	Tuesday		Wedneso	day	Thur	sday	Friday		Satur	day	Sunday
Abbr. Mon			Tue		Wed		Thu		Fri		Sat		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:

26-OCT-2020 Version 4

[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 TrialMax App 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: [------

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

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:

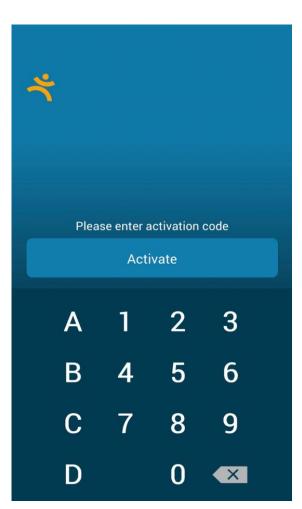
Please continue to complete the illness diary weekly or if you experience COVID-19 symptoms or have a COVID-19 diagnosis. Contact your study doctor with any suspected COVID-19 symptoms.

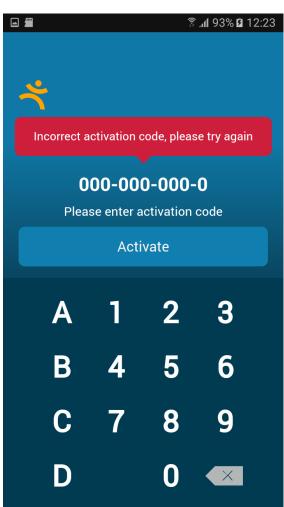
Email notification only: [-----

090177e195746b2f\Approved\Approved On: 06-Nov-2020 14:14 (GMT)

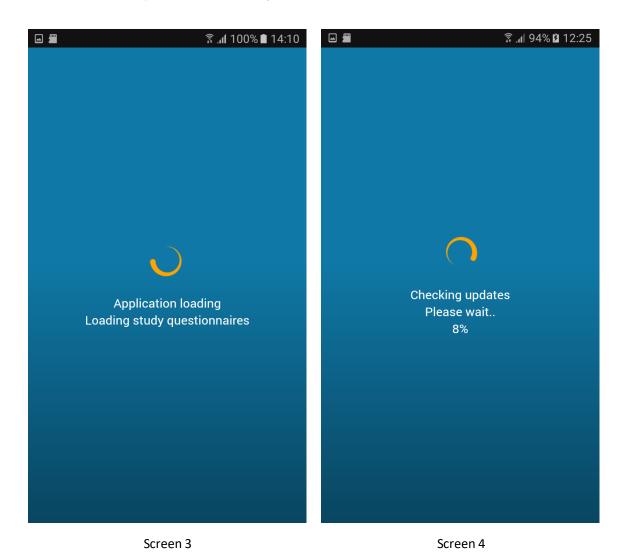
This is an automatic e-mail message sent by Signant Health, an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure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

