

**Annotated Study Book for Study Design: C4591001**

**Study Design Version: 11.0**

**Sponsor: Pfizer**

**Protocol: C4591001**

**Sponsor Drug Name: BLINDED THERAPY**

**C4591001 - COVID19**

**Generated by Central Designer™**

**October 12, 2020 8:47AM**

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**C4591001: ADVERSE EVENT REPORT (AE) - Repeating Form**

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	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																
<b>Adverse Event Report</b>																
1.	Category: [Category]	<input type="radio"/> ADVERSE EVENT														
2.	AE ID: [AE Identifier]	<input type="text"/>														
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms) [Adverse Event]	<input type="text"/>														
4.	Start Date Time: [Start Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/> <input type="button" value="▼"/> : <input type="button" value="▼"/> 24-hour clock														
5.	Is the adverse event still ongoing? [Is the Adverse Event Still Ongoing]	<input type="radio"/> YES <input type="radio"/> NO	End Date Time: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/> <input type="button" value="▼"/> : <input type="button" value="▼"/> 24-hour clock													
6.	Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4														
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). [Serious]	<input type="radio"/> YES Is this serious event associated with congenital anomaly or birth defect? <input type="radio"/> YES <input type="radio"/> NO Did this serious event result in death? <input type="radio"/> YES <input type="radio"/> NO Did this serious event require or prolong hospitalization? <input type="radio"/> YES <input type="radio"/> NO Did this serious event result in persistent or significant disability/incapacity? <input type="radio"/> YES <input type="radio"/> NO Is this serious event life threatening? <input type="radio"/> YES <input type="radio"/> NO Other medically important serious event <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NO														
8.	Is this adverse event the result of a study Medication Error?  If Yes, record the type of medication error on the Medication Error Log. [Is AE a Result of a Medication Error]	<input type="radio"/> YES <input type="radio"/> NO														
9.	Is this event related to study treatment: [Relationship to Study Treatment]	<input type="radio"/> NOT RELATED If Not Related to study treatment(s), this event is due to: <input type="radio"/> CONCOMITANT DRUG TREATMENT <input type="radio"/> CONCOMITANT NON-DRUG TREATMENT <input type="radio"/> OTHER If Other, specify: <input type="text"/>														
10.	Latest Action Taken with Study	<input type="radio"/> DRUG WITHDRAWN <input type="radio"/> NOT APPLICABLE														

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	Treatment: [Action Taken with Study Treatment]  <input checked="" type="radio"/>
11.	Was a Concomitant Medication given? [Concomitant Medication Given]  <input type="radio"/> YES <input type="radio"/> NO
12.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]  <input type="radio"/> YES <input type="radio"/> NO
13.	What was the outcome of this adverse event?: [Outcome]  <input type="radio"/> FATAL <input type="radio"/> NOT RECOVERED/NOT RESOLVED <input type="radio"/> RECOVERED/RESOLVED <input type="radio"/> RECOVERED/RESOLVED WITH SEQUELAE <input type="radio"/> RECOVERING/RESOLVING <input type="radio"/> UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuation]  <input type="radio"/> YES <input type="radio"/> NO
15.	Serious Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]  <input type="text"/>
16.	Comparison Term [hidden] [Comparison Term]  <input type="text"/>
17.	Lowest Level Term [hidden] [Lowest Level Term]  <input type="text"/>
18.	Lowest Level Term Code [hidden] [Lowest Level Term Code]  <input type="text"/>
19.	Dictionary-Derived Term [hidden] [Dictionary-Derived Term]  <input type="text"/>
20.	Preferred Term Code [hidden] [Preferred Term Code]  <input type="text"/>
21.	High Level Term [hidden] [High Level Term]  <input type="text"/>
22.	High Level Term Code [hidden] [High Level Term Code]  <input type="text"/>
23.	High Level Group Term [hidden] [High Level Group Term]  <input type="text"/>
24.	High Level Group Term Code [hidden] [High Level Group Term Code]  <input type="text"/>
25.	Primary System Organ Class [hidden] [Primary System Organ Class]  <input type="text"/>
26.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]  <input type="text"/>

<b>C4591001: LABORATORY DATA - HEMATOLOGY (CD4)</b>					
<b>Laboratory Data Hematology</b>					
1. Lab Panel: [Category for Lab Test]	<input type="radio"/> HEMATOLOGY				
2. Laboratory Name and Address [Vendor Name (DERIVED)]					
3. Collection Date: [Collection Date:]	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>
4. Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD				
<b>Lab Result</b>					
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		CD4_PX4722			
<b>Lab Result Entry</b>					
5.1 Sponsor ID: [Sponsor-Defined Identifier]					
5.2 Test: [Test:]	<input type="radio"/> CD4_PX4722				
5.3 Result: [Result:]					
5.4 Not Done: [hidden] [Not Done:]	<input type="radio"/> NOT DONE				
5.5 LNMT [Lab Normal Range]	Low				
	High				
	Unit	<input type="radio"/> $10^3/\text{mm}^3$			

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**C4591001: COHORT SELECTION (COHORT SEL)****Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1. Select appropriate response - Protocol version [Trigger Response 1]	
2. Select appropriate response - What cohort does the subject belong to? [Trigger Response 10]	<input type="radio"/> STAGE 1 SENTINEL COHORTS <input type="radio"/> STAGE 1 NONSENTINEL COHORTS <input type="radio"/> STAGE 2 COHORTS <input type="radio"/> STAGE 3 COHORTS

**C4591001: 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									
<b>Concomitant Medications</b>									
1.	What is the medication identifier? [Sponsor-Defined Identifier]								
2.	Category: [Category for Medication]		<input checked="" type="radio"/> GENERAL CONCOMITANT MEDICATIONS						
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]		<input checked="" type="radio"/> NO						
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic 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]								
5.	Dose: [Dose Description]								
6.	Dose Unit: [Dose Unit]		<input checked="" type="checkbox"/>						
7.	Dose Frequency: [Dose Frequency]		<input checked="" type="checkbox"/>						
8.	Route: [Route]		<input checked="" type="checkbox"/>						
9.	Start Date: [Start Date]		<input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/>						
10.	Comparison Term [hidden] [Comparison Term]								
11.	Standardized Medication Name - Dictionary derived. [hidden] [Standardized Medication Name]								
12.	Standardized Medication Code - Dictionary derived [hidden] [Standardized Medication Code]								

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<b>C4591001: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS (CONMED VAX) - Repeating Form</b>					
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date
1					
<b>Concomitant Medications</b>					
1.	What is the medication identifier? [Sponsor-Defined Identifier]				
2.	Category: [Category for Medication]	<input checked="" type="radio"/> VACCINATIONS			
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input checked="" type="radio"/> NO			
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic 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]				
5.	Date: [Start Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>			
6.	Comparison Term [hidden] [Comparison Term]				
7.	Standardized Medication Name - Dictionary derived. [hidden] [Standardized Medication Name]				
8.	Standardized Medication Code - Dictionary derived [hidden] [Standardized Medication Code]				

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**C4591001: MAIN INFORMED CONSENT (CONSENT)****Informed Consent**

1. Consent Was: [Consent Was:]	<input type="radio"/> OBTAINED Date Written Consent Obtained   <input type="button" value="▼"/> /   <input type="button" value="▼"/> /   <input type="button" value="▼"/>
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<b>C4591001: CONTACT OUTCOME - MONTH 1 (CONTACT 1M)</b>	
<b>Contact Outcome</b>	
1. Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> CLINIC VISIT <input type="radio"/> TELEHEALTH VISIT
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES Date of Contact: <input checked="" type="checkbox"/> / <input type="checkbox"/> / <input checked="" type="checkbox"/> <input type="radio"/> NO If No, why?  <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>
4. Comments: [Comments/Findings/Details]	<div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>

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<b>C4591001: CONTACT OUTCOME - MONTH 6 (CONTACT 6M)</b>	
<b>Contact Outcome</b>	
1. Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> CLINIC VISIT <input type="radio"/> TELEHEALTH VISIT
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES Date of Contact: <input type="radio"/> /   <input type="radio"/> /   <input type="radio"/> <input type="radio"/> NO If No, why?  <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>
4. Comments: [Comments/Findings/Details]	<div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>

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**C4591001: CONTACT OUTCOME (CONTACT SV)****Contact Outcome**

1. Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> TELEPHONE VISIT
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES Date of Contact: <input type="button"/> / <input type="button"/> / <input type="button"/> <input type="radio"/> NO If No, why?
4. Comments: [Comments/Findings/Details]	

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<b>C4591001: CONTACT OUTCOME - UNPLANNED (CONTACT UV)</b>	
<b>Contact Outcome</b>	
1. Follow-Up Contact Category [hidden] [Follow Up Contact Category]	<input type="radio"/> CONTACT OUTCOME
2. Contact Type: [Type of Contact/Visit]	<input type="radio"/> TELEPHONE VISIT
3. Was contact made? [Was Contact Made]	<input type="radio"/> YES Date of Contact: <input checked="" type="checkbox"/> / <input type="checkbox"/> / <input type="checkbox"/> Contact Outcome: <input type="radio"/> VISIT ARRANGED <input type="radio"/> VISIT ARRANGED, BUT NOT ATTENDED <input type="radio"/> VISIT NOT ARRANGED, REACTION NO LONGER PRESENT <input type="radio"/> VISIT NOT ARRANGED, UNABLE TO ATTEND <input type="radio"/> VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY <input type="radio"/> VISIT NOT REQUIRED, INVESTIGATOR DECISION <input type="radio"/> NO If No, why? <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>
4. Comments: [Comments/Findings/Details]	<div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>

<b>C4591001: MICROBIOLOGY SPECIMEN (COV19 SITE) - Repeating Form</b>						
#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	Comments:
1						
<b>Microbiology Specimen</b>						
1.	Actual Date of Collection: [Date of Collection]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>				
2.	Specimen Type: [Specimen Type]	<input type="radio"/> SERUM <input type="radio"/> BLOOD <input type="radio"/> PLASMA				
3.	Assay Code and Description: [Assay Code and Description]	<input type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2				
4.	Device Type: [Device Type]	<input type="radio"/> SARS-COV-2 DIAGNOSTIC TEST				
5.	Test Result: [Result]	<input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE <input type="radio"/> INDETERMINATE				
6.	Comments/Findings/Details: [Comments:]					

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<b>C4591001: MICROBIOLOGY SPECIMEN (COVID TEST) - Repeating Form</b>									
#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:	Trade Name Other, Specify
1									
<b>Microbiology Specimen</b>									
1.	Actual Date of Collection: [Date of Collection]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>							
2.	Specimen Type: [Specimen Type]	<input type="radio"/> SWABBED MATERIAL <input type="radio"/> RESPIRATORY SECRETIONS							
3.	Specimen Collection Location: [Specimen Collection Location]	<input type="radio"/> NASOPHARYNX <input type="radio"/> LOWER RESPIRATORY SYSTEM <input type="radio"/> THROAT							
4.	Assay Code and Description: [Assay Code and Description]	<input type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2							
5.	Device Type: [Device Type]	<input type="radio"/> SARS-COV-2 DIAGNOSTIC TEST							
6.	Trade Name: [Trade Name]	<input type="button" value="▼"/>							
7.	Test Result: [Result]	<input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE <input type="radio"/> INDETERMINATE							
8.	Comments/Findings/Details: [Comments:]								
9.	Trade Name Other, Specify: [Trade Name Other, Specify]								

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**C4591001: DEATH DETAILS CODED (DEATH DTL)****Death Details**

1. Date of Collection / Notification of Death: [Date of Collection / Notification of Death]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
2.	<b>Cause of Death Status</b>

**Cause of Death Entry**

2.1 Cause of Death Status: [Cause of Death Status]	<input type="radio"/> PRIMARY CAUSE OF DEATH <input type="radio"/> 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 Dictionary-Derived Term [hidden] [Dictionary-Derived Term]	
2.7 Preferred Term Code [hidden] [Preferred Term Code]	
2.8 High Level Term [hidden] [High Level Term]	
2.9 High Level Term Code [hidden] [High Level Term Code]	
2.10 High Level Group Term [hidden] [High Level Group Term]	
2.11 High Level Group Term Code [hidden] [High Level Group Term Code]	
2.12 Primary System Organ Class [hidden] [Primary System Organ Class]	
2.13 Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	

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<b>C4591001: DEMOGRAPHY (DEMOG)</b>	
<b>Demography</b>	
1. Subject ID [Subject ID]	<input type="text"/>
2. Birth Date: [Birth Date]	<input checked="" type="checkbox"/> / <input type="checkbox"/> / <input checked="" type="checkbox"/>
3. Sex: [Sex]	<input type="radio"/> FEMALE <input type="radio"/> MALE
4. Ethnicity: [Ethnicity]	<input type="radio"/> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN <input type="radio"/> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN <input type="radio"/> NOT REPORTED
5. Race: (Check X all that apply): [Race Of Subject]	<input type="checkbox"/> BLACK OR AFRICAN AMERICAN <input type="checkbox"/> AMERICAN INDIAN OR ALASKA NATIVE <input type="checkbox"/> ASIAN <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> WHITE <input type="checkbox"/> NOT REPORTED

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**C4591001: DISPOSITION - FOLLOW-UP (DISP FUP)****Disposition - Follow-Up**

1. Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	<input checked="" type="checkbox"/> / <input type="checkbox"/> / <input checked="" type="checkbox"/>
2. Phase of Disposition: [Disposition Phase]	<input checked="" type="radio"/> FOLLOW-UP
3. Status: [Status]	<input checked="" type="checkbox"/>
4. Specify Status: [Specify Status]	

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**C4591001: DISPOSITION - SCREENING (DISP SCR)****Disposition - Screening**

1. Date of Completion/Discontinuation/Death [Date of Completion/Discontinuation/Death]	<input checked="" type="checkbox"/> / <input type="checkbox"/> / <input checked="" type="checkbox"/>
2. Phase of Disposition: [Disposition Phase]	<input checked="" type="radio"/> SCREENING
3. Status: [Status]	<input checked="" type="checkbox"/>
4. Specify Status: [Specify Status]	

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**C4591001: DISPOSITION - TREATMENT (DISP TRT)****Disposition - Treatment**

1. Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	<input checked="" type="checkbox"/> / <input type="checkbox"/> / <input checked="" type="checkbox"/>
2. Phase of Disposition: [Disposition Phase]	<input checked="" type="radio"/> VACCINATION
3. Status: [Status]	<input checked="" type="checkbox"/>
4. Specify Status: [Specify Status]	

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<b>C4591001: DATE OF VISIT (DOV)</b>		
<b>Date of Visit</b>		
1. Date of Visit [Date of Visit]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>	
2. Erroneous Visit [Visit Error]	<input checked="" type="radio"/> ERRONEOUS VISIT	

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<b>C4591001: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)</b>		
<b>Date of Visit</b>		
1. Date of Visit [Date of Visit]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>	
2. Erroneous Visit [Visit Error]	<input checked="" type="radio"/> ERRONEOUS VISIT	
<b>COVID-19 Illness Visit</b>		
3. COVID-19 Illness Visit: [COVID-19 Illness Visit]	<input type="button" value="▼"/>	

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<b>C4591001: DATE OF VISIT - ILLNESS ONSET (DOV ILL)</b>		
<b>Date of Visit</b>		
1. Date of Visit [Date of Visit]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>	
2. Erroneous Visit [Visit Error]	<input checked="" type="radio"/> ERRONEOUS VISIT	
<b>COVID-19 Illness Visit</b>		
3. COVID-19 Illness Visit: [COVID-19 Illness Visit]	<input type="button" value="▼"/>	

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<b>C4591001: DATE OF VISIT - REPEAT SWAB (DOV SWAB)</b>		
<b>Date of Visit</b>		
1. Date of Visit [Date of Visit]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>	
2. Erroneous Visit [Visit Error]	<input checked="" type="radio"/> ERRONEOUS VISIT	
<b>COVID-19 Repeat Swab</b>		
3. COVID-19 Repeat Swab: [COVID-19 Repeat Swab]	<input type="button" value="▼"/>	

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**C4591001: INFORM ENROLLMENT (ENROLL)****InForm Enrollment**

1. Subject ID  
[Subject ID]

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**C4591001: HIV STATUS (HIV)****HIV Status**

1. Select appropriate response -  
What is the subject HIV status?  
[Trigger Response 2]
- The subject is known to be HIV POSITIVE  
 The subject is NOT known to be HIV POSITIVE

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<b>C4591001: LAB CHEMISTRY (HIV RNA)</b>					
<b>Lab Chemistry Details</b>					
1. Lab Panel: [Category for Lab Test]	<input type="radio"/> CLINICAL CHEMISTRY				
2. Laboratory Name and Address [Vendor Name]					
3. Collection Date: [Collection Date:]	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>
4. Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD				
<b>Lab Result</b>					
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		HIV RNA (Ultrasensitive)			
<b>Lab Result Entry</b>					
5.1	Sponsor ID: [Sponsor-Defined Identifier]				
5.2	Test: [Test:]	<input type="radio"/> HIV RNA (Ultrasensitive)			
5.3	Result: [Result:]				
5.4	Not Done: [hidden] [Not Done:]	<input type="radio"/> NOT DONE			
5.5	LNMT [Lab Normal Range]	Low			
		High			
		Unit	<input type="radio"/> /mL		

**C4591001: HEALTH CARE UTILIZATION (HLTHCARE)****Health Care Utilization**

1. Evaluation Interval: [hidden] [Evaluation Interval]	<input type="radio"/> SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE
2. Disease Name: [hidden] [Disease Name]	<input type="radio"/> RESPIRATORY ILLNESS

**Health Care Utilization**

# ▼	Pre-Specified	Type of Practitioner	Occurrence of Visits or Contacts
3.a	YES	SPECIALIST	
3.b	YES	EMERGENCY ROOM	
3.c	YES	PRIMARY CARE PHYSICIAN	
3.d	YES	URGENT CARE	
3.e	YES	TELEPHONE CONSULTATION	
3.f	YES	OTHER	

**Health Care Utilization Entry**

3.1	Pre-Specified: [hidden] [Pre-Specified]	<input type="radio"/> YES
3.2	Physician or Healthcare Professional: [Type of Practitioner]	<input type="radio"/> SPECIALIST <input type="radio"/> EMERGENCY ROOM <input type="radio"/> PRIMARY CARE PHYSICIAN <input type="radio"/> URGENT CARE <input type="radio"/> TELEPHONE CONSULTATION <input type="radio"/> OTHER
3.3	Occurrence of Visits or Contacts: [Occurrence of Visits or Contacts]	<input type="radio"/> YES Number of Visits or Contacts: <input type="text"/> <input type="radio"/> NO

**Health Care Utilization Other**

4.	Other Type of Practitioner Specify: [Other Type of Practitioner Specify]	<input type="text"/>
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**Health Care Utilization**

5.	Has the subject been hospitalized due to potential COVID-19 illness? [Been Hospitalized]	<input type="radio"/> YES Has the subject been in intensive care due to potential COVID-19 illness? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NO
----	---	---

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<b>C4591001: HOSPITALIZATION DETAILS (HOSP) - Repeating Form</b>				
#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing
1				

**Hospitalization Details**

1. Hospitalization Category: [Hospitalization Category]	<input type="radio"/> HOSPITALIZATION STATUS
2. Hospitalization Term: [Hospitalization Term]	<input type="radio"/> ICU <input type="radio"/> HOSPITAL
3. Admission Date: [Admission Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
4. Ongoing? [Ongoing]	<input type="radio"/> YES <input type="radio"/> NO Discharge Date: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>

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**C4591001: ILLNESS DETAILS (ILL POTEN)****Illness Details**

1. Category of Clinical Event: [Category of Clinical Event:]	<input checked="" type="radio"/> POTENTIAL COVID-19 ILLNESS
2. Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	<input checked="" type="radio"/> YES Respiratory Illness Diagnosis: <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div> Date of Diagnosis: <div style="display: flex; justify-content: space-around; align-items: center;"> <span><input checked="" type="checkbox"/></span> /            <span><input checked="" type="checkbox"/></span> /            <span><input checked="" type="checkbox"/></span> </div> <input type="radio"/> NO
3. Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
4. Comparison Term: [hidden] [Comparison Term]	<div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div>
5. Lowest Level Term [hidden] [Lowest Level Term]	<div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
6. Lowest Level Term Code [hidden] [Lowest Level Term Code]	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>
7. Dictionary Derived Term [hidden] [Dictionary Derived Term]	<div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
8. Preferred Term Code [hidden] [Preferred Term Code]	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>
9. High Level Term [hidden] [High Level Term]	<div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
10. High Level Term Code [hidden] [High Level Term Code]	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>
11. High Level Group Term [hidden] [High Level Group Term]	<div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
12. High Level Group Term Code [hidden] [High Level Group Term Code]	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>
13. Primary System Organ Class [hidden] [Primary System Organ Class]	<div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
14. Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>