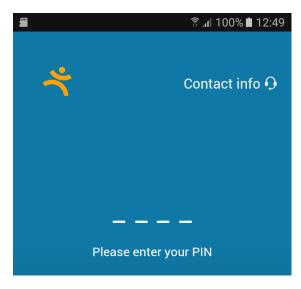
2 Common





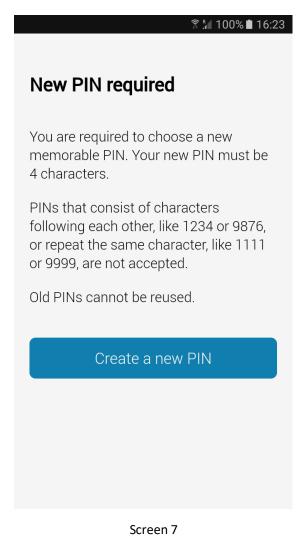
Screen 2 Screen 2

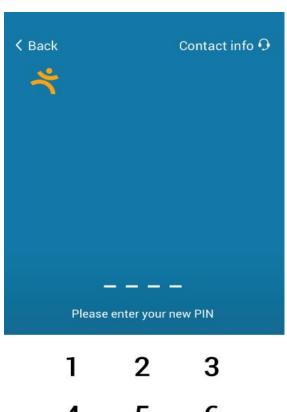






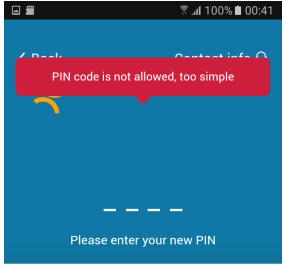
Screen 5 Screen 6



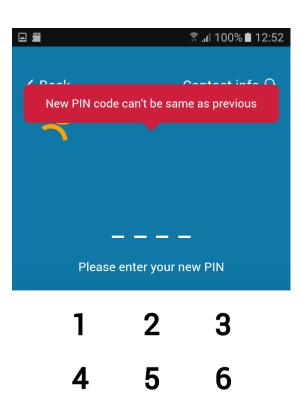


Screen 8

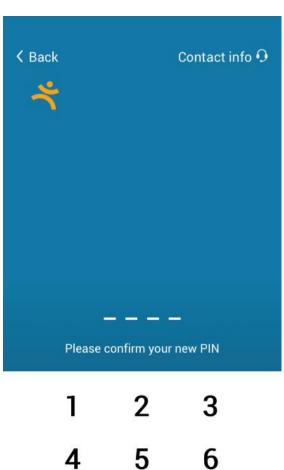




Screen 9 Screen 10



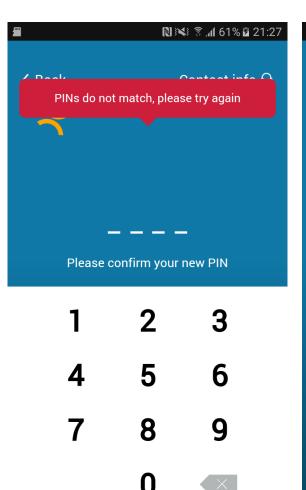
Screen 11



Screen 12

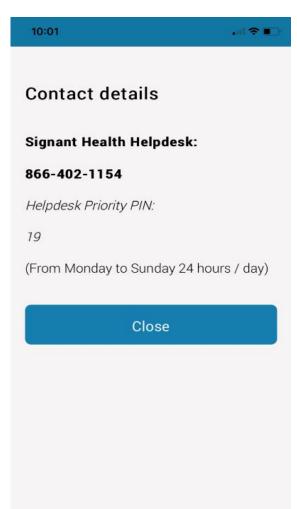
8

0



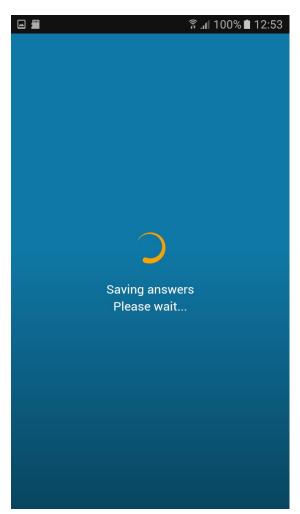


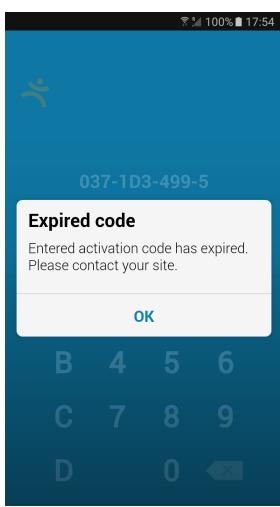
Screen 13 Screen 14



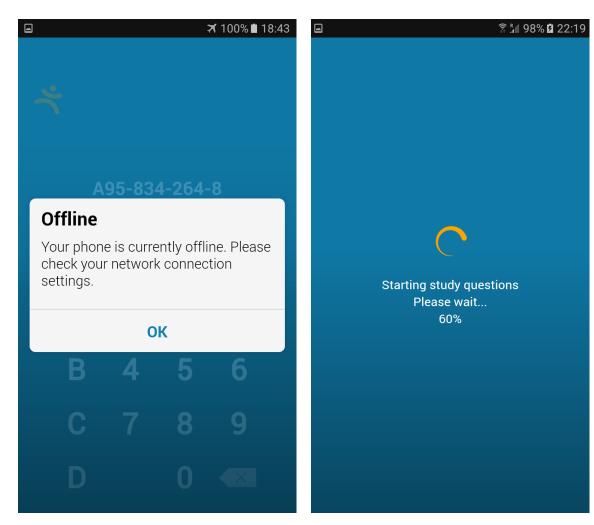


Screen 15 Screen 16

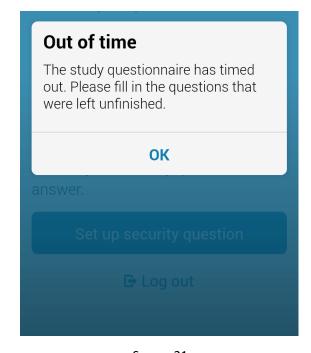




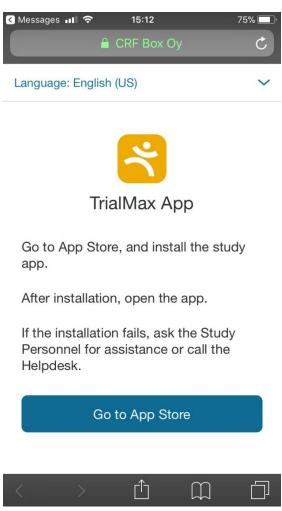
Screen 17 Screen 18



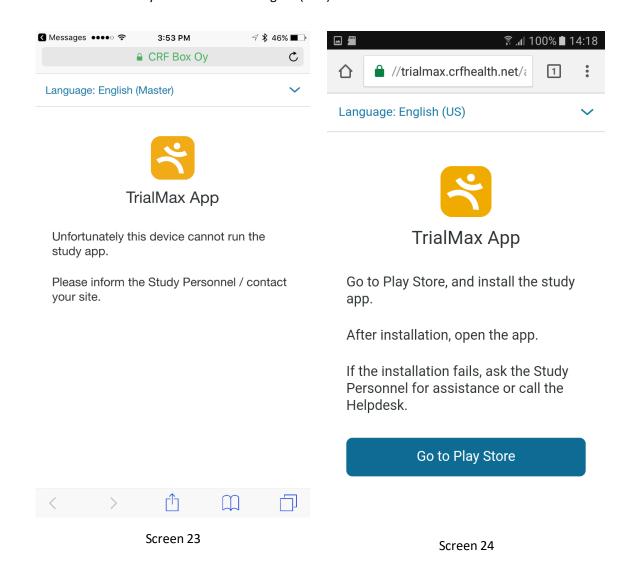
Screen 19 Screen 20

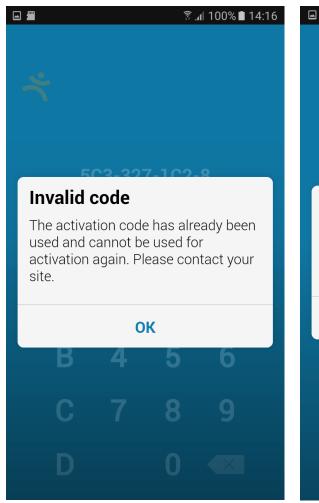


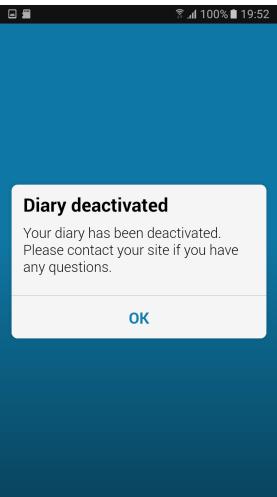
Screen 21



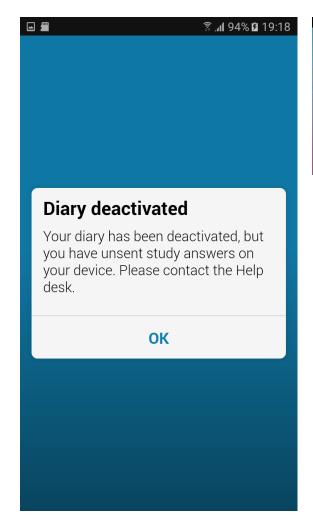
Screen 22







Screen 25 Screen 26



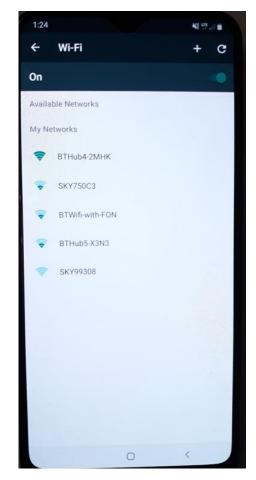


Screen 28

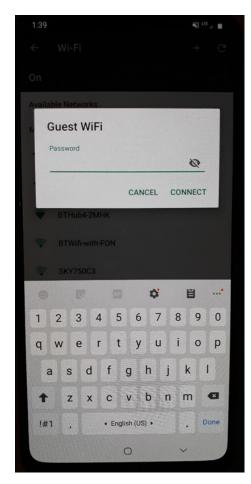
Screen 27



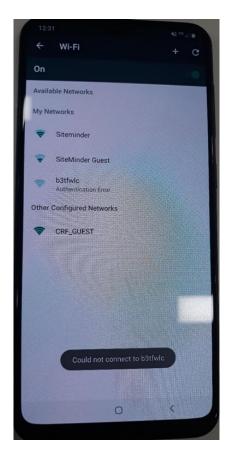
Screen 29



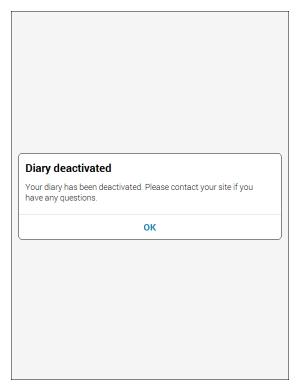
Screen 30



Screen 31



Screen 32



Message 1

Note: Other messages that could appear on the device include:

'Invalid PIN'

'Installing study questions'

'Securing study questions'

'Unsent answers'

'There are a lot of unsent study answers. Please make sure your device is connected to the Internet.'

'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.'

'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.'

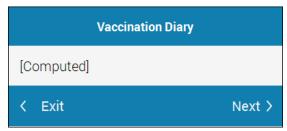
'Low storage space'

'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





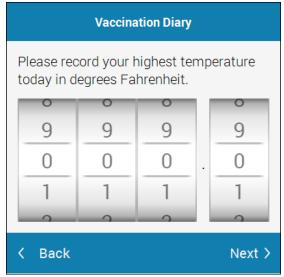
Screen 1

Message 1

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

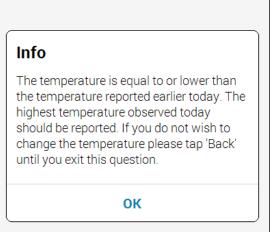
- {1} Will display a date
- {2} Will display a number of days.

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



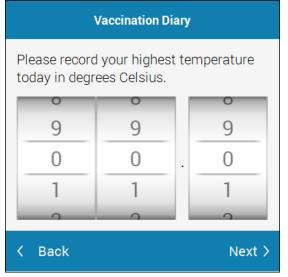
Screen 3



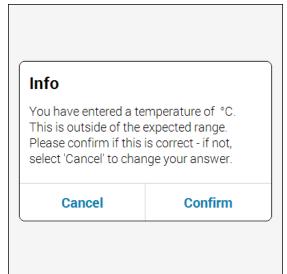


Message 1 Message 2





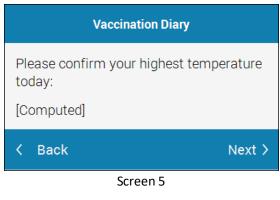
Message 3 Screen 4



Message 3

Info

as possible.