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<b>C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE) - Repeating Form</b>				
#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade
1				
<b>Illness Details</b>				
1.	Category of Clinical Event: [Category of Clinical Event:]	<input type="radio"/> SEVERE COVID-19 ILLNESS		
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	<input type="radio"/> SIGNIFICANT ACUTE RENAL DYSFUNCTION <input type="radio"/> SIGNIFICANT ACUTE HEPATIC DYSFUNCTION <input type="radio"/> SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION		
3.	Was a diagnosis obtained? [Diagnosis Obtained]	<input type="radio"/> YES Diagnosis: <input type="text"/> Start Date: <input type="text"/> / <input type="text"/> / <input type="text"/> Ongoing?: <input type="radio"/> YES <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/>		
4.	Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5		
5.	Comparison Term: [hidden] [Comparison Term]	<input type="text"/>		
6.	Lowest Level Term [hidden] [Lowest Level Term]	<input type="text"/>		
7.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	<input type="text"/>		
8.	Dictionary Derived Term [hidden] [Dictionary Derived Term]	<input type="text"/>		
9.	Preferred Term Code [hidden] [Preferred Term Code]	<input type="text"/>		
10.	High Level Term [hidden] [High Level Term]	<input type="text"/>		
11.	High Level Term Code [hidden] [High Level Term Code]	<input type="text"/>		
12.	High Level Group Term [hidden] [High Level Group Term]	<input type="text"/>		
13.	High Level Group Term Code [hidden] [High Level Group Term Code]	<input type="text"/>		
14.	Primary System Organ Class [hidden] [Primary System Organ Class]	<input type="text"/>		
15.	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	<input type="text"/>		

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**C4591001: ILLNESS DETAILS - SEVERE (ILL SEVERE)****Illness Details**

1. Category of Clinical Event: [Category of Clinical Event:]	<input checked="" type="radio"/> SEVERE COVID-19 ILLNESS
2. Subcategory of Clinical Event: [Subcategory of Clinical Event]	<input checked="" type="radio"/> SIGNIFICANT ACUTE RENAL DYSFUNCTION <input checked="" type="radio"/> SIGNIFICANT ACUTE HEPATIC DYSFUNCTION <input checked="" type="radio"/> SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3. Was a diagnosis obtained? [Diagnosis Obtained]	<input checked="" type="radio"/> YES Diagnosis: <input type="text"/> Start Date: <input type="text"/> / <input type="text"/> / <input type="text"/> Ongoing?: <input checked="" type="radio"/> YES <input type="radio"/> NO End Date: <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="radio"/> NO
4. Toxicity Grade: [Toxicity Grade]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
5. Comparison Term: [hidden] [Comparison Term]	<input type="text"/>
6. Lowest Level Term [hidden] [Lowest Level Term]	<input type="text"/>
7. Lowest Level Term Code [hidden] [Lowest Level Term Code]	<input type="text"/>
8. Dictionary Derived Term [hidden] [Dictionary Derived Term]	<input type="text"/>
9. Preferred Term Code [hidden] [Preferred Term Code]	<input type="text"/>
10. High Level Term [hidden] [High Level Term]	<input type="text"/>
11. High Level Term Code [hidden] [High Level Term Code]	<input type="text"/>
12. High Level Group Term [hidden] [High Level Group Term]	<input type="text"/>
13. High Level Group Term Code [hidden] [High Level Group Term Code]	<input type="text"/>
14. Primary System Organ Class [hidden] [Primary System Organ Class]	<input type="text"/>
15. Primary System Organ Class Code [hidden] [Primary System Organ Class Code]	<input type="text"/>

<b>C4591001: IMAGING (IMAGING) - Repeating Form</b>				
#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment
1				
<b>Imaging</b>				
1.	Date of Assessment: [Date of Assessment]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>		
2.	Location of Assessment: [Location of Assessment]	<input type="radio"/> CHEST <input type="radio"/> HEAD <input type="radio"/> OTHER If other, specify: <input type="text"/>		
3.	Type of Imaging Exam: [Imaging Method]	<input type="radio"/> CT SCAN <input type="radio"/> X-RAY <input type="radio"/> ULTRASOUND <input type="radio"/> MRI <input type="radio"/> OTHER If other, specify: <input type="text"/>		
4.	Assessment: [Overall Assessment]	<input type="radio"/> ABNORMAL If abnormal, specify findings: <input type="text"/> <input type="radio"/> INDETERMINATE <input type="radio"/> NORMAL <input type="radio"/> UNKNOWN <input type="radio"/> NOT EVALUABLE		

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

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of 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
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.k	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A00
2.l	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A00
2.m	16	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.n	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

**Exclusion Criteria Entry**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/>		
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		

	<input type="radio"/> NO
2.4 Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input checked="" type="checkbox"/>

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

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**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of 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
2.f	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.g	11	Women who are pregnant or breastfeeding		EX11A00
2.h	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.i	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.j	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.k	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.l	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.m	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

**Exclusion Criteria Entry**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/>		
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div> <input type="radio"/> NO		
2.4	Criterion ID: (For Pfizer use			

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only) [Criterion ID: (For Pfizer use only)]		<input checked="" type="checkbox"/>
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**C4591001: INCLUSION/EXCLUSION CRITERIA (IN EX STG3)**

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of 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
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.m	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

**Exclusion Criteria Entry**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/>		
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		

	<input type="radio"/> NO
2.4 Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input checked="" type="checkbox"/>

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<b>C4591001: INCLUSION/EXCLUSION CRITERIA (INC EXC)</b>	
	<b>Criterion Description</b>
1.	
<b>Inclusion Criteria Not Met Entry</b>	
1.1	Description of Inclusion Criterion Not Met [Criterion Description]   
	<b>Criterion Description</b>
2.	
<b>Exclusion Criteria Met Entry</b>	
2.1	Description of Exclusion Criterion Met [Criterion Description]   

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

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		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 condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.j	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.k	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.l	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.m	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.n	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

**Exclusion Criteria Entry**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/>		
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div> <input type="radio"/> NO		

2.4 Criterion ID: (For Pfizer use only)  
[Criterion ID: (For Pfizer use only)]



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

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.l	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A00
2.m	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A00
2.n	16	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.o	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

**Exclusion Criteria Entry**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/>		
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		

		<input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input checked="" type="checkbox"/>

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

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.g	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.h	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.i	11	Women who are pregnant or breastfeeding		EX11A00
2.j	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.k	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.l	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.m	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.n	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.o	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01

**Exclusion Criteria Entry**

2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/>		
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
2.3	Criterion met? [Criterion met?]	<input type="radio"/> YES Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		

		<input type="radio"/> NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input checked="" type="checkbox"/>

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

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Sentinel participants in Stage 1 only: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A04
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.q	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.r	18	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen		EX19A01

		(HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit		
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A01
2.v	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01
<b>Exclusion Criteria Entry</b>				
2.1	Exclusion Number: [Exclusion Number]	<input type="button" value="▼"/>		
2.2	Criterion Description: [Criterion Description]	<input type="button" value="▼"/>		
2.3	Criterion met? [Criterion met?]	<input checked="" type="radio"/> YES Describe details if relevant <input type="button" value="▼"/>		
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="▼"/>		

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

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19		EX06A00
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.m	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.n	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A00
2.o	15	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A00
2.p	16	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A00
2.q	17	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A00
2.r	18	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A00
2.s	19	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit		EX19A00

2.t	20	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A00
2.u	21	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00
<b>Exclusion Criteria Entry</b>				
2.1	Exclusion Number: [Exclusion Number]	<input checked="" type="checkbox"/>		
2.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
2.3	Criterion met? [Criterion met?]	<input checked="" type="radio"/> YES Describe details if relevant <input type="radio"/> NO		
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input checked="" type="checkbox"/>		

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

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

**Inclusion Criteria**

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

**Inclusion Criteria Entry**

1.1	Inclusion Number: [Inclusion Number]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4		
1.2	Criterion Description: [Criterion Description]	<input checked="" type="checkbox"/>		
1.3	Criterion met? [Criterion met?]	<input type="radio"/> YES <input type="radio"/> NO Describe details if relevant <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div>		
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="radio"/> IN01A00 <input type="radio"/> IN02A00 <input type="radio"/> IN03A00 <input type="radio"/> IN04A00		

**Exclusion Criteria**

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medications intended to prevent COVID-19		EX04A00
2.e	5	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19		EX05A00
2.f	6	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)		EX06A01
2.g	7	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)		EX07A00
2.h	8	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination		EX08A00
2.i	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.j	10	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection		EX10A00
2.k	11	Women who are pregnant or breastfeeding		EX11A00
2.l	12	Previous vaccination with any coronavirus vaccine		EX12A00
2.m	13	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids		EX13A01
2.n	14	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids		EX22A01
2.o	15	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study		EX14A01
2.p	16	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX15A01
2.q	17	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX16A01
2.r	18	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit		EX17A01
2.s	19	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator		EX18A01
2.t	20	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen		EX19A01

		(HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit		
2.u	21	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention		EX20A01
2.v	22	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A01
<b>Exclusion Criteria Entry</b>				
2.1	Exclusion Number: [Exclusion Number]	<input type="button" value="▼"/>		
2.2	Criterion Description: [Criterion Description]	<input type="button" value="▼"/>		
2.3	Criterion met? [Criterion met?]	<input checked="" type="radio"/> YES Describe details if relevant <input type="button" value="▼"/>		
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	<input type="button" value="▼"/>		

**C4591001: CASEBOOK SIGNATURE FORM (INVSIG)****Casebook Signature Form**

- |   |  |
|---|--|
| 1. Casebook Signature<br>[Casebook Signature] | <input type="radio"/> Click Here to Enable |
|---|--|

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**C4591001: CENTRAL LAB SAMPLE COLLECTION (LAB)****Central Lab Sample Collection**

1. Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>
2. Specimen Type: [Specimen Type]	<input checked="" type="radio"/> 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	

**Lab Test Entry**

3.1	Lab Panel: [Category for Lab Test]	<input checked="" type="radio"/> HEMATOLOGY <input checked="" type="radio"/> CLINICAL CHEMISTRY
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	<input checked="" type="radio"/> DIFFERENTIAL <input checked="" type="radio"/> BLOOD CHEMISTRY
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	<input checked="" type="radio"/> YES <input checked="" type="radio"/> NO

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**C4591001: CENTRAL LAB SAMPLE COLLECTION - BASELINE (LAB BSL)****Central Lab Sample Collection**

1. Collection Date: [Collection Date:]	<input type="text"/> / <input type="text"/> / <input type="text"/>
2. Specimen Type: [Specimen Type]	<input checked="" type="radio"/> 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	

**Lab Test Entry**

3.1	Lab Panel: [Category for Lab Test]	<input checked="" type="radio"/> HEMATOLOGY <input checked="" type="radio"/> CLINICAL CHEMISTRY
3.2	Lab Sub-Panel: [Subcategory for Lab Test]	<input checked="" type="radio"/> DIFFERENTIAL <input checked="" type="radio"/> BLOOD CHEMISTRY <input checked="" type="radio"/> VIROLOGY
3.3	Was the lab sub-panel collected?: [Lab Sub-Panel Collected]	<input checked="" type="radio"/> YES <input checked="" type="radio"/> NO

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<b>C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form</b>					
#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result
1					
<b>Lab Chemistry Details</b>					
1.	Lab Panel: [Category for Lab Test]	<input type="radio"/> CLINICAL CHEMISTRY			
2.	Laboratory Name and Address [Vendor Name]				
3.	Collection Date: [Collection Date:]	<input type="button" value="▼"/> /	<input type="button" value="▼"/> /	<input type="button" value="▼"/>	
4.	Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD			
<b>Lab Result</b>					
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		C Reactive Protein_PX329			
<b>Lab Result Entry</b>					
5.1	Sponsor ID: [Sponsor-Defined Identifier]				
5.2	Test: [Test:]	<input type="radio"/> C Reactive Protein_PX329			
5.3	Result: [Result:]				
5.4	Not Done: [hidden] [Not Done:]	<input type="radio"/> NOT DONE			
5.5	LNMT [Lab Normal Range]	Low			
		High			
		Unit	<input type="button" value="▼"/>		

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<b>C4591001: LOCAL LABORATORY DATA - REPEATING CHEMISTRY (LAB CHEM) - Repeating Form</b>					
#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result
1					
<b>Lab Chemistry Details</b>					
1.	Lab Panel: [Category for Lab Test]	<input type="radio"/> CLINICAL CHEMISTRY			
2.	Laboratory Name and Address [Vendor Name]				
3.	Collection Date: [Collection Date:]	<input type="button" value="▼"/> /	<input type="button" value="▼"/> /	<input type="button" value="▼"/>	
4.	Specimen Type: [Specimen Type]	<input type="radio"/> BLOOD			
<b>Lab Result</b>					
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab Normal Range
5.a		C Reactive Protein_PX329			
5.b		Alanine Aminotransferase_PX30			
5.c		Aspartate Aminotransferase_PX28			
5.d		Alkaline Phosphatase_PX35			
5.e		Bilirubin_PX21			
5.f		Blood Urea Nitrogen_PX47			
5.g		Creatinine_PX48			
<b>Lab Result Entry</b>					
5.1	Sponsor ID: [Sponsor-Defined Identifier]				
5.2	Test: [Test:]	<input type="radio"/>			
5.3	Result: [Result:]				
5.4	Not Done: [Not Done:]	<input type="radio"/> NOT DONE			
5.5	LNMT [Lab Normal Range]	Low			
		High			
		Unit	<input type="radio"/>		

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<b>C4591001: LOCAL LABORATORY DATA - REPEATING Hematology (LAB HEM) - Repeating Form</b>					
#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result
1					
<b>Laboratory Data Hematology</b>					
1.	Lab Panel: [Category for Lab Test]	<input checked="" type="radio"/> HEMATOLOGY			
2.	Laboratory Name and Address [Vendor Name (DERIVED)]				
3.	Collection Date: [Collection Date:]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>			
4.	Specimen Type: [Specimen Type]	<input checked="" type="radio"/> BLOOD			
<b>Lab Result</b>					
#	Sponsor-Defined Identifier	Test:	Result:	Not Done:	Lab 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			
<b>Lab Result Entry</b>					
5.1	Sponsor ID: [Sponsor-Defined Identifier]				
5.2	Test: [Test:]	<input type="button" value="▼"/>			
5.3	Result: [Result:]				
5.4	Not Done: [Not Done:]	<input checked="" type="radio"/> NOT DONE			
5.5	LNMT [Lab Normal Range]	Low <input type="text"/> High <input type="text"/> Unit <input type="button" value="▼"/>			

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**C4591001: LAB URINALYSIS - PREGNANCY TEST (LAB PREG)****Lab Urinalysis**

1. Lab Panel: [Category for Lab Test]	<input type="radio"/> URINALYSIS
2. Lab Sub-Panel: [Subcategory for Lab Test]	<input type="radio"/> PREGNANCY
3. Collection Date: [Collection Date:]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
4. Laboratory Name and Address (Derived) [Vendor Name (DERIVED)]	<input type="text"/>
5. Specimen Type: [Specimen Type]	<input type="radio"/> URINE

**Lab Result**

#	Sponsor-Defined Identifier	Test:	Result:	Not Done:
6.a		Choriogonadotropin Beta_PX113		

**Lab Result Entry**

6.1 Sponsor ID: [Sponsor-Defined Identifier]	<input type="text"/>
6.2 Test: [Test:]	<input type="radio"/> Choriogonadotropin Beta_PX113
6.3 Result: [Result:]	<input type="radio"/> NEGATIVE <input type="radio"/> POSITIVE
6.4 Not Done: [Not Done:]	<input type="radio"/> NOT DONE

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<b>C4591001: MEDICATION ERROR (MED ERROR) - Repeating Form</b>											
#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE	Serious Adverse Event Number	
1											
<b>Medication Error</b>											
1.	Category: [Category]	<input type="radio"/> MEDICATION ERROR									
2.	Medication Error (Type of Medication Error): [Medication Error]										
3.	If this is a dispensing error, record the incorrect container number that was dispensed/administered to the subject: [hidden] [Incorrect package ID]										
4.	Start Date: [Start Date]	<input type="checkbox"/> / <input type="checkbox"/> / <input type="checkbox"/>									
5.	Is the medication error still ongoing? [Is the medication error Still Ongoing]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="checkbox"/> / <input type="checkbox"/> / <input type="checkbox"/>									
6.	Latest Action Taken with Study Treatment: [Study Medication Errors Action]	<input type="radio"/> NO ACTION TAKEN <input type="radio"/> PERMANENTLY DISCONTINUED									
7.	Was a Concomitant Medication given? [Concomitant Medication Given]	<input type="radio"/> YES <input type="radio"/> NO									
8.	Was a Non-Drug Treatment given? [Non-Drug Treatment Given]	<input type="radio"/> YES <input type="radio"/> NO									
9.	Did the Medication Error cause the subject to be discontinued from the study? [Caused Study Discontinuation]	<input type="radio"/> YES <input type="radio"/> NO									
10.	Was this medication error associated with any adverse events? [Medication Error Associated With AE]	<input type="radio"/> YES AE ID: <input type="text"/> AE ID: <input type="text"/> AE ID: <input type="text"/> AE ID: <input type="text"/> <input type="radio"/> NO									
11.	Serious Adverse Event Number: For Pfizer Use Only [Serious Adverse Event Number]	<input type="text"/>									
12.	Comparison Term [hidden] [Comparison Term]										
13.	Lowest Level Term [hidden] [Lowest Level Term]										
14.	Lowest Level Term Code [hidden] [Lowest Level Term Code]	<input type="text"/>									
15.	Dictionary-Derived Term [hidden] [Dictionary-Derived Term]										

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

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<b>C4591001: GENERAL MEDICAL HISTORY (MEDHX)</b>				
	<b>Line/MH Number</b>	<b>Medical History Term</b>	<b>Start Date</b>	<b>Ongoing</b>
1.				
<b>Medical History Details Entry</b>				
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]	<input type="button" value="▼"/> /	<input type="button" value="▼"/> /	<input type="button" value="▼"/>
1.4	Ongoing: [Ongoing]	<input checked="" type="radio"/> YES <input type="radio"/> NO	End Date:	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
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	Dictionary Derived Term [hidden] [Dictionary Derived Term]			
1.9	Preferred Term Code [hidden] [Preferred Term Code]			
1.10	High Level Term [hidden] [High Level Term]			
1.11	High Level Term Code [hidden] [High Level Term Code]			
1.12	High Level Group Term [hidden] [High Level Group Term]			
1.13	High Level Group Term Code [hidden] [High Level Group Term Code]			
1.14	Primary System Organ Class [hidden] [Primary System Organ Class]			
1.15	Primary System Organ Class Code [hidden] [Primary System Organ Class Code]			

<b>C4591001: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form</b>			
#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)
1			
<b>Oxygenation Parameters</b>			
1.	Date Time of Assessment: [Date Time of Assessment]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/> <input type="button" value="▼"/> : <input type="button" value="▼"/> 24-hour clock	
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	<input type="text"/>	
3.	FiO2 (Fraction of Inhaled Oxygen): [FiO2 (Fraction of Inhaled Oxygen)]	<input type="text"/>	

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**C4591001: PHYSICAL EXAMINATION (PHYS EXAM)****Physical Examination**

1. Exam Date: [Exam Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
------------------------------	--

**Physical Examination Result**

#	Body System Examined	Result
2.a	GENERAL APPEARANCE	
2.b	SKIN	
2.c	HEAD	
2.d	EYES	
2.e	EARS	
2.f	NOSE	
2.g	THROAT	
2.h	HEART	
2.i	LUNGS	
2.j	ABDOMEN	
2.k	MUSCULOSKELETAL	
2.l	EXTREMITIES	
2.m	NEUROLOGICAL	
2.n	LYMPH NODES	

**Physical Examination Result Entry**

2.1 Body System Examined: [Body System Examined]	<input type="button" value="▼"/>
2.2 Result: [Result]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL <small>If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as appropriate).</small> <div style="border: 1px solid #ccc; height: 40px; margin-top: 10px;"></div> <p>Are there clinically significant findings?</p> <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NOT DONE

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<b>C4591001: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION (PRIORCOV19)</b>	
<b>Electronic Sample Tracking</b>	
1. Data Origin [Data Origin]	<input checked="" type="radio"/> SITE
2. Sample Type [Sample Type]	<input checked="" type="radio"/> SERUM
3. Sample Collected? [Sample Collected]	<input checked="" type="radio"/> NO <input checked="" type="radio"/> YES Date of Collection: <input checked="" type="text"/> / <input checked="" type="text"/> / <input checked="" type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
5.	<b>Sample ID</b>
<b>Aliquot Entry</b> Please enter barcode for each aliquot. 5.1 Sample ID [Sample ID] <input type="text"/>	