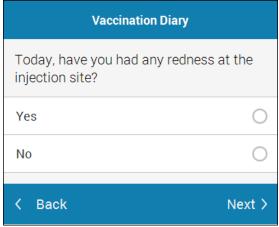


[Computed] will display the temperature selected on Screen 3 or Screen 4

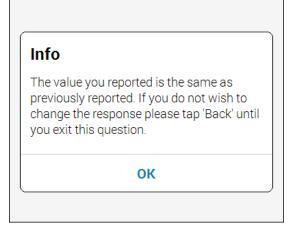
Please contact your study doctor as soon

Message 1

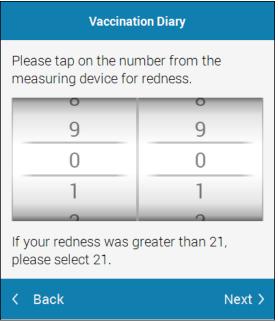
OK



Screen 6



Message 2



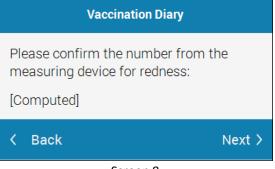
Screen 7

Info The measurement is equal to or lower than that reported earlier today. The highest

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

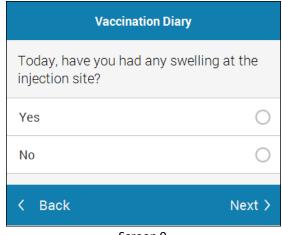
OK

Message 2

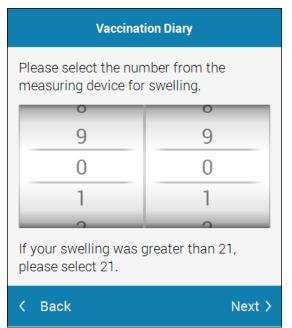


Screen 8

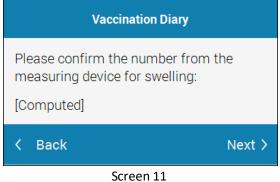
[Computed] will display the number selected on Screen 7.



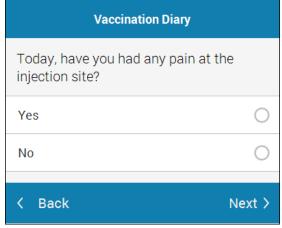
Screen 9



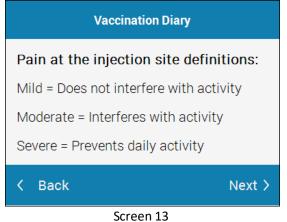
Screen 10

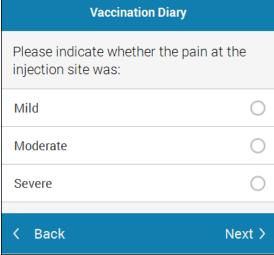


[Computed] will display the number selected on Screen 10.



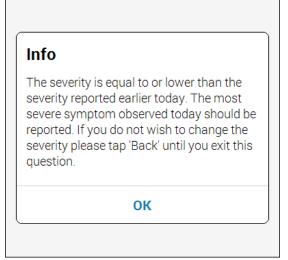
Screen 12



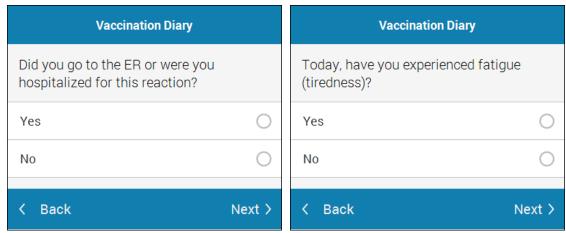


Screen 14

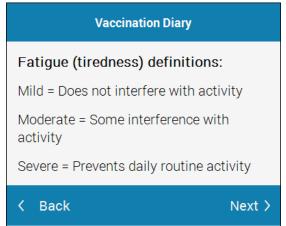




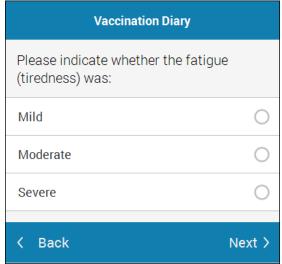
Message 2 Message 4



Screen 15 Screen 16



Screen 17



Screen 18



Vaccination Diary

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

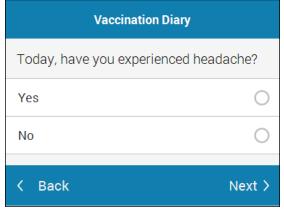
Yes ○

No ○

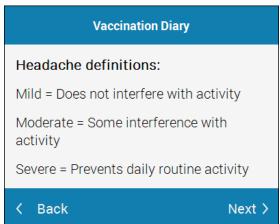
✓ Back Next >

Screen 19

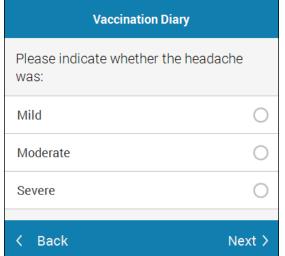
Message 2

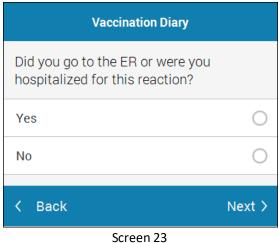


Screen 20

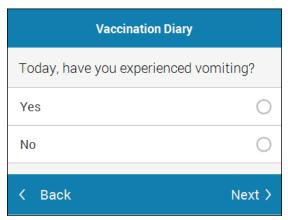


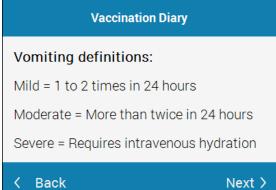
Screen 21



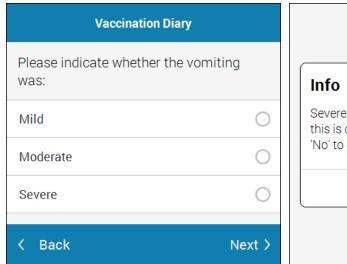


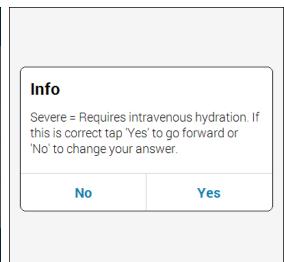
Screen 22





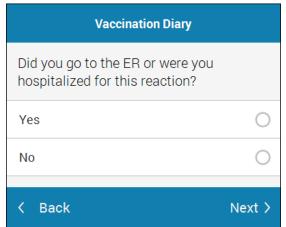
Screen 24 Screen 25



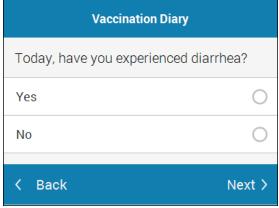


Screen 26

Message 2

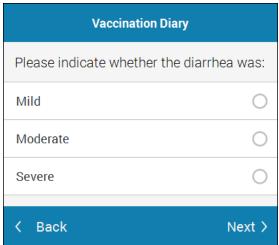


Screen 27



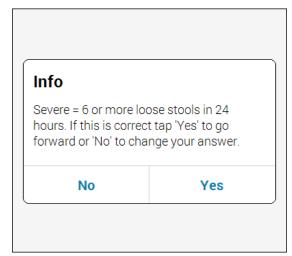
Screen 28



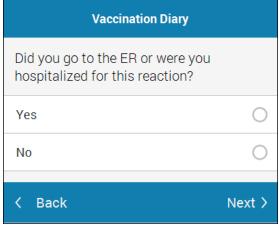


Screen 29

Screen 30

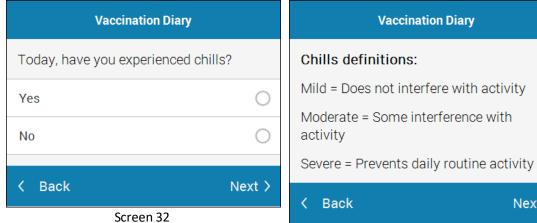


Message 2

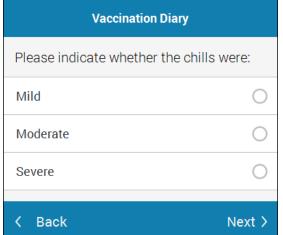


Screen 31

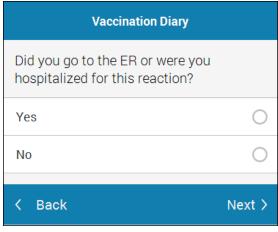
Next >



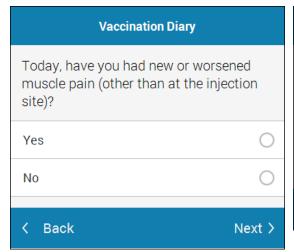
Screen 33



Screen 34



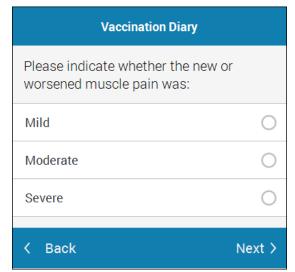
Screen 35



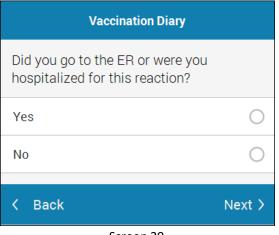
Screen 36



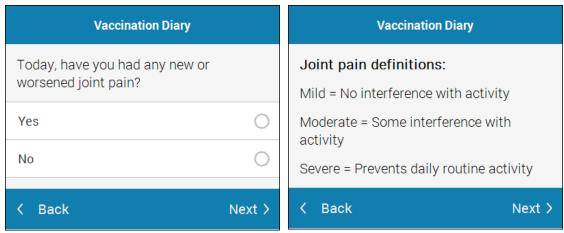
Screen 37



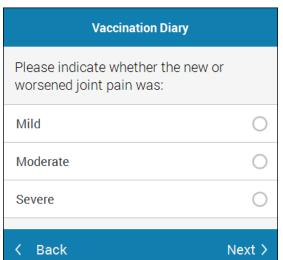
Screen 38



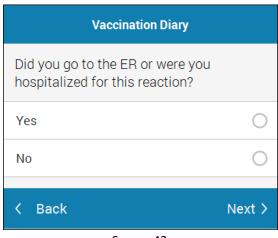
Screen 39



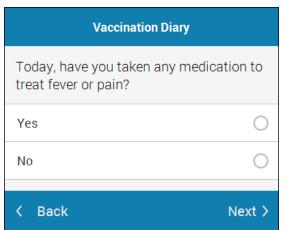
Screen 40 Screen 41

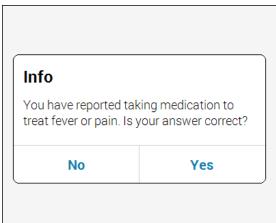


Screen 42



Screen 43





Screen 44

Message 2

Vaccination Diary Thank you! You have now completed the diary for today. Please save your answers by selecting 'Save'. If you wish to change your answers, select 'Back'. If your symptoms worsen today, please select 'Update Symptoms' from the main menu to update your symptoms. [Computed] Save Back