<b>C4591001: CONCOMITANT MEDICATIONS - PROHIBITED (PROHIB CM) - Repeating Form</b>										
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing
1										
<b>Concomitant Medications</b>										
1.	What is the medication identifier? [Sponsor-Defined Identifier]									
2.	Category: [Category for Medication]	<input type="radio"/> CONCOMITANT IMMUNOSUPPRESSIVE THERAPY <input type="radio"/> CORTICOSTEROIDS <input type="radio"/> IMMUNOGLOBULINS								
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input type="radio"/> NO								
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic 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]									
5.	Dose: [Dose Description]									
6.	Dose Unit: [Dose Unit]	<input type="button" value="▼"/>								
7.	Dose Frequency: [Dose Frequency]	<input type="button" value="▼"/>								
8.	Route: [Route]	<input type="button" value="▼"/>								
9.	Start Date: [Start Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>								
10.	Ongoing? [Ongoing]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>								
11.	Comparison Term [hidden] [Comparison Term]									
12.	Standardized Medication Name - Dictionary derived. [hidden] [Standardized Medication Name]									
13.	Standardized Medication Code - Dictionary derived [hidden] [Standardized Medication Code]									

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<b>C4591001: RADIATION TREATMENT (PROHIB ND) - Repeating Form</b>						
#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?
1						
<b>Radiation Treatment</b>						
1.	Category: [Category]	<input checked="" type="radio"/> RADIATION THERAPY				
2.	What is the treatment Identifier? [Treatment Identifier]					
3.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input checked="" type="radio"/> YES				
4.	Treatment: [Treatment]					
5.	Start Date: [Start Date]	<input checked="" type="checkbox"/>	/	<input checked="" type="checkbox"/>	/	<input checked="" type="checkbox"/>
6.	Ongoing? [Ongoing?]	<input checked="" type="radio"/> YES	<input type="radio"/> NO	End Date: <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/>		
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.	Dictionary Derived Term [hidden] [Dictionary 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]					

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<b>C4591001: VITAL SIGNS - PULSE OX ROOM AIR (PULSE OX) - Repeating Form</b>			
#	Date:	Vital Signs Details	
1			
<b>Vital Signs</b>			
1.	Date: [Date:]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>	
<b>Vital Signs Details</b>			
#	Record Identifier:	Oxygen Saturation	
2.1	Record Identifier: [Record Identifier:]	<input checked="" type="radio"/> 1	
2.2	SPO2 Pulse Oximetry % [Oxygen Saturation]	<input type="text"/>	

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**C4591001: RANDOMIZATION (RAND)****Disposition**

1. Randomization Date : [Randomization Date :]	<input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/>
2. Randomization Number: [Randomization Number]	
3. Randomization Group: [Randomization Group]	

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**C4591001: REACTOGENICITY DIARY (REAC DIARY)****Reactogenicity Diary**

1. Select appropriate response -  
Reactogenicity diary collection  
[Trigger Response 9]

- YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT  
 NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

**C4591001: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT (REACTION)****Unplanned Assessment Of Local Reaction**

1. CISR Category [hidden] [CISR Category]	<input type="radio"/> UNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT
2. Date of Assessment: [Date of Assessment]	<input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> / <input type="checkbox"/>
3. Injection Site Location [Injection Site Location]	<input type="radio"/> DELTOID MUSCLE
4. Injection Site Body Side: [Injection Site Body Side]	<input type="radio"/> LEFT <input type="radio"/> RIGHT

**Reaction**

#	Reaction:	Reaction Present:
5.a	REDNESS	
5.b	SWELLING	

**Reaction Entry**

5.1	Reaction: [Reaction:]	<input type="radio"/> REDNESS <input type="radio"/> SWELLING
5.2	Reaction Present: [Reaction Present:]	<input type="radio"/> YES Maximum Diameter (cm): <input type="text"/> Minimum Diameter (cm): <input type="text"/> Meets Grade 4 Reaction Criteria: <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> 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:]	<input checked="" type="checkbox"/>
6.2	Symptom Present: [Symptom Present:]	<input type="radio"/> YES Symptom Grade: <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 Event related to Study Treatment? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NO

<b>C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form</b>						
#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?
1						
<b>Respiratory Treatment</b>						
1.	What is the treatment Identifier? [Treatment Identifier]					
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES				
3.	Treatment: [Treatment]	<input type="radio"/> INTUBATION <input type="radio"/> NON-INVASIVE POSITIVE PRESSURE VENTILATION <input type="radio"/> CPAP <input type="radio"/> OXYGEN THERAPY				
4.	Treatment: [Treatment]					
5.	Start Date: [Start Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>				
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.	Dictionary Derived Term [hidden] [Dictionary 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]					

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<b>C4591001: RESPIRATORY TREATMENT (RESP TX) - Repeating Form</b>						
#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?
1						
<b>Respiratory Treatment</b>						
1.	What is the treatment Identifier? [Treatment Identifier]					
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	<input type="radio"/> YES				
3.	Treatment: [Treatment]	<input type="radio"/> NON-INVASIVE POSITIVE PRESSURE VENTILATION <input type="radio"/> CPAP <input type="radio"/> MECHANICAL VENTILATION <input type="radio"/> EXTRACORPOREAL MEMBRANE OXYGENATION <input type="radio"/> HIGH FLOW OXYGEN THERAPY				
4.	Treatment: [Treatment]					
5.	Start Date: [Start Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>				
6.	Ongoing? [Ongoing?]	<input type="radio"/> YES <input type="radio"/> NO End Date: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>				
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.	Dictionary Derived Term [hidden] [Dictionary 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]					

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<b>C4591001: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB)</b>	
<b>Electronic Sample Tracking</b>	
1. Data Origin [Data Origin]	<input checked="" type="radio"/> SITE
2. Sample Type [Sample Type]	<input type="radio"/> NASAL_SWAB <input checked="" type="radio"/> NASAL_SWAB_SELF
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO <input checked="" type="radio"/> YES Date of Collection: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	<input type="text"/>
<b>Sample ID</b>	
5.	<input type="text"/>
<b>Aliquot Entry</b>	
Please enter barcode for each aliquot.	
5.1 Sample ID [Sample ID]	<input type="text"/>

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**C4591001: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY (SAMP TRK)****Electronic Sample Tracking**

1. Data Origin [Data Origin]	<input type="radio"/> SITE
2. Sample Type [Sample Type]	<input type="radio"/> SERUM
3. Sample Collected? [Sample Collected]	<input type="radio"/> NO <input type="radio"/> YES Date of Collection: [ <input type="text"/> / <input type="text"/> / <input type="text"/> ]
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
5.	<b>Sample ID</b>
5.1 Sample ID [Sample ID]	

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**C4591001: INFORM SCREENING (SCREEN)****InForm Screening**

1. InForm Initials [hidden] [InForm Initials]	<input type="text"/>
2. Birth Date: [Birth Year]	<input type="button"/> / <input type="button"/> / <input type="button"/>

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**C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB)****Electronic Sample Tracking**

1. Data Origin [Data Origin]	<input checked="" type="radio"/> SITE
2. Sample Type [Sample Type]	<input checked="" type="radio"/> NASAL_SWAB_SELF
3. Sample Collected? [Sample Collected]	<input checked="" type="radio"/> NO <input type="radio"/> YES Date of Collection: <input checked="" type="text"/> / <input checked="" type="text"/> / <input checked="" type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
5.	<b>Sample ID</b>
5.1 Sample ID [Sample ID]	

**C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)****Signs and Symptoms**

1. Date of Assessment: [Date of assessment]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
2. Date of First Symptom Started: [First Symptom Started Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
3. Symptoms Ongoing? [Symptoms Ongoing]	<input type="radio"/> YES <input type="radio"/> NO Date of Last Symptom Resolved: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>

**Symptoms**

# ▼	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	

**Symptoms Entry**

4.1	Event Pre-specified: [hidden] [Event Pre-specified]	<input type="radio"/> YES
4.2	Symptoms: [Symptoms]	<input type="button" value="▼"/>
4.3	Was symptom present? [Symptom Present]	<input type="radio"/> YES <input type="radio"/> NO
5. ▼	<b>Symptoms - Other</b>	

**Symptoms - 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	Dictionary Derived Term [hidden] [Dictionary Derived Term]	
5.6	Preferred Term Code [hidden] [Preferred Term Code]	
5.7	High Level Term [hidden] [High Level Term]	
5.8	High Level Term Code [hidden] [High Level Term Code]	
5.9	High Level Group Term [hidden] [High Level Group Term]	
5.10	High Level Group Term Code [hidden] [High Level Group Term Code]	
5.11	Primary System Organ Class [hidden] [Primary System Organ Class]	
5.12	Primary System Organ Class Code [hidden] [Primary System Organ Class]	

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**C4591001: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)****Signs and Symptoms**

1. Date of Assessment: [Date of assessment]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
2. Date of First Symptom Started: [First Symptom Started Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
3. Symptoms Ongoing? [Symptoms Ongoing]	<input type="radio"/> YES <input type="radio"/> NO Date of Last Symptom Resolved: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>

**Symptoms**

# ▼	Event Pre-specified	Symptoms	Symptom Present
4.a	YES	FEVER	
4.b	YES	NEW OR INCREASED COUGH	
4.c	YES	NEW OR INCREASED SHORTNESS OF BREATH	
4.d	YES	CHILLS	
4.e	YES	NEW OR INCREASED MUSCLE PAIN	
4.f	YES	NEW LOSS OF TASTE OR SMELL	
4.g	YES	NEW OR INCREASED SORE THROAT	
4.h	YES	DIARRHEA	
4.i	YES	VOMITING	

**Symptoms Entry**

4.1	Event Pre-specified: [hidden] [Event Pre-specified]	<input type="radio"/> YES
4.2	Symptoms: [Symptoms]	<input type="button" value="▼"/>
4.3	Was symptom present? [Symptom Present]	<input type="radio"/> YES <input type="radio"/> NO
5. ▼	Symptoms - Other	

**Symptoms - 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	Dictionary Derived Term [hidden] [Dictionary Derived Term]	
5.6	Preferred Term Code [hidden] [Preferred Term Code]	
5.7	High Level Term [hidden] [High Level Term]	
5.8	High Level Term Code [hidden] [High Level Term Code]	
5.9	High Level Group Term [hidden] [High Level Group Term]	
5.10	High Level Group Term Code [hidden] [High Level Group Term Code]	
5.11	Primary System Organ Class [hidden] [Primary System Organ Class]	
5.12	Primary System Organ Class Code [hidden] [Primary System Organ Class]	

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**C4591001: STRATIFICATION (STRAT)****Stratification**

1. Select appropriate response - Randomization Stage [Trigger Response 3]	<input checked="" type="radio"/> Non-Sentinel Stage 1
2. Select appropriate response - Randomization Age Group [Trigger Response 4]	<input type="radio"/> Age 18 to 55 <input checked="" type="radio"/> Age 65 to 85
3. Select appropriate response - Randomization Dose [Trigger Response 5]	<input type="radio"/> 10 mcg <input type="radio"/> 20 mcg <input checked="" type="radio"/> 30 mcg
4. Select appropriate response - Randomization Dose Group [Trigger Response 8]	<input type="radio"/> 21 Day <input checked="" type="radio"/> 60 Day
5. Select appropriate response - BNT Number [Trigger Response 7]	<input type="radio"/> (BNT162b1 or PBO) <input type="radio"/> (BNT162b2 or PBO) <input checked="" type="radio"/> (BNT162b3 or PBO)

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**C4591001: STRATIFICATION (STRAT)****Stratification**

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

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**C4591001: STRATIFICATION (STRAT)****Stratification**

- |   |   |
|---|---|
| 1. Select appropriate response - Randomization Stage [Trigger Response 3]     | <input checked="" type="radio"/> Stage 2  |
| 2. Select appropriate response - Randomization Age Group [Trigger Response 4] | <input type="radio"/> Age 18 to 55<br><input type="radio"/> Age 56 to 85  |
| 3. Select appropriate response - Randomization Dose [Trigger Response 5]      | <input type="radio"/> 10 mcg<br><input type="radio"/> 20 mcg<br><input type="radio"/> 30 mcg                                  |
| 4. Select appropriate response - BNT Number [Trigger Response 7]              | <input type="radio"/> (BNT162b1 or PBO)<br><input type="radio"/> (BNT162b2 or PBO)<br><input type="radio"/> (BNT162b3 or PBO) |

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<b>C4591001: SUBJECT STATUS (SUB STATU)</b>	
<b>Subject Status</b>	
1. Subject Status [Subject Status]	<input type="button" value="▼"/>
2. Subject Status Date [Status Date]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>

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<b>C4591001: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE)</b>	
<b>Electronic Sample Tracking</b>	
1. Data Origin [Data Origin]	<input checked="" type="radio"/> SITE
2. Sample Type [Sample Type]	<input checked="" type="radio"/> NASAL_SWAB
3. Sample Collected? [Sample Collected]	<input checked="" type="radio"/> NO <input checked="" type="radio"/> YES Date of Collection: <input checked="" type="text"/> / <input checked="" type="text"/> / <input checked="" type="text"/>
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
5.	<b>Sample ID</b>
<b>Aliquot Entry</b> Please enter barcode for each aliquot. 5.1   Sample ID [Sample ID]   <input type="text"/>	

<b>C4591001: MICROBIOLOGY SPECIMEN (SWAB SITE) - Repeating Form</b>									
#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Trade Name	Result	Comments:	
1									
<b>Microbiology Specimen</b>									
1.	Actual Date of Collection: [Date of Collection]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>							
2.	Specimen Type: [Specimen Type]	<input checked="" type="radio"/> SWABBED MATERIAL							
3.	Specimen Collection Location: [Specimen Collection Location]	<input checked="" type="radio"/> NASAL CAVITY							
4.	Assay Code and Description: [Assay Code and Description]	<input checked="" type="radio"/> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2							
5.	Device Type: [Device Type]	<input checked="" type="radio"/> SARS-COV-2 DIAGNOSTIC TEST							
6.	Trade Name: [Trade Name]	<input checked="" type="radio"/> CEPHEID XPERT XPRESS SARS-COV-2 TEST							
7.	Test Result: [Result]	<input checked="" type="radio"/> POSITIVE <input checked="" type="radio"/> NEGATIVE <input checked="" type="radio"/> INDETERMINATE							
8.	Comments/Findings/Details: [Comments:]								

**C4591001: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE)****Vaccination 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]	<input checked="" type="radio"/> YES Ongoing? <input type="radio"/> YES <input type="radio"/> NO Stop Date: <input type="radio"/> NO	
#	Symptom:	Were fever or systemic symptoms present on the last day the Subject Diary was completed?
2.a	FEVER	
2.b	FATIGUE	
2.c	HEADACHE	
2.d	CHILLS	
2.e	VOMITING	
2.f	DIARRHEA	
2.g	NEW OR WORSENED MUSCLE PAIN	
2.h	NEW OR WORSENED JOINT PAIN	
2.1	Symptom: [Symptom:]	<input type="radio"/>
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?]	<input checked="" type="radio"/> YES Ongoing? <input type="radio"/> YES <input type="radio"/> NO Stop Date: <input type="radio"/> NO
3.	Injection Site Location: [Injection Site Location:]	<input checked="" type="radio"/> DELTOID MUSCLE
4.	Injection Site Body Side: [Injection Site Body Side:]	<input checked="" type="radio"/> LEFT <input type="radio"/> RIGHT
#	Injection Site Reaction:	Were injection site reactions present on the last day the Subject Diary was completed?
5.a	REDNESS	
5.b	SWELLING	
5.c	PAIN AT INJECTION SITE	
5.1	Injection Site Reaction: [Injection Site Reaction:]	<input type="radio"/> REDNESS <input type="radio"/> SWELLING <input type="radio"/> PAIN AT INJECTION SITE
5.2	Were injection site reactions present on the last day the Subject Diary was completed? [Were injection site reactions present on the last day the Subject Diary was completed?]	<input checked="" type="radio"/> YES Ongoing? <input type="radio"/> YES <input type="radio"/> NO Stop Date: <input type="radio"/> NO

<b>C4591001: TRANSFUSIONS (TRANSFUSE) - Repeating Form</b>		
#	Transfusion Type	Date of Transfusion
1	1. Transfusion Type: [Transfusion Type]  <input type="radio"/> PACKED RBC <input type="radio"/> PLATELETS <input type="radio"/> WHOLE BLOOD <input type="radio"/> PLASMA <input type="radio"/> OTHER Specify: <input type="text"/>	
2.	2. Date of Transfusion: [Date of Transfusion]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>

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**C4591001: TREATMENT UNBLINDED (TRN UNBLN)****Treatment Unblinded**

1. Date Treatment Unblinded : [Date Treatment Unblinded :]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
2. Primary Reason for Unblinding: [Primary Reason for Unblinding]	<input type="radio"/> SUBJECT SAFETY CONCERN <input type="radio"/> OTHER If other, specify: <input type="text"/>

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

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**C4591001: VACCINATION (VACIN TRT)****Vaccination**

1. Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	<input type="radio"/> YES Date of First Delay: <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> Reason(s) for Temporary Delay of Vaccination <input type="checkbox"/> FEVER OR ACUTE ILLNESS <input type="checkbox"/> RECENT SYSTEMIC CORTICOSTEROID TREATMENT <input type="checkbox"/> RECENT NON-STUDY VACCINATION <input type="checkbox"/> ANTICIPATED NON-STUDY VACCINATION <input type="radio"/> NO
2. Treatment Name [Treatment Name]	<input type="text"/>
3. Formulation: [Formulation:]	<input type="radio"/> INJECTION
4. Dose Date Time: [Dose Date Time:]	<input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> : <input checked="" type="checkbox"/> 24-hour clock
5. Anatomical Location: [Anatomical Location:]	<input type="radio"/> DELTOID MUSCLE
6. Body Side: [Body Side:]	<input type="radio"/> LEFT <input type="radio"/> RIGHT
7. Route: [Route:]	<input type="radio"/> INTRAMUSCULAR
8. Container Number: [hidden] [PAC / Kit Number:]	<input type="text"/>
9. Actual Dose: [Actual Dose:]	<input type="text"/>
10. Unit: [Unit:]	<input type="radio"/> mL
11. Timeframe Subject Was Observed [Timeframe Subject Was Observed]	<input type="radio"/> THE PROTOCOL SPECIFIED OBSERVATION PERIOD
12. Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	<input type="radio"/> YES <input type="radio"/> NO If No, specify reason: <input type="text"/>
13. Comparison Term [hidden] [Comparison Term]	<input type="text"/>
14. Standardized Medication Name - Dictionary Derived. [hidden] [Standardized Medication Name]	<input type="text"/>
15. Standardized Medication Code - Dictionary Derived [hidden]	<input type="text"/>

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[Standardized  
Medication  
Code]

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**C4591001: VACCINATION (VACIN TRT)****Vaccination**

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

	Dictionary Derived. [hidden] [Standardized Medication Name]
17.	Standardized Medication Code - Dictionary Derived [hidden] [Standardized Medication Code]

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<b>C4591001: CONCOMITANT MEDICATIONS - VASOPRESSORS (VASOPRESS) - Repeating Form</b>						
#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Ongoing
1						
<b>Concomitant Medications</b>						
1.	What is the medication identifier? [Sponsor-Defined Identifier]					
2.	Category: [Category for Medication]	<input type="radio"/> GENERAL CONCOMITANT MEDICATIONS				
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	<input type="radio"/> NO				
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic 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]					
5.	Start Date: [Start Date]	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>
6.	Ongoing? [Ongoing]	<input type="radio"/> YES	<input type="radio"/> NO	End Date: <input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>		
7.	Comparison Term [hidden] [Comparison Term]					
8.	Standardized Medication Name - Dictionary derived. [hidden] [Standardized Medication Name]					
9.	Standardized Medication Code - Dictionary derived [hidden] [Standardized Medication Code]					

**C4591001: VITAL SIGNS - TEMP (VITAL TEMP)****Vital Signs**

1. Date: [Date:]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
---------------------	--

**Vital Signs Details**

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:
2.a 1				

**Vital Signs Details Entry**

2.1 Record Identifier: [Record Identifier:]	<input checked="" type="radio"/> 1
2.2 Temperature: [Temperature]	<input type="text"/>
2.3 Unit: [Temperature Unit]	<input checked="" type="radio"/> F <input type="radio"/> C
2.4 Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD

**C4591001: VITAL SIGNS - BASELINE (VITALS BSL)****Vital Signs**

1. Date: [Date:]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
2. Weight: [Weight]	<input type="text"/>
3. Unit: [Weight Unit]	<input type="radio"/> kg <input type="radio"/> LB
4. Height: [Height]	<input type="text"/>
5. Unit: [Height Unit]	<input type="radio"/> cm <input type="radio"/> in
6. Body Mass Index: [Body Mass Index]	<input type="text"/>

**Vital Signs Details**

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:
7.a	1			

**Vital Signs Details Entry**

7.1 Record Identifier: [Record Identifier:]	<input type="radio"/> 1
7.2 Temperature: [Temperature]	<input type="text"/>
7.3 Unit: [Temperature Unit]	<input type="radio"/> C <input type="radio"/> F
7.4 Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD

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**C4591001: VITAL SIGNS - BASELINE (VITALS BSL)****Vital Signs**

1. Date: [Date:]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
2. Weight: [Weight]	<input type="text"/>
3. Unit: [Weight Unit]	<input type="radio"/> kg <input type="radio"/> LB
4. Height: [Height]	<input type="text"/>
5. Unit: [Height Unit]	<input type="radio"/> cm <input type="radio"/> in
6. Body Mass Index: [Body Mass Index]	<input type="text"/>

**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:]	<input type="radio"/> 1
7.2 Temperature: [Temperature]	<input type="text"/>
7.3 Unit: [Temperature Unit]	<input type="radio"/> C <input type="radio"/> F
7.4 Temperature Location: [Temperature Location:]	<input type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD
7.5 Systolic: [Systolic:]	<input type="text"/>
7.6 Diastolic: [Diastolic:]	<input type="text"/>
7.7 BP Position: [BP Position]	<input type="radio"/> SITTING
7.8 Pulse: [Pulse:]	<input type="text"/>

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<b>C4591001: VITAL SIGNS - COVID (VITALS COV) - Repeating Form</b>						
#	Date:	Vital Signs Details				
1						
<b>Vital Signs</b>						
1.	Date: [Date:]	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>	/	<input type="button" value="▼"/>
<b>Vital Signs Details</b>						
#	Record Identifier:	Systolic:	Diastolic:	Respiratory Rate in respirations/minute	Heart Rate in beats/minute	
2.a	1					
<b>Vital Signs Details Entry</b>						
2.1	Record Identifier: [Record Identifier:]	<input checked="" type="radio"/> 1				
2.2	Systolic: [Systolic:]	<input type="text"/>				
2.3	Diastolic: [Diastolic:]	<input type="text"/>				
2.4	Respiratory Rate in respirations/minute: [Respiratory Rate in respirations/minute]	<input type="text"/>				
2.5	Heart Rate in beats/minute: [Heart Rate in beats/minute]	<input type="text"/>				

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**C4591001: VITAL SIGNS (VITALS FUP)****Vital Signs**

1. Date: [Date:]	<input type="button" value="▼"/> / <input type="button" value="▼"/> / <input type="button" value="▼"/>
---------------------	--

**Vital Signs Details**

#	Record Identifier:	Temperature	Temperature Unit	Temperature Location:	Systolic:	Diastolic:	BP Position:	Pulse:
2.a 1							SITTING	

**Vital Signs Details Entry**

2.1 Record Identifier: [Record Identifier:]	<input checked="" type="radio"/> 1
2.2 Temperature: [Temperature]	<input type="text"/>
2.3 Unit: [Temperature Unit]	<input checked="" type="radio"/> F <input type="radio"/> C
2.4 Temperature Location: [Temperature Location:]	<input checked="" type="radio"/> ORAL CAVITY <input type="radio"/> EAR <input type="radio"/> RECTUM <input type="radio"/> AXILLA <input type="radio"/> FOREHEAD
2.5 Systolic: [Systolic:]	<input type="text"/>
2.6 Diastolic: [Diastolic:]	<input type="text"/>
2.7 BP Position: [BP Position]	<input checked="" type="radio"/> SITTING
2.8 Pulse: [Pulse:]	<input type="text"/>

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**C4591001: WITHDRAWAL OF CONSENT (WOC)****Withdrawal Of Consent**

1. Withdrawal of Consent Date :  
[Withdrawal of Consent Date :]

/ / /

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

## App Subject Facing Screen Report

Localized texts are displayed in English (US).

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8 Form: Security question .....	55

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

Month	January	February	March	April	May	June	July	August	September	October	November	December
Abbr.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	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 Helpdesk. ]

### SMS Body for Provisioned Devices:

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

[Activation Code]

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

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

**Email notification only:** [ Hello, ]

The information below will guide you on how to install the 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:** [ -----

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

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

**SMS Body for BYOD subjects:**

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

Activate the TrialMax App with code:  
[Activation Code]

**App notification:**

Please fill in your diary!

**Email notification subject :**  
COVID-19 Illness Diary Reminder

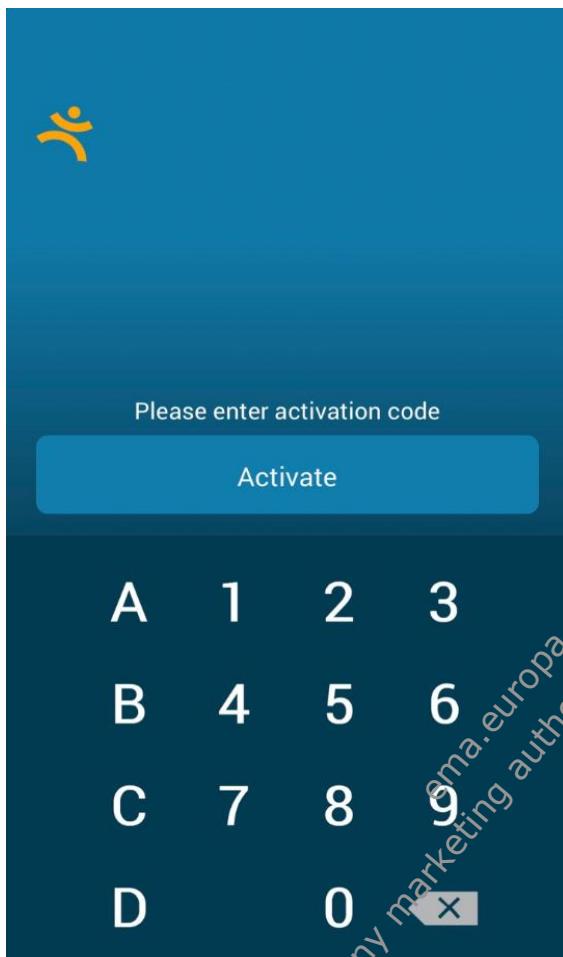
**Email and SMS Body for COVID-19 Illness Diary Reminder:**

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

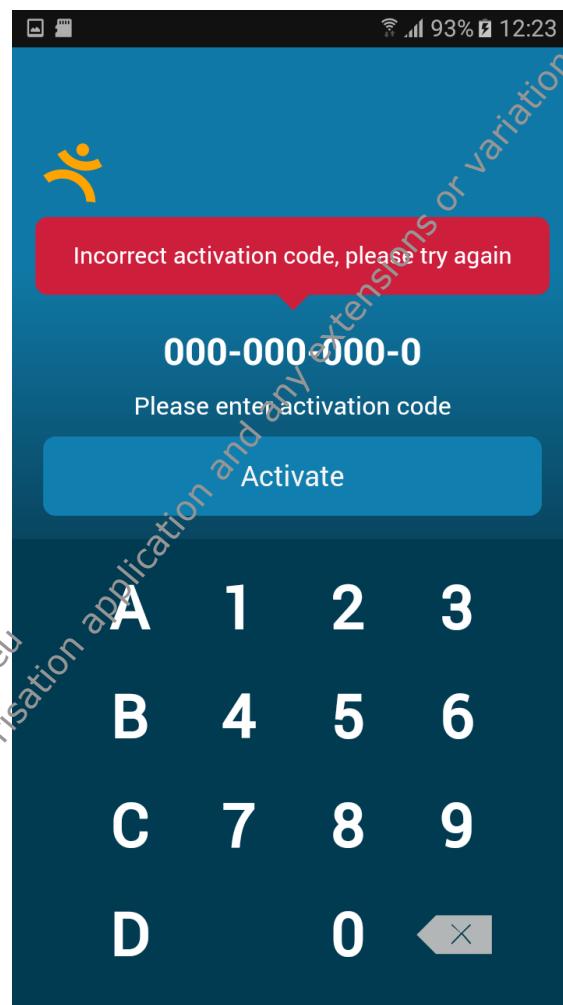
**Email notification only:** [ -----

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

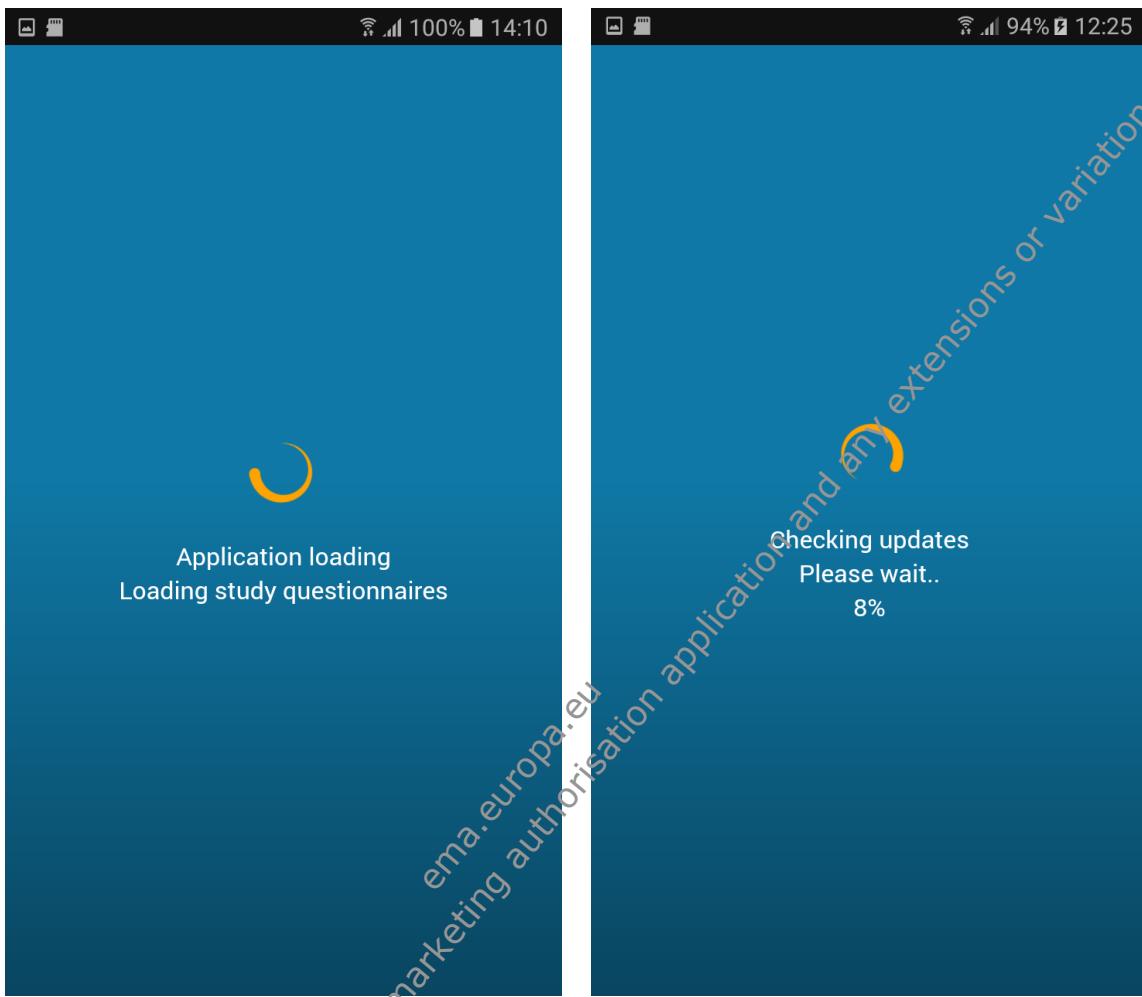
2 Common

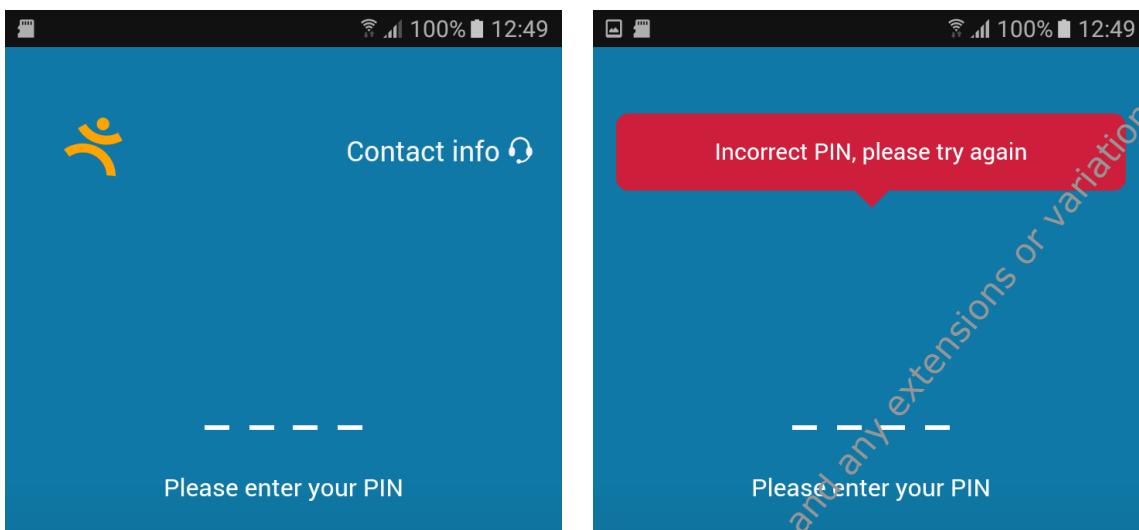


Screen 1



Screen 2





1      2      3  
4      5      6  
7      8      9  
0

Screen 5

1      2      3  
4      5      6  
7      8      9  
0

Screen 6



## New PIN required

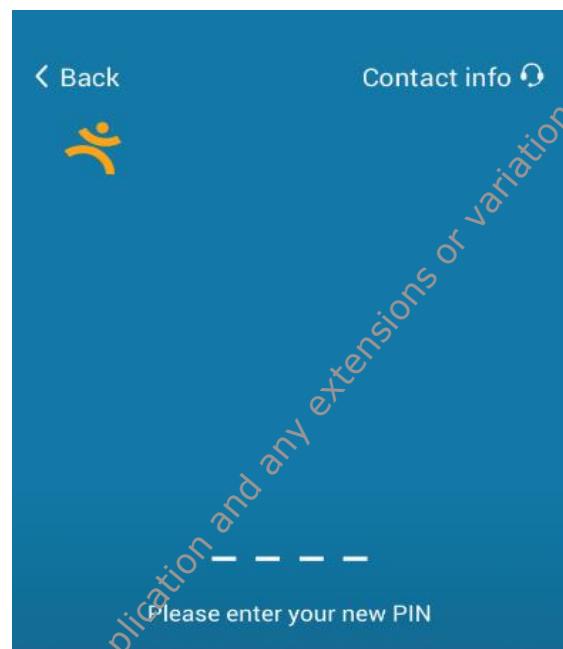
You are required to choose a new memorable PIN. Your new PIN must be 4 characters.

PINs that consist of characters following each other, like 1234 or 9876, or repeat the same character, like 1111 or 9999, are not accepted.

Old PINs cannot be reused.

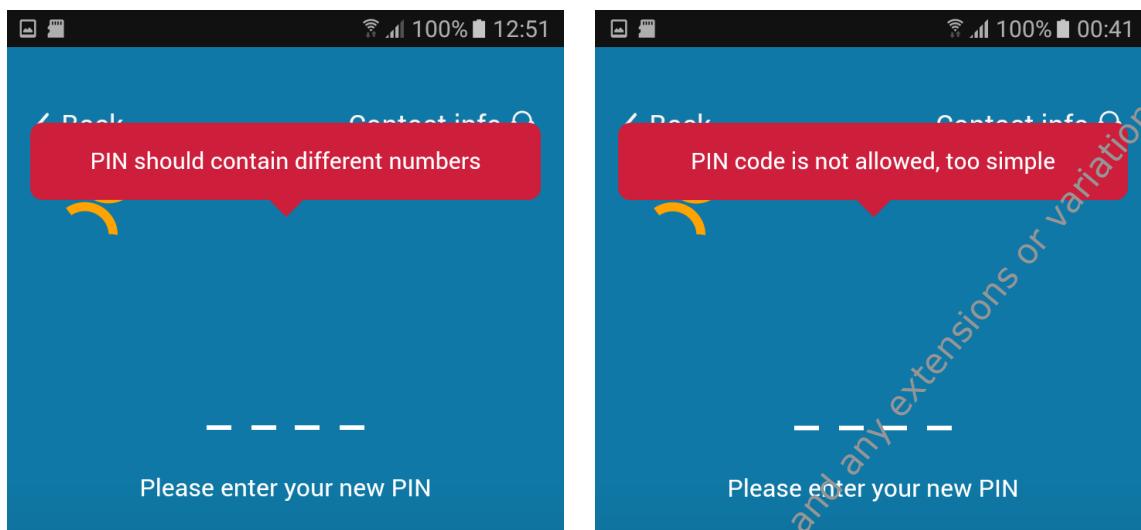
**Create a new PIN**

Screen 7



<b>1</b>	<b>2</b>	<b>3</b>
<b>4</b>	<b>5</b>	<b>6</b>
<b>7</b>	<b>8</b>	<b>9</b>
<b>0</b>		◀ X

Screen 8

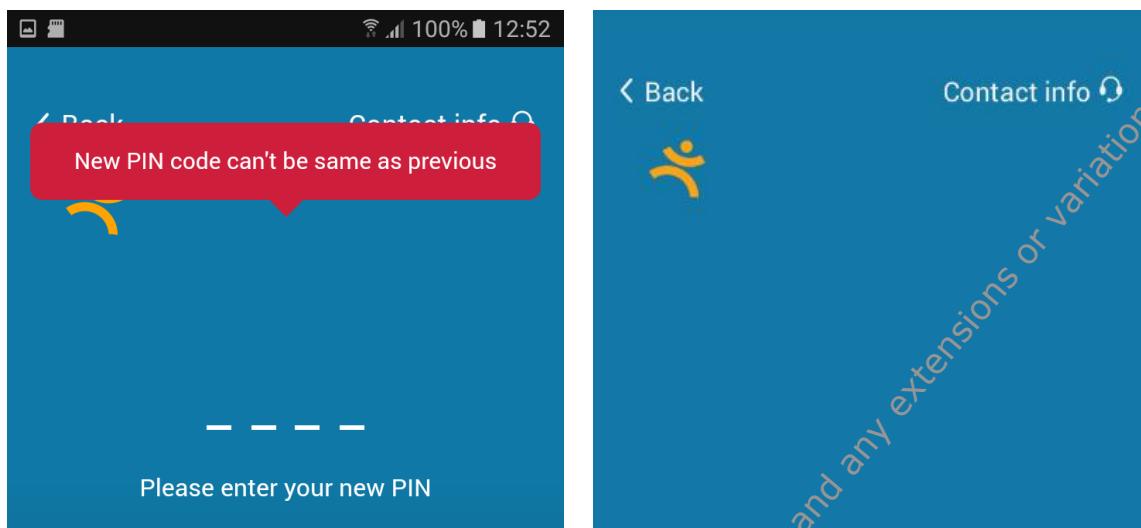


1      2      3  
4      5      6  
7      8      9  
0

Screen 9

1      2      3  
4      5      6  
7      8      9  
0

Screen 10

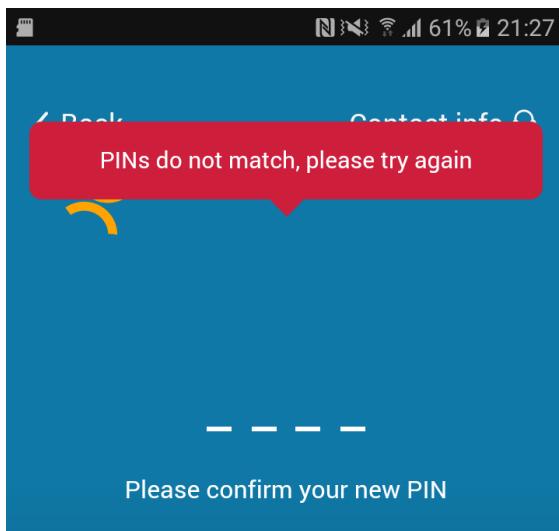


1      2      3  
4      5      6  
7      8      9  
0

Screen 11

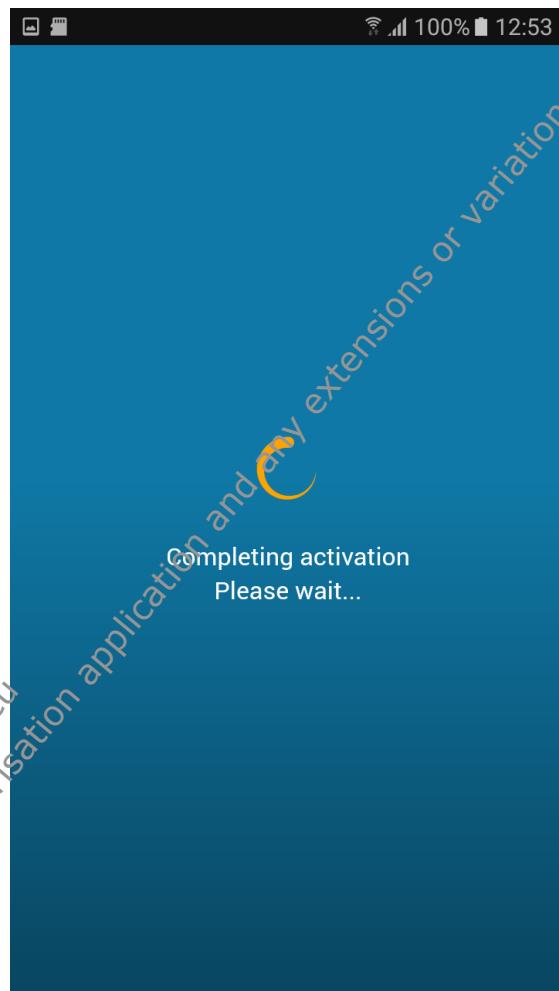
1      2      3  
4      5      6  
7      8      9  
0