Screen 45

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

Where {1} = a number of days

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

Vaccination Diary Thank you! You have now updated the diary for today. Please save your answers by selecting 'Save'. If you wish to change your answers, select 'Back'. If your symptoms worsen again today, please select 'Update Symptoms' from the main menu to update your symptoms. [Computed] Save Back

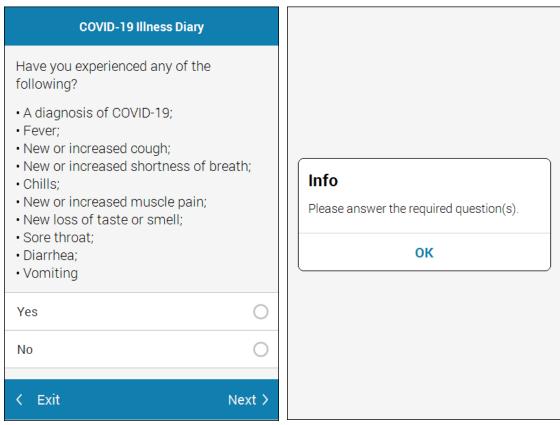
Screen 46

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

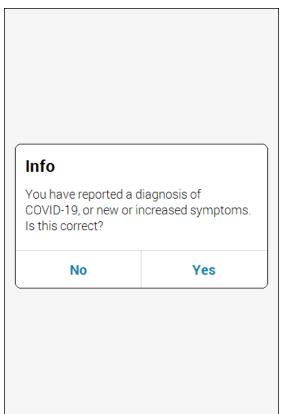
Where $\{1\}$ = a number of days

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

4 Form: COVID-19 Illness Diary

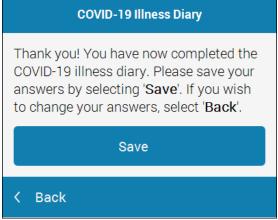


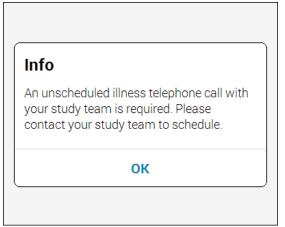
Screen 1 Message 1





Message 2 Message 3





Screen 2 Message 1

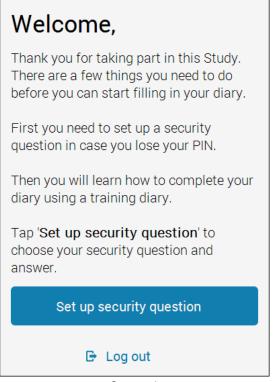
Info

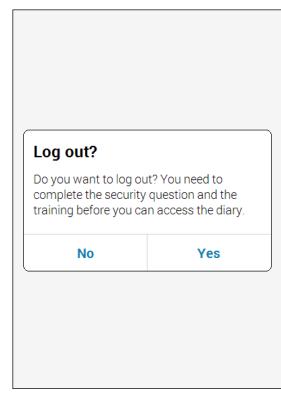
Thank you for completing COVID-19 Illness Diary. If you become ill, please complete illness diary. If you remain well, your next check-in is required in 7 days.

ОК

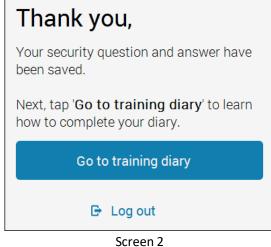
Message 2

5 Form: Patient main menu





Screen 1 Message 1





Log out?

access the diary.

No

Do you want to log out? You need to

complete the training before you can

Yes

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.

OK

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)

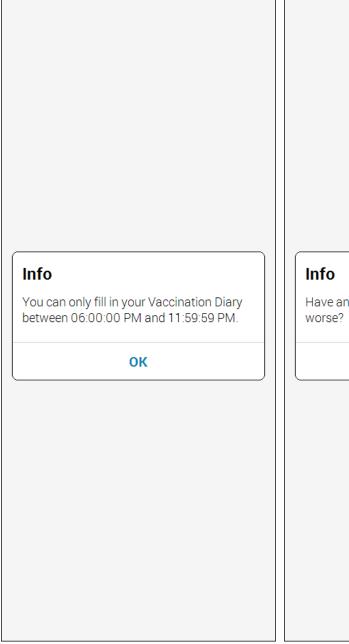
- ◆ Training review
 - Settings
 - □ Log out

Screen 4

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

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 "Vaccination Diary"

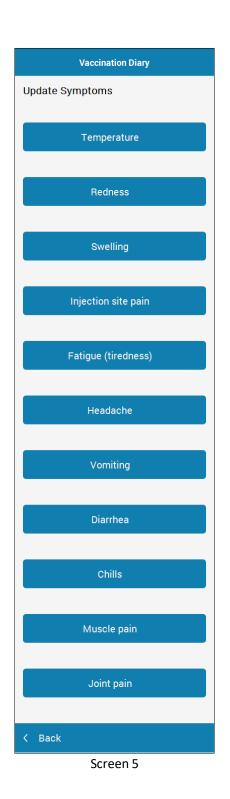


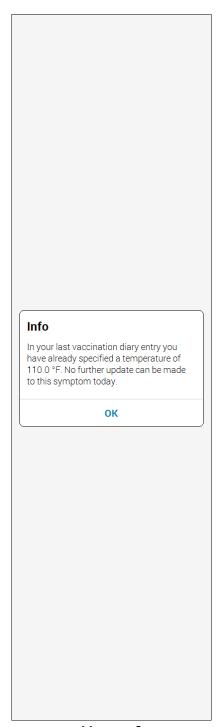
Info
Have any of your symptoms become worse?

No
Yes

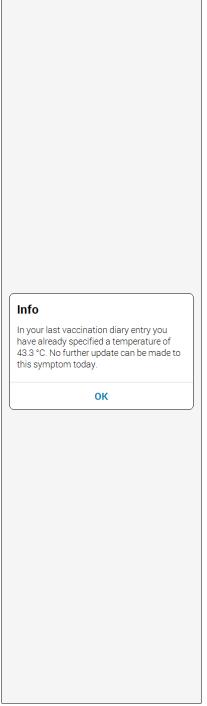
Message 1

Device text will format out the leading 0's and seconds. Actual popup will read "6:00 PM and 11:59 PM"





Message 2



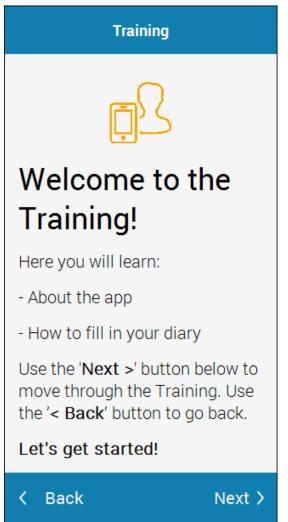
Info In your last vaccination diary you have already specified the highest measurement of 21. No further update can be made to this symptom today. ОК Message 5

Info

In your last vaccination diary entry you specified that the symptom was severe and that you went to the hospital. No further update can be made to this symptom today.

ОК

6 Form: Subject training diary

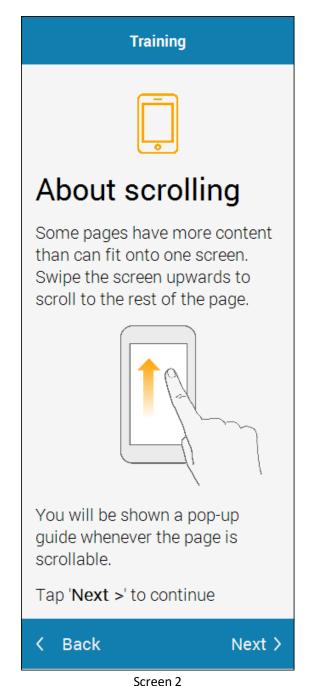


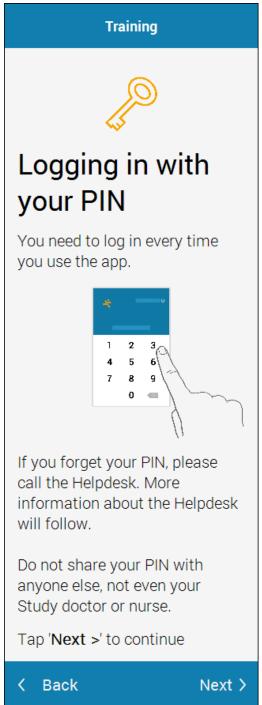
Confirm

Do you want to log out? You need to complete the training before you can access the diary.

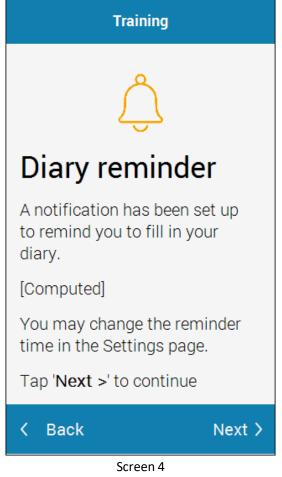
No Yes

Screen 1

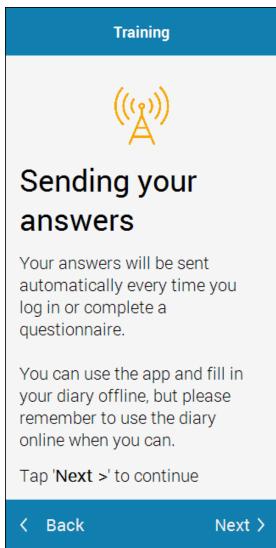




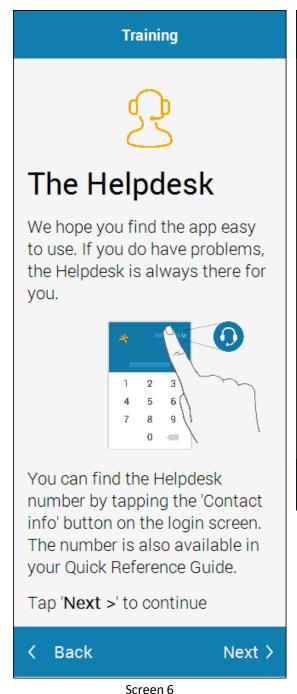
Screen 3

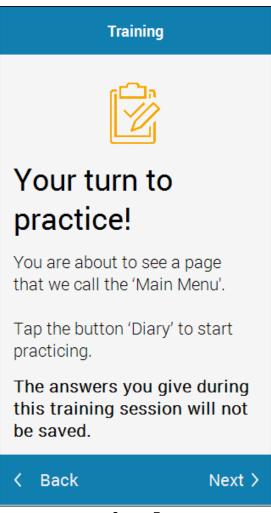


[Computed] will display 'Your reminder time is {1}.', where {1} will be the selected diary reminder time.