Screen 12

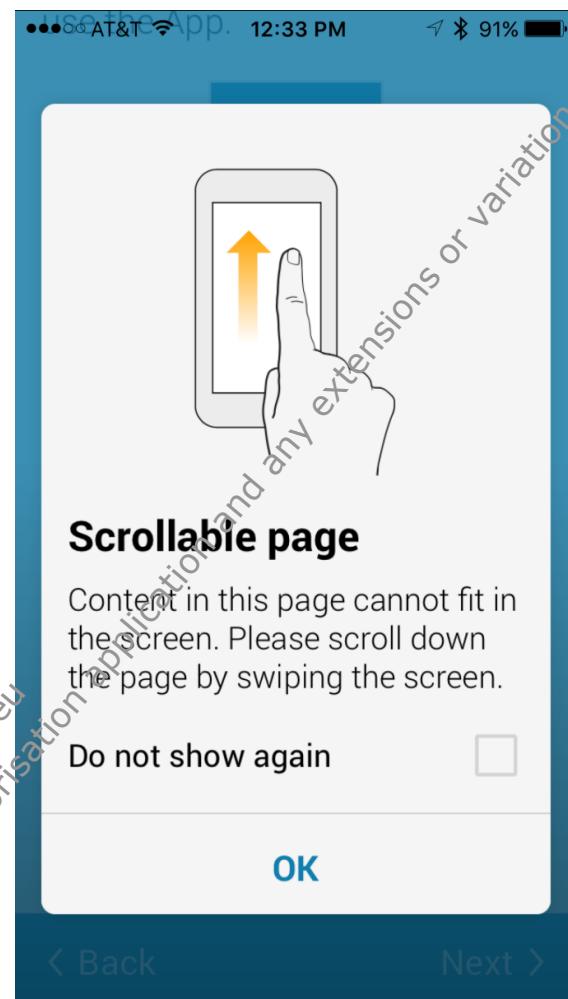
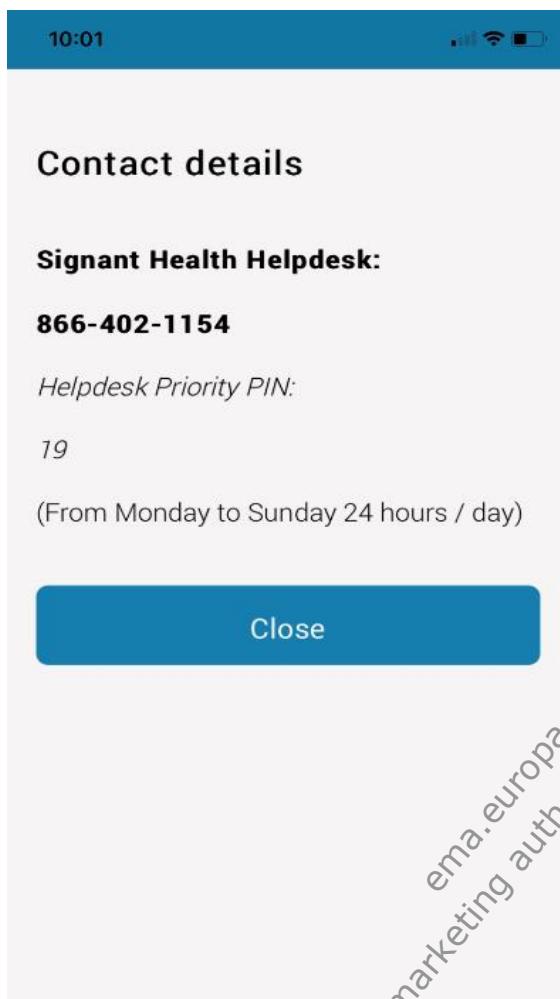


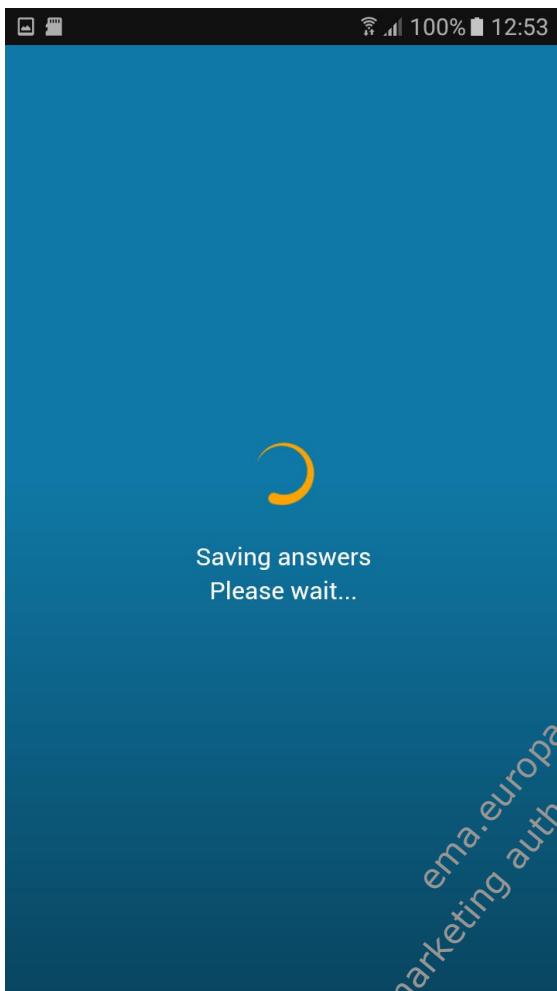
1      2      3  
4      5      6  
7      8      9  
0

Screen 13

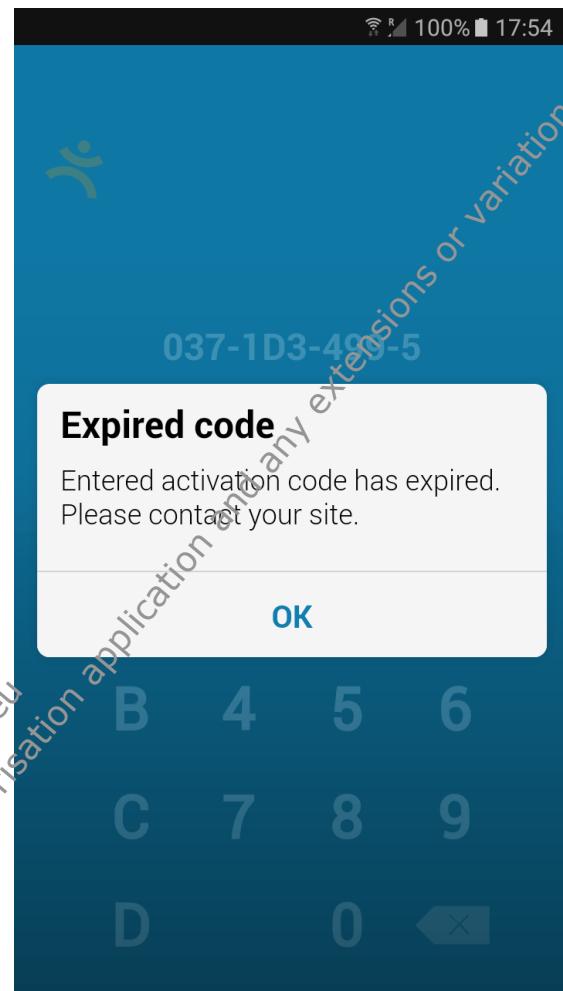


Screen 14

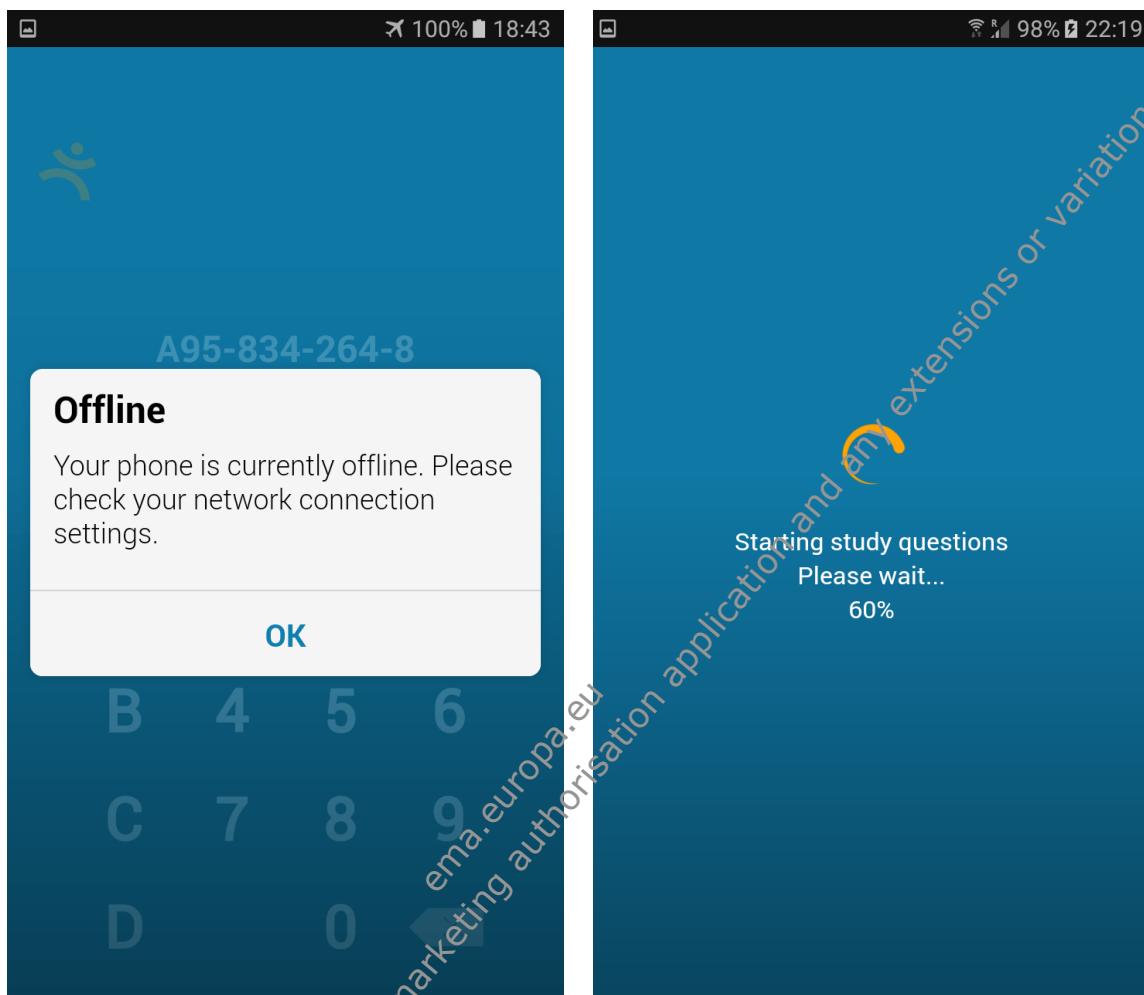


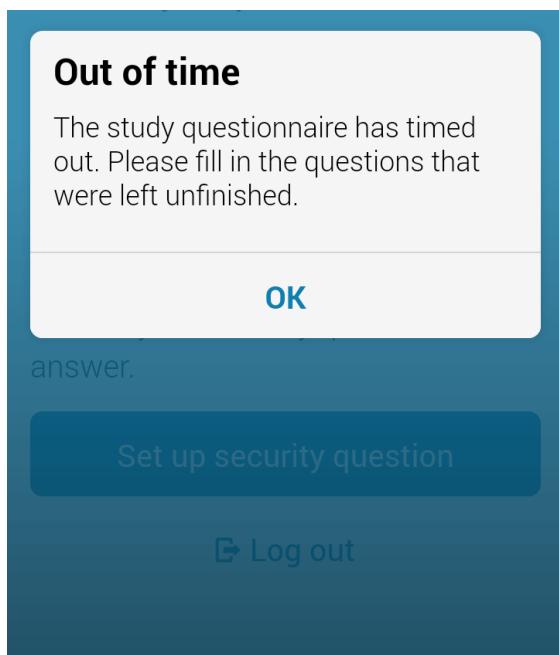


Screen 17



Screen 18





Screen 21



Language: English (US)



TrialMax App

Go to App Store and install the study app.

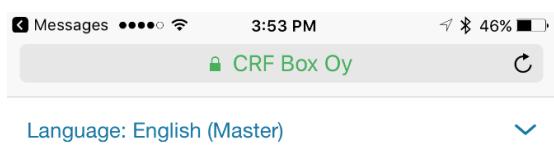
After installation, open the app.

If the installation fails, ask the Study Personnel for assistance or call the helpdesk.

[Go to App Store](#)

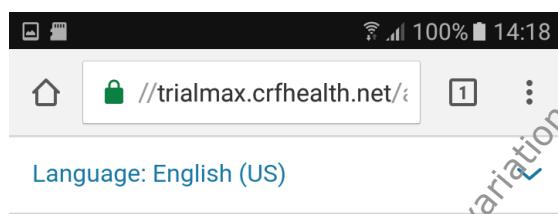


Screen 22



Unfortunately this device cannot run the study app.

Please inform the Study Personnel / contact your site.



TrialMax App

Go to Play Store, and install the study app.

After installation, open the app.

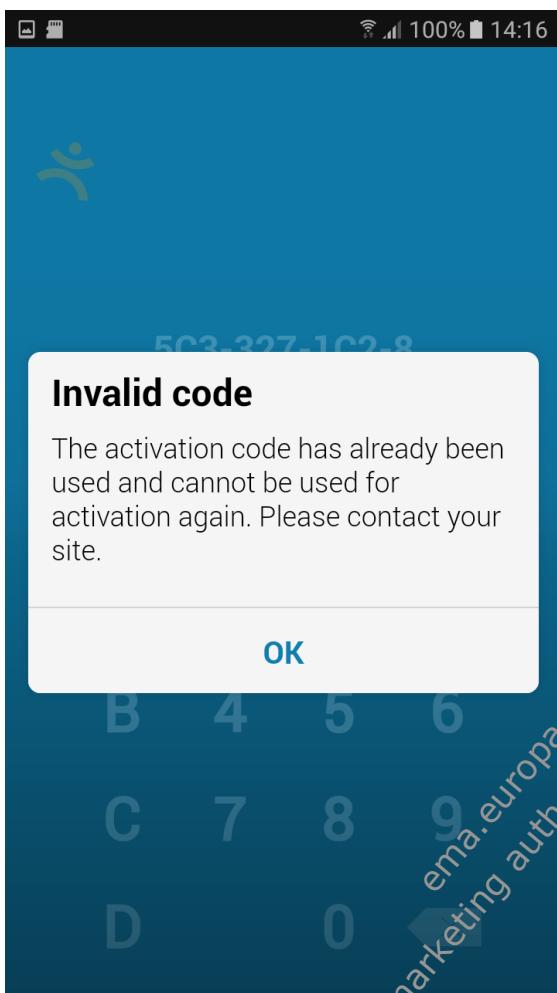
If the installation fails, ask the Study personnel for assistance or call the Helpdesk.

[Go to Play Store](#)

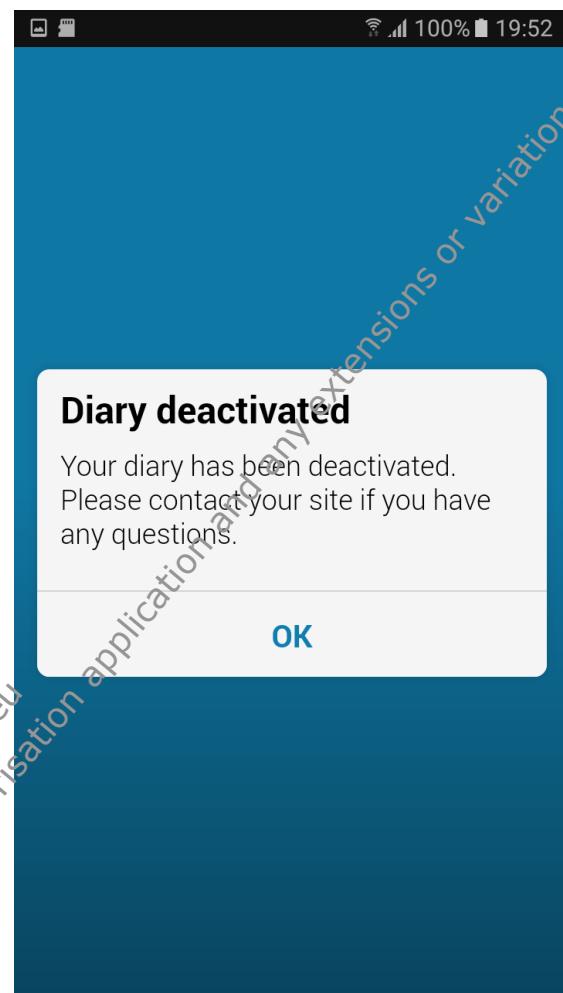


Screen 23

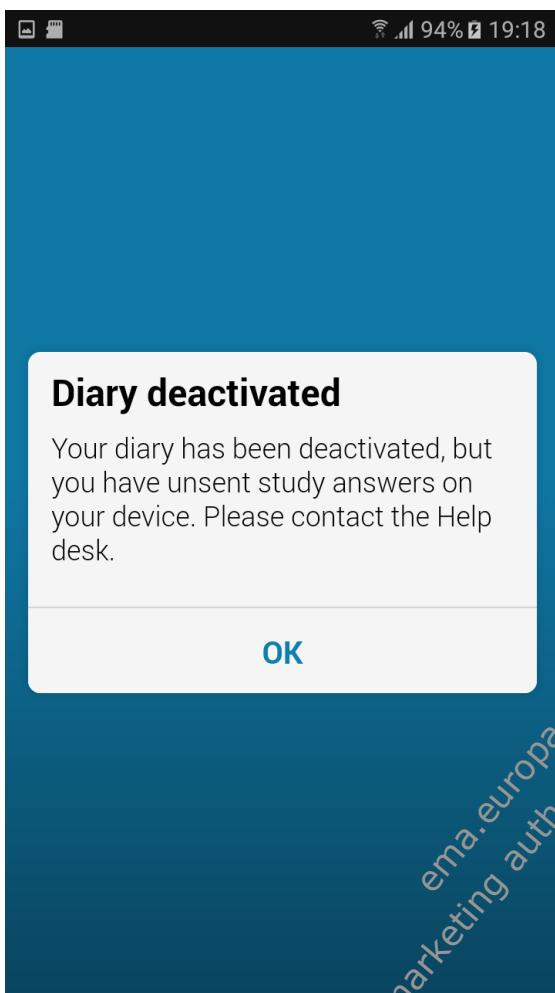
Screen 24



Screen 25



Screen 26

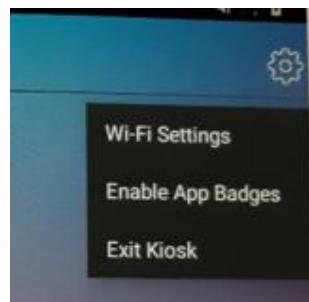


Screen 27

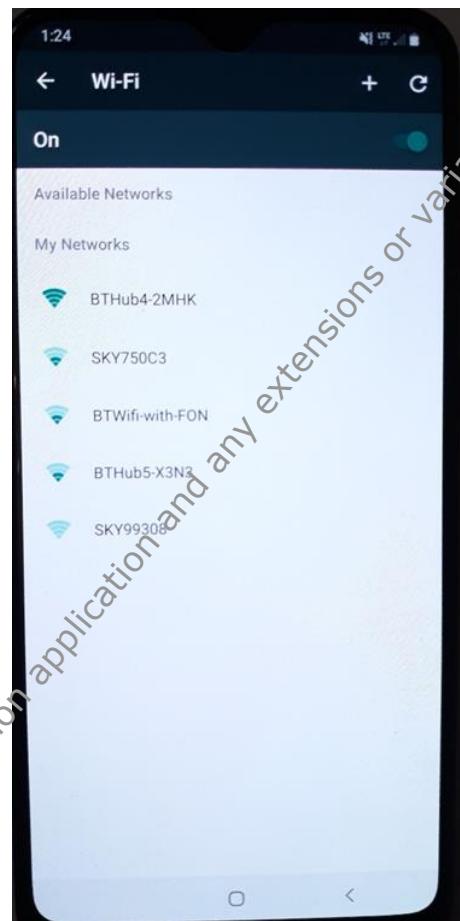


Screen 28

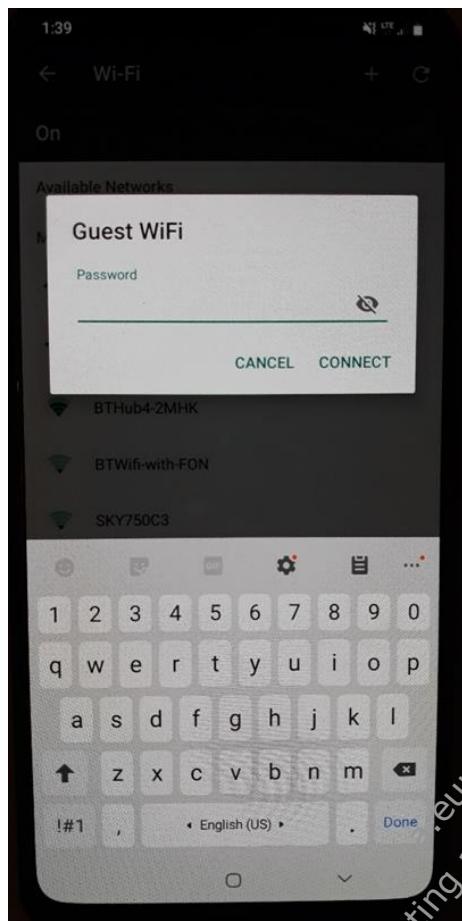
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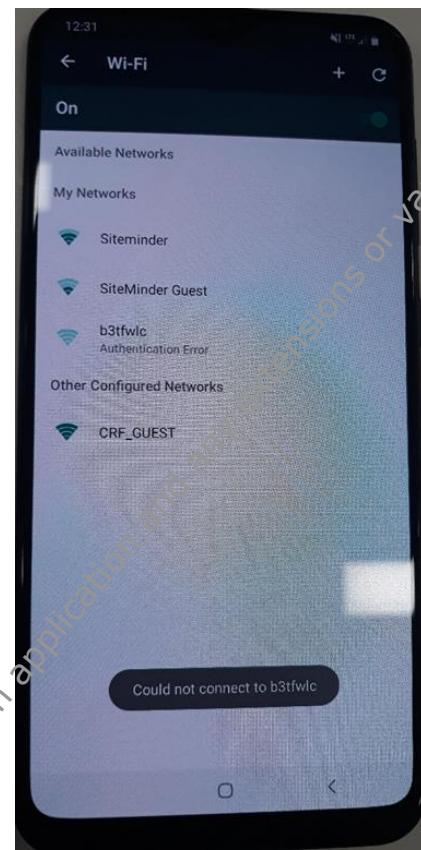
Screen 29



Screen 30

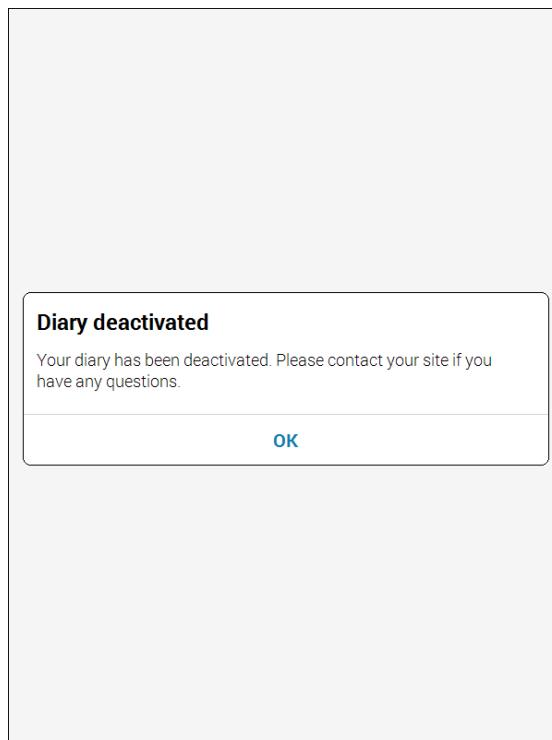


Screen 31



Screen 32

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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

Vaccination Diary
[Computed]
< Exit      Next >

Screen 1

Confirm	
Do you really want to exit without saving?	
No	Yes

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)."

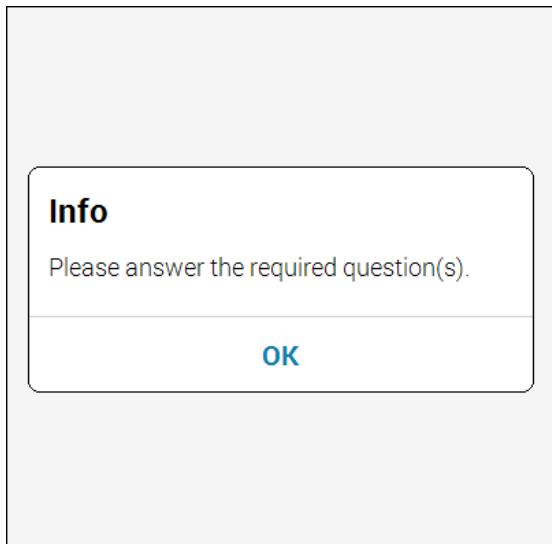
{1} Will display a date

{2} Will display a number of days.

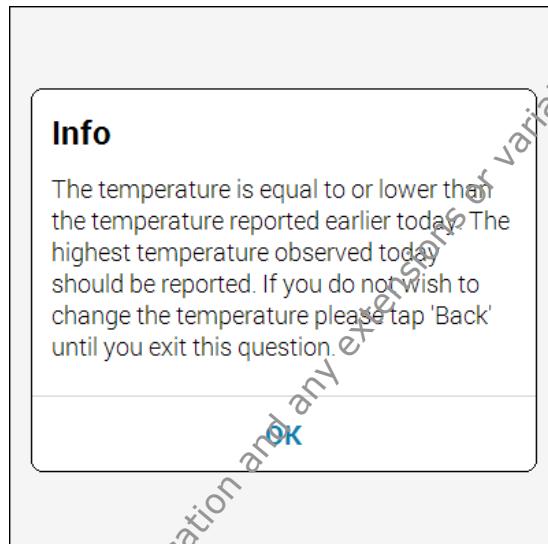
Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 day(s).

Vaccination Diary																				
Please record your highest temperature today in degrees Fahrenheit.																				
<table border="1"><tr><td>°</td><td>°</td><td>°</td><td>°</td></tr><tr><td>9</td><td>9</td><td>9</td><td>9</td></tr><tr><td>0</td><td>0</td><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td><td>2</td><td>2</td></tr></table>	°	°	°	°	9	9	9	9	0	0	0	0	1	1	1	1	2	2	2	2
°	°	°	°																	
9	9	9	9																	
0	0	0	0																	
1	1	1	1																	
2	2	2	2																	
< Back      Next >																				

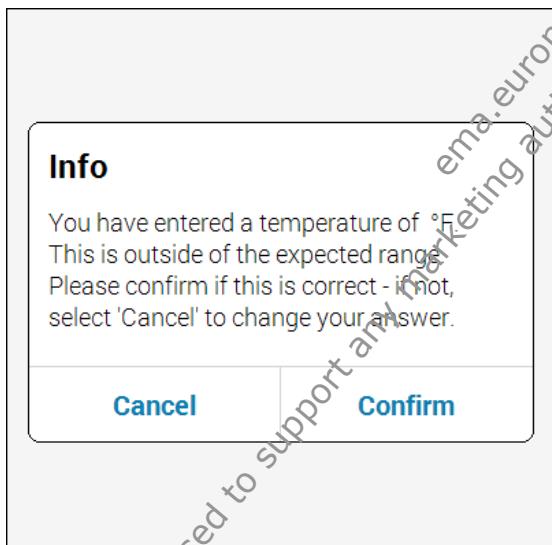
Screen 3



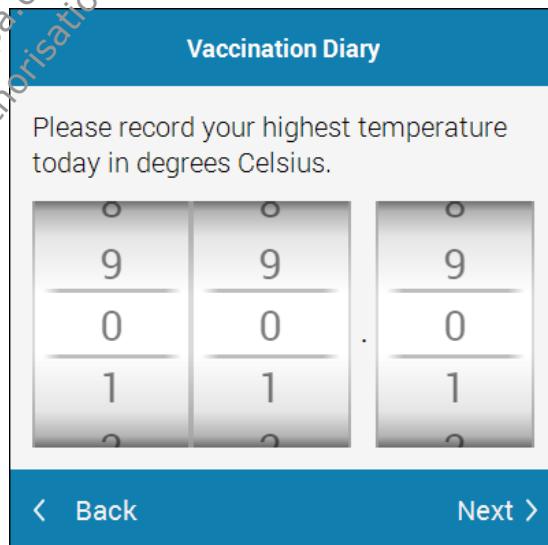
Message 1



Message 2



Message 3



Screen 4

**Info**

You have entered a temperature of °C.  
This is outside of the expected range.  
Please confirm if this is correct - if not,  
select 'Cancel' to change your answer.

**Cancel**      **Confirm**

Message 3

**Vaccination Diary**

Please confirm your highest temperature today:  
[Computed]

< Back      Next >

Screen 5

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

**Info**

Please contact your study doctor as soon as possible.

**OK**

Message 1

**Vaccination Diary**

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

Yes        
No     

< Back      Next >

Screen 6

**Info**

The value you reported is the same as previously reported. If you do not wish to change the response please tap 'Back' until you exit this question.

**OK**

Message 2

**Vaccination Diary**

Please tap on the number from the measuring device for redness.



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

< Back      Next >

Screen 7

**Info**

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

**OK**

Message 2

**Vaccination Diary**

Please confirm the number from the measuring device for redness:

[Computed]

< Back      Next >

Screen 8

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

**Vaccination Diary**

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

Yes

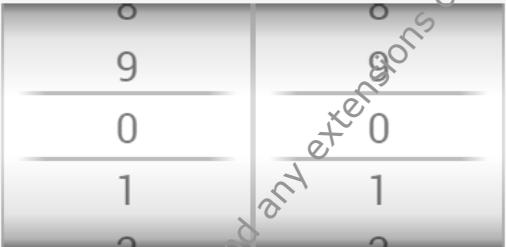
No

< Back **Next >**

Screen 9

**Vaccination Diary**

Please select the number from the measuring device for swelling.



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

< Back **Next >**

Screen 10

**Vaccination Diary**

Please confirm the number from the measuring device for swelling:

[Computed]

< Back **Next >**

Screen 11

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

**Vaccination Diary**

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

Yes

No

< Back **Next >**

Screen 12

**Vaccination Diary**

**Pain at the injection site definitions:**

Mild = Does not interfere with activity

Moderate = Interferes with activity

Severe = Prevents daily activity

< Back      Next >

Screen 13

**Vaccination Diary**

Please indicate whether the pain at the injection site was:

Mild

Moderate

Severe

< Back      Next >

Screen 14

**Info**

Severe = Prevents daily activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No      Yes

Message 2

**Info**

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

OK

Message 4

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back      Next >	

Screen 15

Vaccination Diary	
Today, have you experienced fatigue (tiredness)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back      Next >	

Screen 16

Vaccination Diary	
<b>Fatigue (tiredness) definitions:</b>	
Mild = Does not interfere with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
< Back      Next >	

Screen 17

Vaccination Diary	
Please indicate whether the fatigue (tiredness) was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back      Next >	

Screen 18

<b>Info</b>  Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.  <table border="1"><tr><td>No</td><td>Yes</td></tr></table>		No	Yes
No	Yes		
Vaccination Diary  Did you go to the ER or were you hospitalized for this reaction?  Yes <input type="radio"/> No <input type="radio"/>  <b>&lt; Back</b> <b>Next &gt;</b>			

Message 2

<b>Vaccination Diary</b>  Today, have you experienced headache?  Yes <input type="radio"/> No <input type="radio"/>  <b>&lt; Back</b> <b>Next &gt;</b>	
<b>Vaccination Diary</b>  <b>Headache definitions:</b>  Mild = Does not interfere with activity Moderate = Some interference with activity Severe = Prevents daily routine activity  <b>&lt; Back</b> <b>Next &gt;</b>	

Screen 20

Screen 21

Vaccination Diary	
Please indicate whether the headache was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
< Back Next >	

Screen 22

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 23

Vaccination Diary	
Today, have you experienced vomiting?	
Yes	<input type="radio"/>
No	<input type="radio"/>
< Back Next >	

Screen 24

Vaccination Diary	
<b>Vomiting definitions:</b>	
Mild = 1 to 2 times in 24 hours	
Moderate = More than twice in 24 hours	
Severe = Requires intravenous hydration	
< Back Next >	

Screen 25

**Vaccination Diary**

Please indicate whether the vomiting was:

Mild

Moderate

Severe

< Back Next >

Screen 26

**Info**

Severe = Requires intravenous hydration. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No Yes

Message 2

**Vaccination Diary**

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

Yes

No

< Back Next >

Screen 27

**Vaccination Diary**

Today, have you experienced diarrhea?

Yes

No

< Back Next >

Screen 28

**Vaccination Diary**

**Diarrhea definitions:**

Mild = 2 to 3 loose stools in 24 hours

Moderate = 4 to 5 loose stools in 24 hours

Severe = 6 or more loose stools in 24 hours

< Back      Next >

Screen 29

**Vaccination Diary**

Please indicate whether the diarrhea was:

Mild

Moderate

Severe

< Back      Next >

Screen 30

**Info**

Severe = 6 or more loose stools in 24 hours. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No  Yes

< Back      Next >

Message 2

**Vaccination Diary**

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

Yes

No

< Back      Next >

Screen 31

Vaccination Diary

Today, have you experienced chills?

Yes

No

< Back Next >

Screen 32

Vaccination Diary

**Chills definitions:**

Mild = Does not interfere with activity

Moderate = Some interference with activity

Severe = Prevents daily routine activity

< Back Next >

Screen 33

Vaccination Diary

Please indicate whether the chills were:

Mild

Moderate

Severe

< Back Next >

Screen 34

Vaccination Diary

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

Yes

No

< Back Next >

Screen 35

Vaccination Diary	
Today, have you had new or worsened muscle pain (other than at the injection site)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#">&lt; Back</a> <a href="#">Next &gt;</a>	

Screen 36

Vaccination Diary	
<b>Muscle pain definitions:</b>	
Mild = No interference with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
<a href="#">&lt; Back</a>	<a href="#">Next &gt;</a>

Screen 37

Vaccination Diary	
Please indicate whether the new or worsened muscle pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<a href="#">&lt; Back</a> <a href="#">Next &gt;</a>	

Screen 38

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#">&lt; Back</a>	<a href="#">Next &gt;</a>

Screen 39

**Vaccination Diary**

Today, have you had any new or worsened joint pain?

Yes

No

< Back **Next >**

Screen 40

**Vaccination Diary**

**Joint pain definitions:**

Mild = No interference with activity

Moderate = Some interference with activity

Severe = Prevents daily routine activity

< Back **Next >**

Screen 41

**Vaccination Diary**

Please indicate whether the new or worsened joint pain was:

Mild

Moderate

Severe

< Back **Next >**

Screen 42

**Vaccination Diary**

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

Yes

No

< Back **Next >**

Screen 43

**Vaccination Diary**

Today, have you taken any medication to treat fever or pain?

Yes

No

< Back Next >

Screen 44

**Info**

You have reported taking medication to treat fever or pain. Is your answer correct?

No	Yes
----	-----

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

**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).

[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

**COVID-19 Illness Diary**

Have you experienced any of the following?

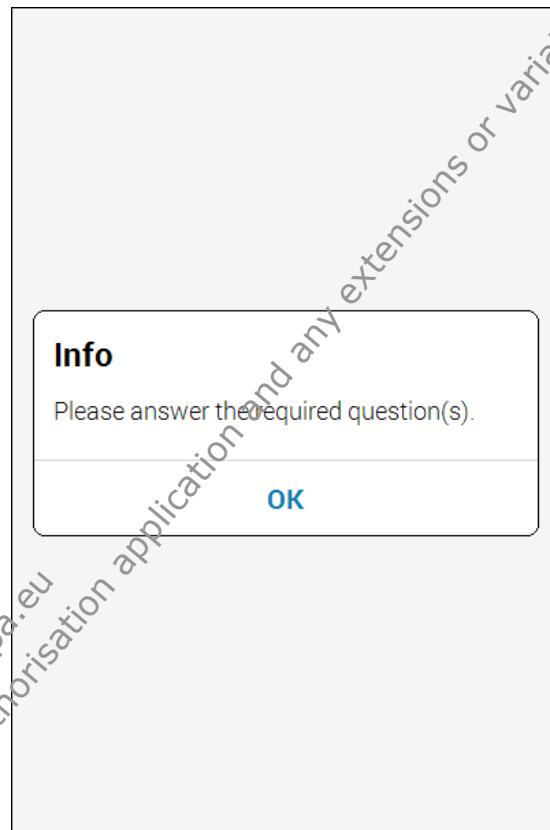
- A diagnosis of COVID-19;
- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste or smell;
- Sore throat;
- Diarrhea;
- Vomiting

Yes

No

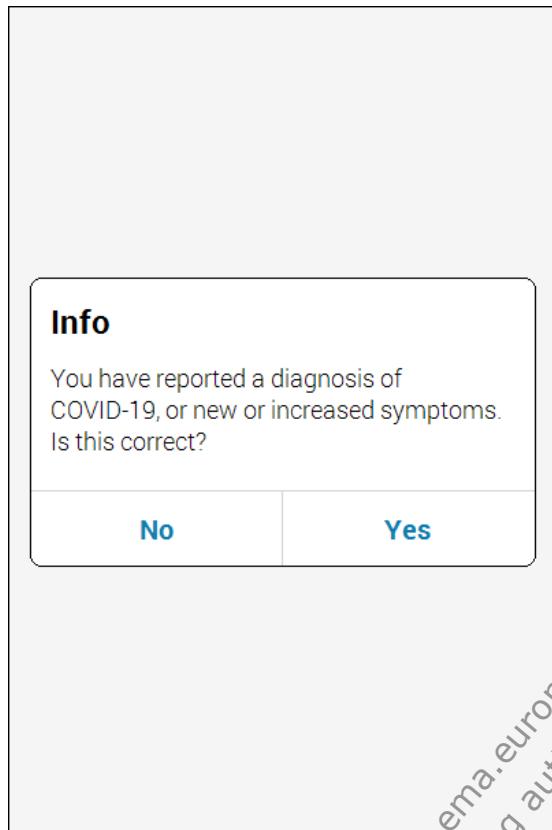
< Exit Next >

Screen 1



Message 1

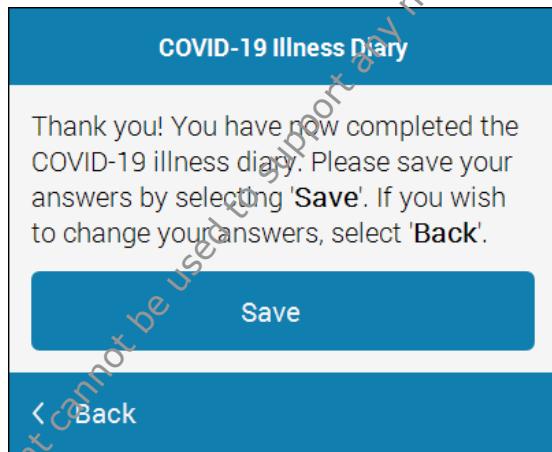
This document cannot be used to support any marketing authorisation application and any extensions or variations thereof



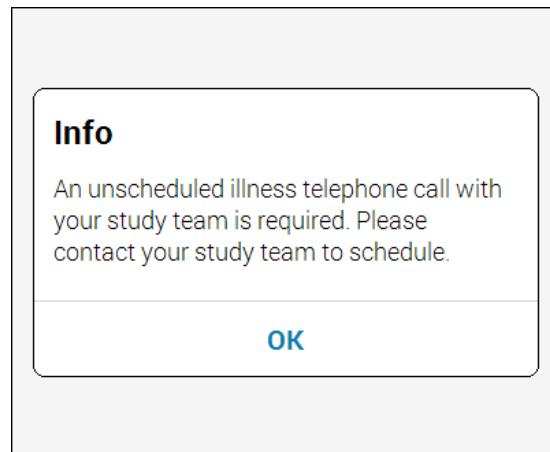
Message 2



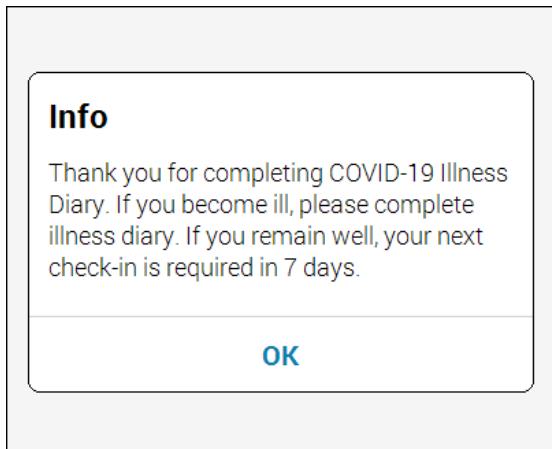
Message 3



Screen 2



Message 1



Message 2

## 5 Form: Patient main menu

**Welcome,**

Thank you for taking part in this Study.  
There are a few things you need to do before you can start filling in your diary.