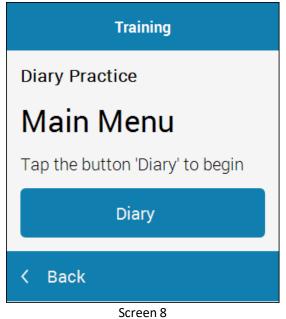


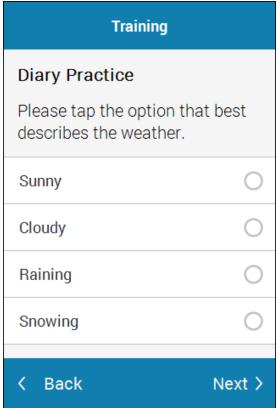
Screen 5



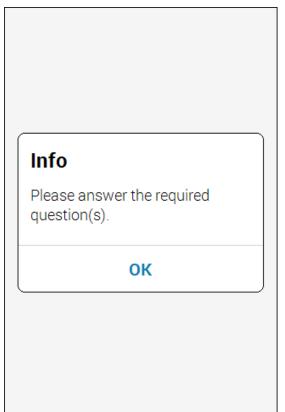


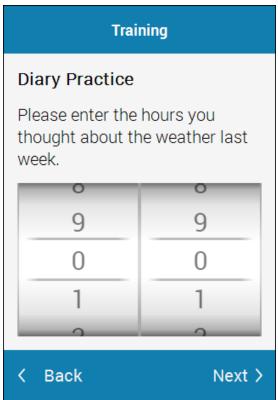
Screen 7





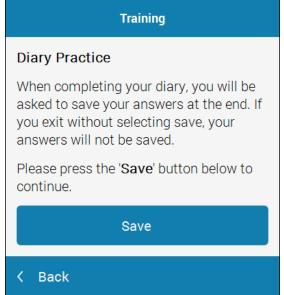
Screen 9



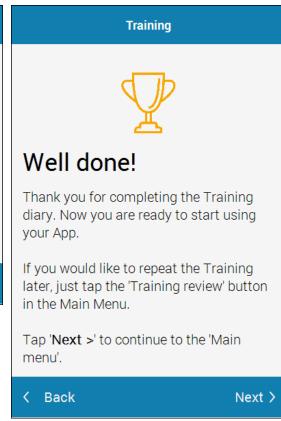


Message 1

Screen 10

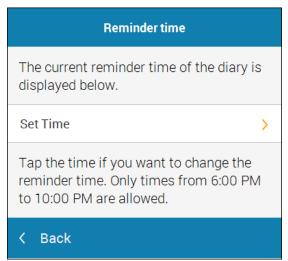


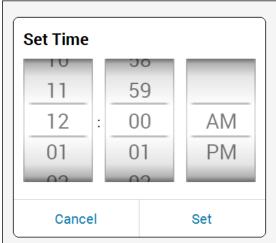
Screen 11



Screen 12

7 Form: Settings





Screen 1 Popup input 1

8 Form: Security question

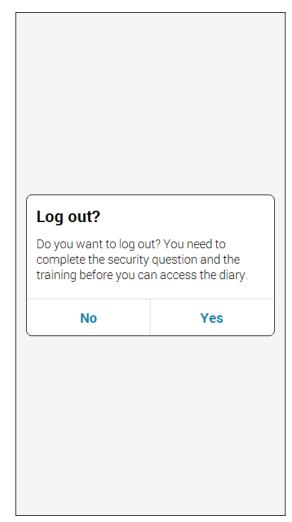
Security question	
Choose your security question. The answer should have only two digit question and answer will be needed you forget your PIN.	ts. Your
[Computed]	\circ
[Computed]	0
[Computed]	0
[Computed]	\circ
Then tap the 'Next >' button	
< Back	Next >

Screen 1

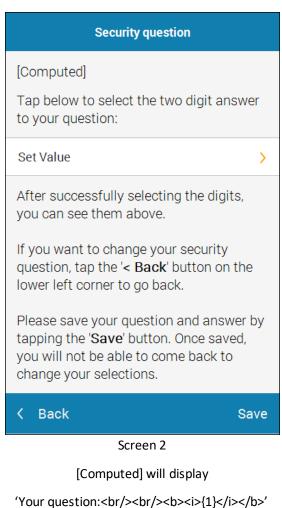
[Computed] will show one of the following:

'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)'

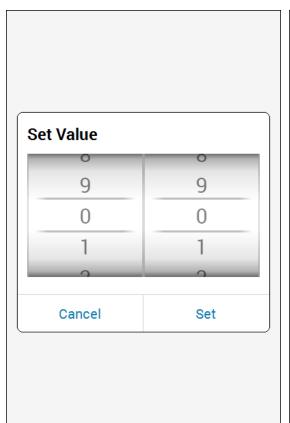
Message 1

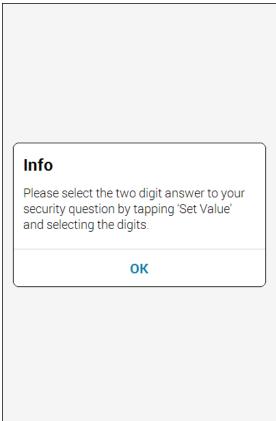


Message 2



{1} will show the question selected on Screen 1





Popup input 1 Message 1