First you need to set up a security question in case you lose your PIN.

Then you will learn how to complete your diary using a training diary.

Tap 'Set up security question' to choose your security question and answer.

**Set up security question**

**Log out**

Screen 1

**Log out?**

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

No	Yes
----	-----

Message 1

**Thank you,**

Your security question and answer have been saved.

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

**Go to training diary**

**Log out**

Screen 2

**Log out?**

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

No	Yes
----	-----

Message 1

## Reminder time changed

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

[Computed]

[Computed]

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

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

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

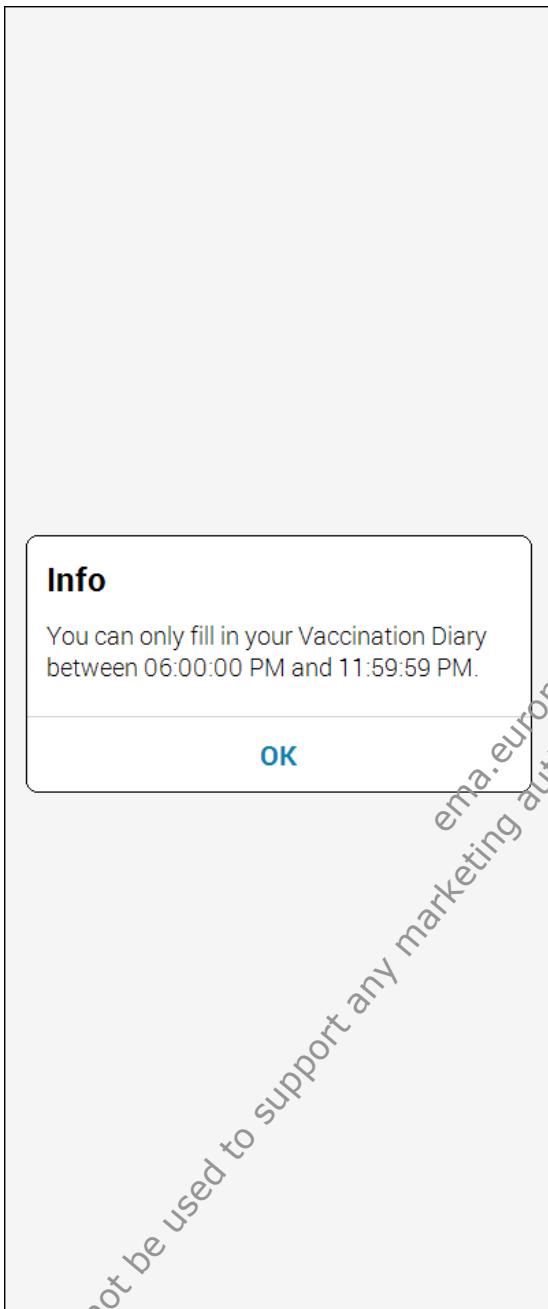
➡️ Log out

Screen 4

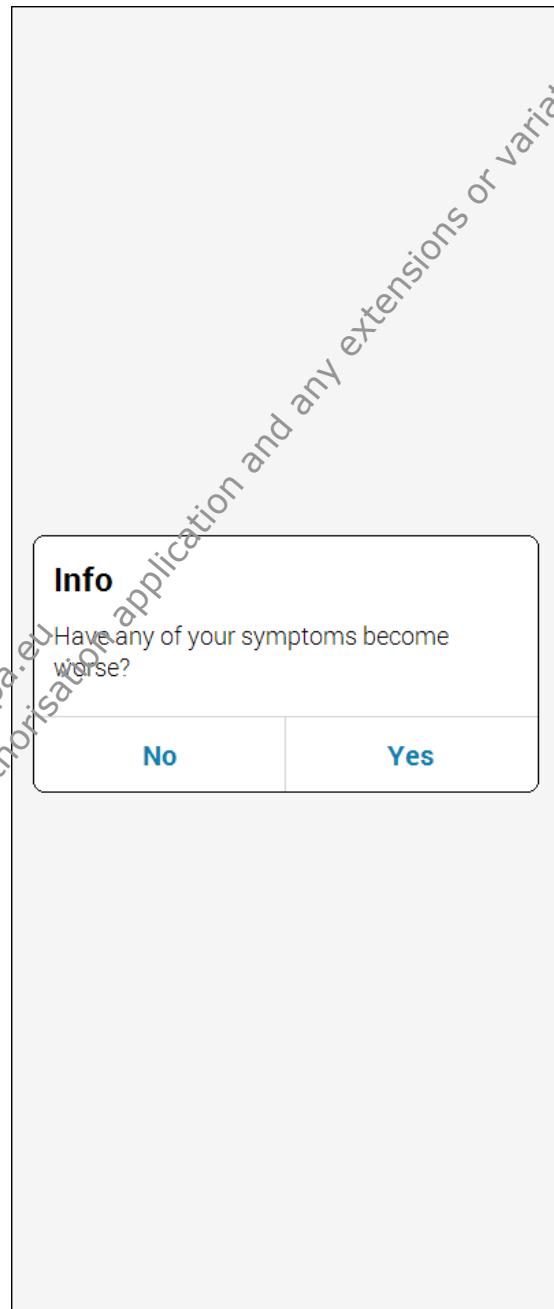
First [Computed] text below Hello, will either display: "<b>You are being reminded to complete your weekly COVID-19 Illness Diary.</b>" or "<b>You are being reminded to complete your daily <u>Vaccination Diary</u>.</b>"

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

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



Message 1



Message 2

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

Vaccination Diary

Update Symptoms

Temperature

Redness

Swelling

Injection site pain

Fatigue (tiredness)

Headache

Vomiting

Diarrhea

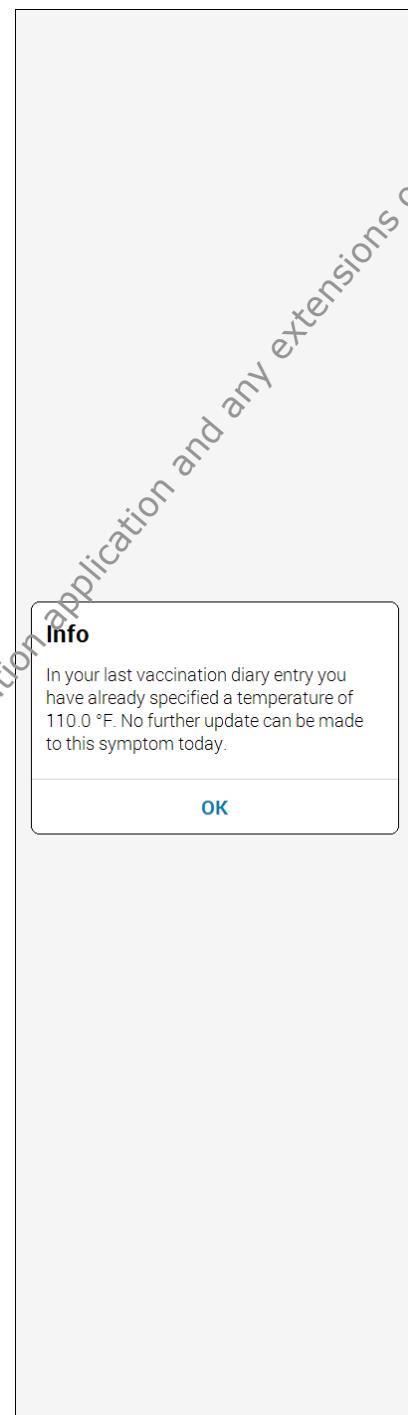
Chills

Muscle pain

Joint pain

< Back

Screen 5



Message 2

**Info**

In your last vaccination diary entry you have already specified a temperature of 43.3 °C. No further update can be made to this symptom today.

OK

Message 3

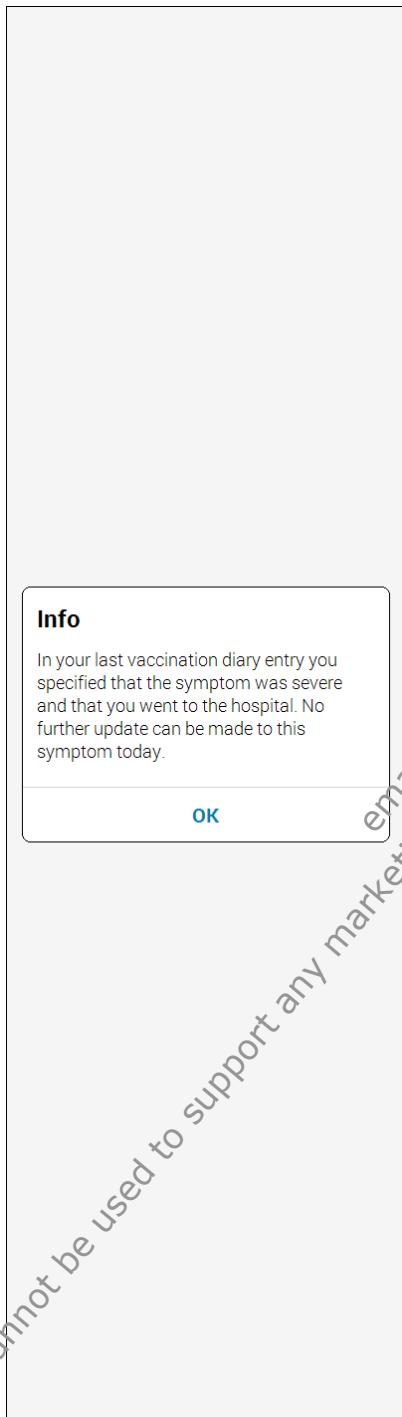
**Info**

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

OK

Message 5

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Message 9

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ema.europa.eu

## 6 Form: Subject training diary

**Training**



# Welcome to the Training!

Here you will learn:

- About the app
- How to fill in your diary

Use the '**Next >**' button below to move through the Training. Use the '**< Back**' button to go back.

**Let's get started!**

**< Back**      **Next >**

Screen 1

**Confirm**

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

**No**      **Yes**

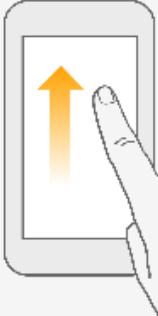
Message 1

**Training**



## About scrolling

Some pages have more content than can fit onto one screen. Swipe the screen upwards to scroll to the rest of the page.



You will be shown a pop-up guide whenever the page is scrollable.

Tap '**Next >**' to continue

**< Back** **Next >**

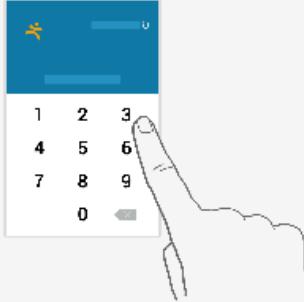
Screen 2

**Training**



## Logging in with your PIN

You need to log in every time you use the app.



If you forget your PIN, please call the Helpdesk. More information about the Helpdesk will follow.

Do not share your PIN with anyone else, not even your Study doctor or nurse.

Tap '**Next >**' to continue

**< Back** **Next >**

Screen 3

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**Training**



## Diary reminder

A notification has been set up to remind you to fill in your diary.

[Computed]

You may change the reminder time in the Settings page.

Tap 'Next >' to continue

**< Back** **Next >**

Screen 4

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

**Training**



## Sending your answers

Your answers will be sent automatically every time you log in or complete a questionnaire.

You can use the app and fill in your diary offline, but please remember to use the diary online when you can.

Tap 'Next >' to continue

**< Back** **Next >**

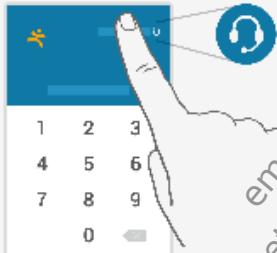
Screen 5

**Training**



## The Helpdesk

We hope you find the app easy to use. If you do have problems, the Helpdesk is always there for you.



You can find the Helpdesk number by tapping the 'Contact info' button on the login screen. The number is also available in your Quick Reference Guide.

Tap 'Next >' to continue

< Back      Next >

Screen 6

**Training**



## Your turn to practice!

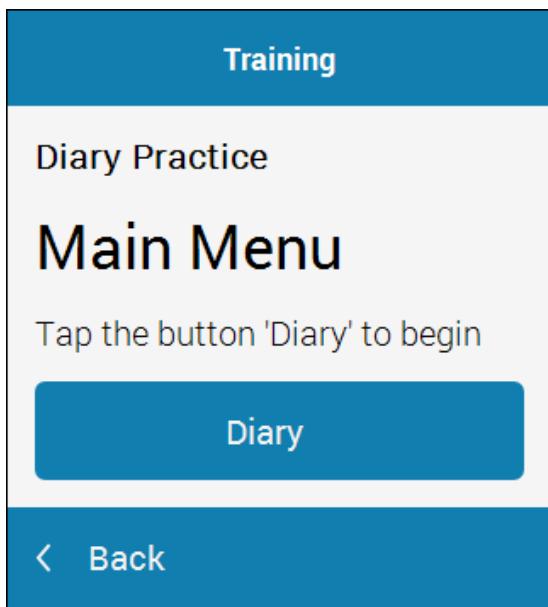
You are about to see a page that we call the 'Main Menu'.

Tap the button 'Diary' to start practicing.

The answers you give during this training session will not be saved.

< Back      Next >

Screen 7



Screen 8

**Training**

Diary Practice

Please tap the option that best describes the weather.

Sunny

Cloudy

Raining

Snowing

< Back      Next >

This screen is titled 'Training' and 'Diary Practice'. It contains a text instruction: 'Please tap the option that best describes the weather.' Below this are four weather options: 'Sunny', 'Cloudy', 'Raining', and 'Snowing', each accompanied by a radio button. At the bottom left is a back arrow labeled '< Back' and at the bottom right is a next arrow labeled 'Next >'.

Screen 9

**Info**

Please answer the required question(s).

**OK**

**Training**

**Diary Practice**

Please enter the hours you thought about the weather last week.

9	9
0	0
1	1
2	2

**< Back**      **Next >**

Message 1      Screen 10

**Training**

**Diary Practice**

When completing your diary, you will be asked to save your answers at the end. If you exit without selecting save, your answers will not be saved.

Please press the 'Save' button below to continue.

**Save**

**< Back**

Screen 11

**Training**



**Well done!**

Thank you for completing the Training diary. Now you are ready to start using your App.

If you would like to repeat the Training later, just tap the 'Training review' button in the Main Menu.

Tap 'Next >' to continue to the 'Main menu'.

**< Back**      **Next >**

Screen 12

## 7 Form: Settings

Reminder time
The current reminder time of the diary is displayed below.
<b>Set Time</b> >
Tap the time if you want to change the reminder time. Only times from 6:00 PM to 10:00 PM are allowed.
<b>&lt; Back</b>

Screen 1

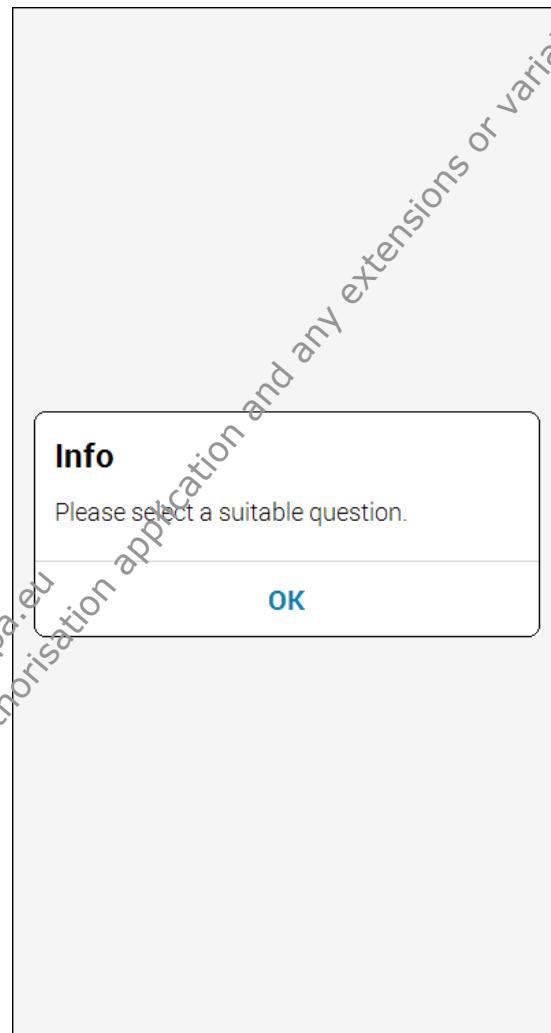
Set Time		
10	:	50
11	:	59
12	:	00
01	:	01
02	:	PM
<b>Cancel</b>		<b>Set</b>

Popup input 1

## 8 Form: Security question

Security question	
Choose your security question. The answer should have only two digits. Your question and answer will be needed if you forget your PIN.	
[Computed]	<input type="radio"/>
Then tap the 'Next >' button	
<a href="#">&lt; Back</a>	<a href="#">Next &gt;</a>

Screen 1



Message 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)'

<p><b>Log out?</b></p> <p>Do you want to log out? You need to complete the security question and the training before you can access the diary.</p> <table border="1" style="margin-top: 10px;"><tr><td style="padding: 5px; text-align: center;">No</td><td style="padding: 5px; text-align: center;">Yes</td></tr></table>	No	Yes	<p><b>Security question</b></p> <p>[Computed]</p> <p>Tap below to select the two digit answer to your question:</p> <p style="text-align: right;">Set Value &gt;</p> <p>After successfully selecting the digits, you can see them above.</p> <p>If you want to change your security question, tap the '<b>&lt; Back</b>' button on the lower left corner to go back.</p> <p>Please save your question and answer by tapping the '<b>Save</b>' button. Once saved, you will not be able to come back to change your selections.</p> <p style="text-align: left; background-color: #0070C0; color: white; padding: 5px;"><b>&lt; Back</b> <b>Save</b></p>
No	Yes		

Message2

Screen 2

[Computed] will display

'Your question:<br/><br/><b><i>{1}</i></b>'

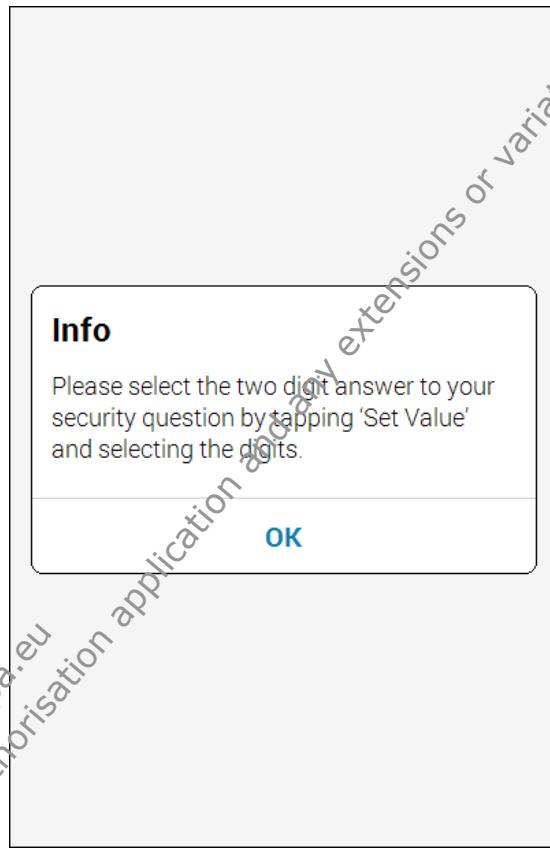
{1} will show the question selected on Screen 1

**Set Value**

○	○
9	9
0	0
1	1
2	2

**Cancel**      **Set**

Popup input 1



Message 1

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# SCREEN REPORT APPROVAL

## Content for Approval

Language	English for United States		
Subject screen report	PPD	SR_enUS	Version 3 Date 02-Oct-2020

## CUSTOMER

### Approval

Name and Title: PPD	Signature:
Company: Pfizer	Role: Study Manager Date: 02-oct-2020   13:16 EDT DocuSigned by: PPD PPD

02-oct-2020 | 13:16 EDT

## SIGNANT HEALTH

### Approval

Name: PPD	Signature:
Title: PPD	Date: 02-oct-2020   13:15 EDT DocuSigned by: PPD PPD

02-oct-2020 | 13:15 EDT

# A-1426-0082 / C4591001

## App Subject Facing Screen Report

Localized texts are displayed in English (US).

### Contents

1 Notifications / Subject card.....	2
2 Common.....	5
3 Form: Vaccination Diary.....	22
4 Form: Patient Main Menu.....	37
5 Form: Subject training diary.....	42
6 Form: Settings .....	49
7 Form: Security question.....	50

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

Month	January	February	March	April	May	June	July	August	September	October	November	December
Abbr.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	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 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

### **Email notification only: [ ----- ]**

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

### **SMS Body for Provisioned Devices:**

Welcome to the C4591001 Study! Activate the TrialMax App with code:  
[Activation Code]

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

Welcome to the C4591001 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

**Email notification only:** [ -----

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

**SMS Body for BYOD subjects:**

Welcome to the C4591001 Study! To install the TrialMax App, select the link:

[Link]

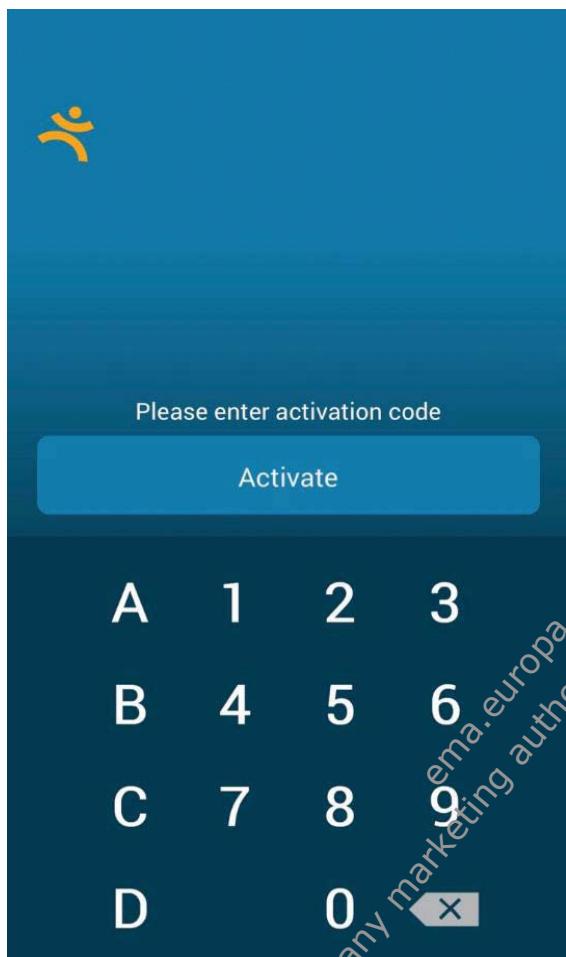
Activate the TrialMax App with code:

[Activation Code]

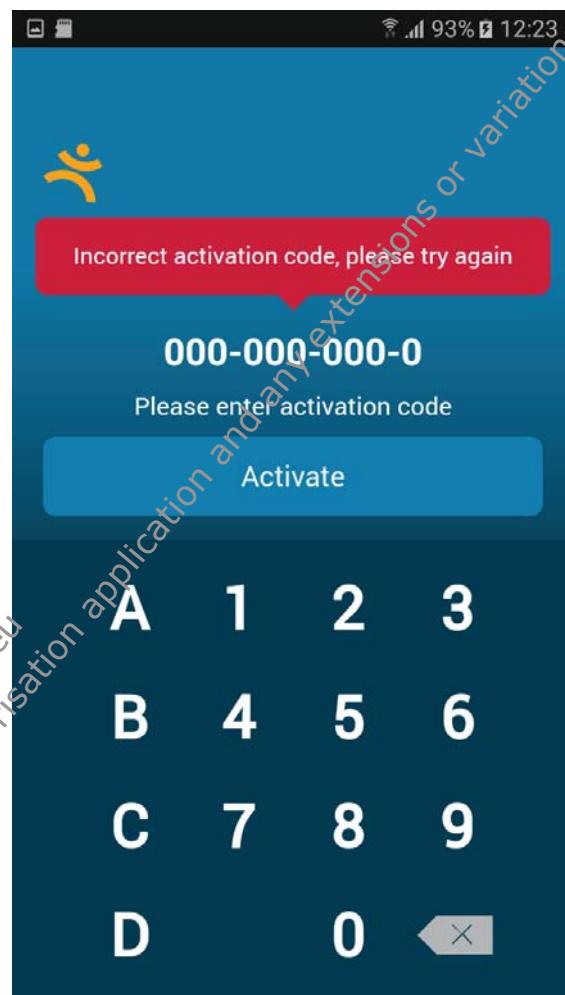
**App notification:**

Please fill in your vaccination diary!

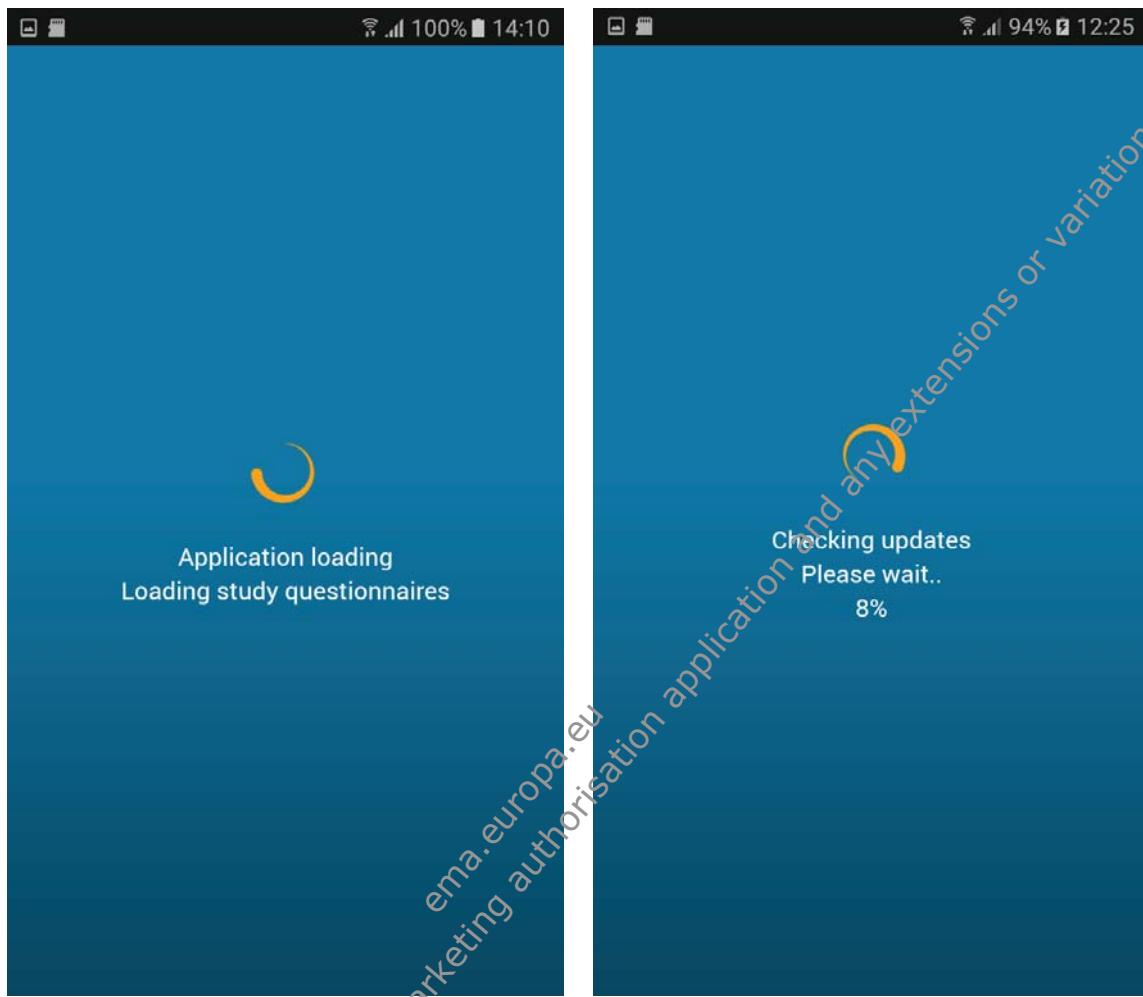
## 2 Common

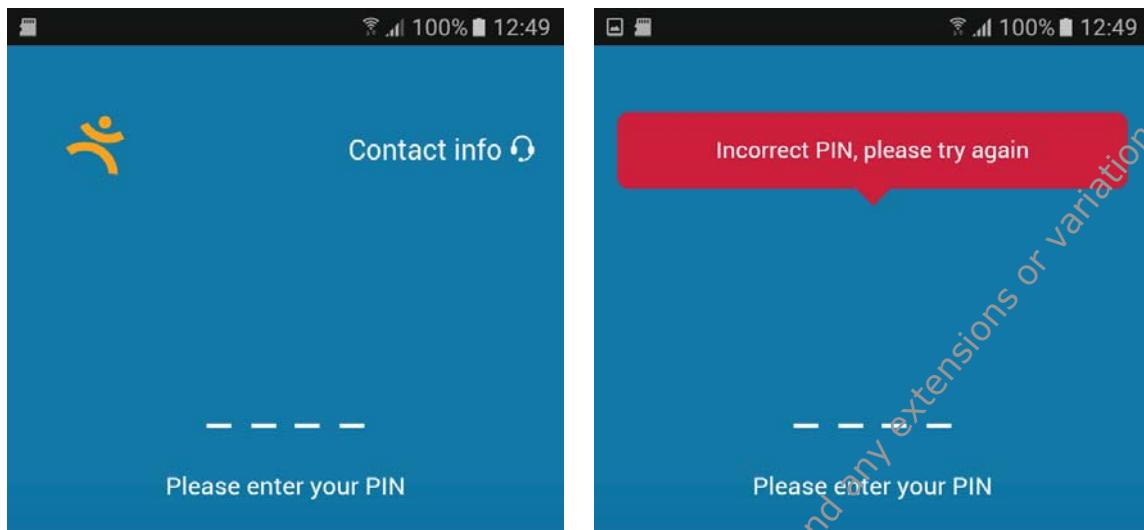


Screen 1



Screen 2



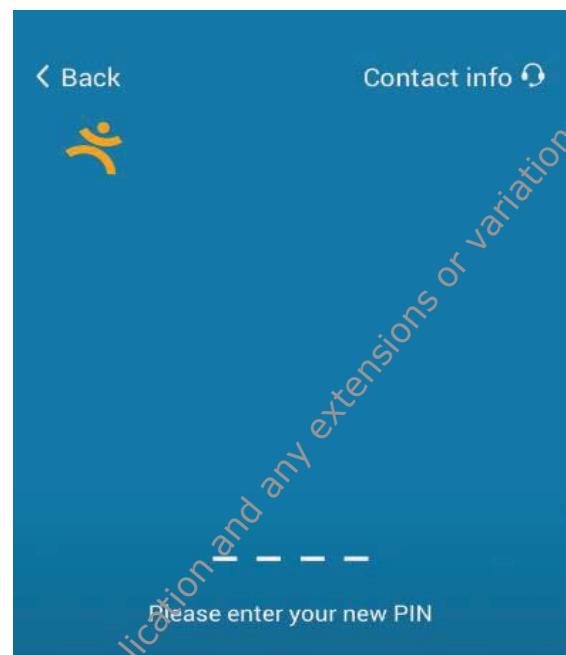
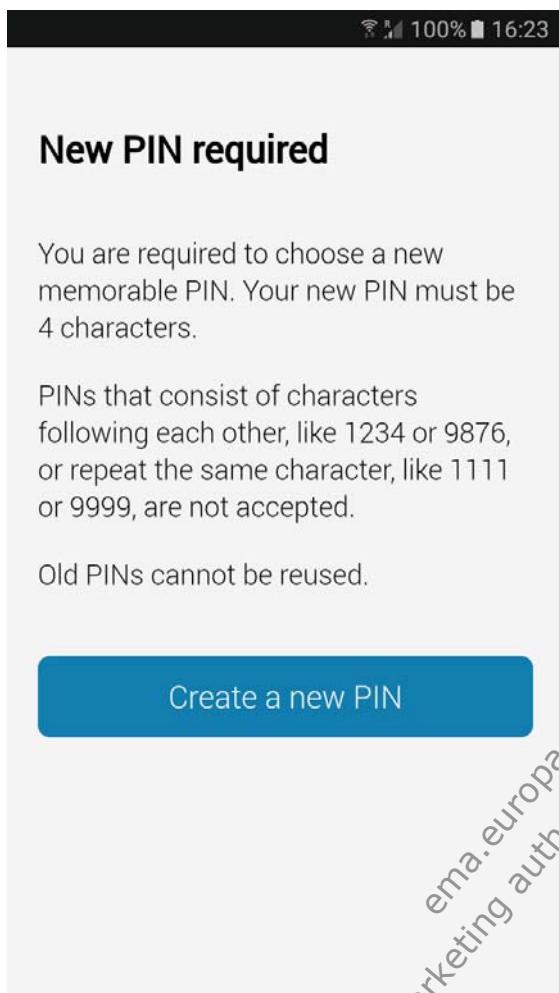


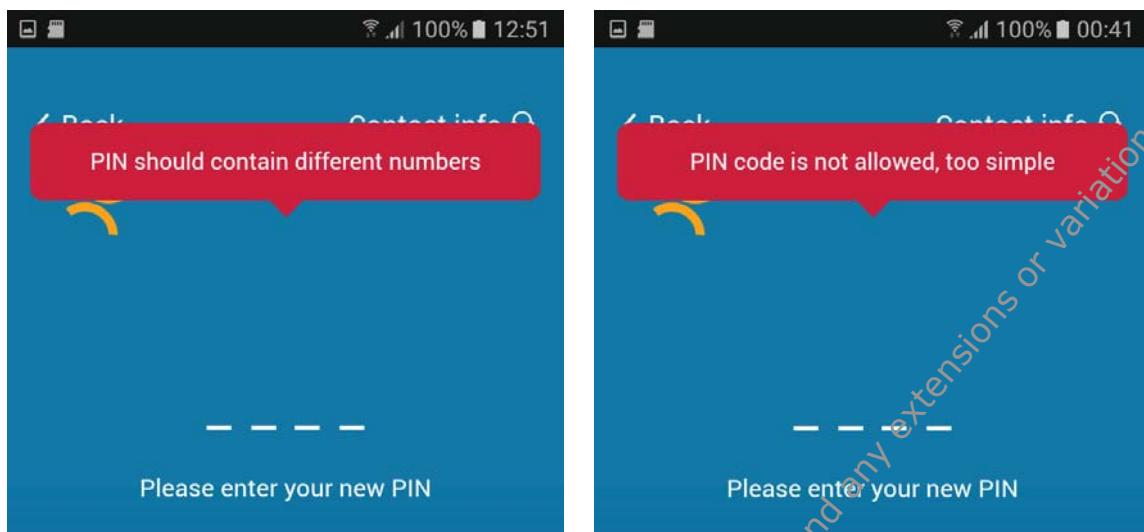
<b>1</b>	<b>2</b>	<b>3</b>
<b>4</b>	<b>5</b>	<b>6</b>
<b>7</b>	<b>8</b>	<b>9</b>
<b>0</b>		

Screen 5

<b>1</b>	<b>2</b>	<b>3</b>
<b>4</b>	<b>5</b>	<b>6</b>
<b>7</b>	<b>8</b>	<b>9</b>
<b>0</b>		

Screen 6



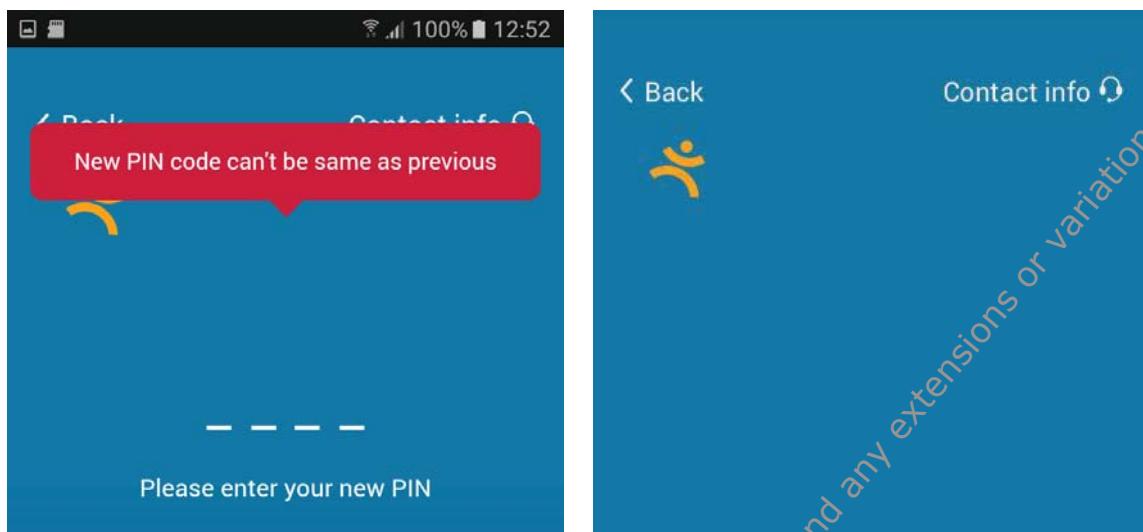


<b>1</b>	<b>2</b>	<b>3</b>
<b>4</b>	<b>5</b>	<b>6</b>
<b>7</b>	<b>8</b>	<b>9</b>
<b>0</b>		

Screen 9

<b>1</b>	<b>2</b>	<b>3</b>
<b>4</b>	<b>5</b>	<b>6</b>
<b>7</b>	<b>8</b>	<b>9</b>
<b>0</b>		

Screen 10

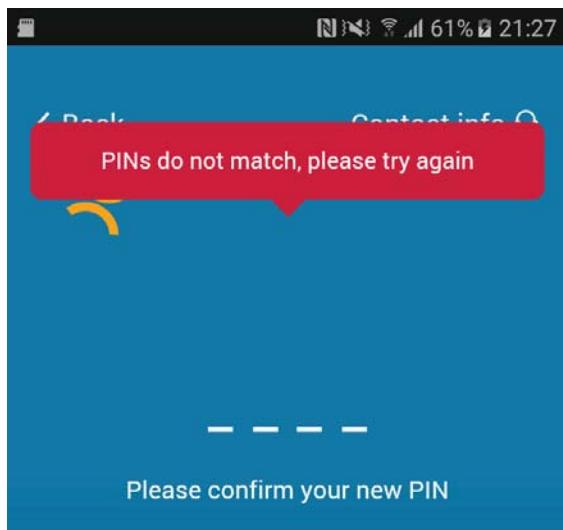


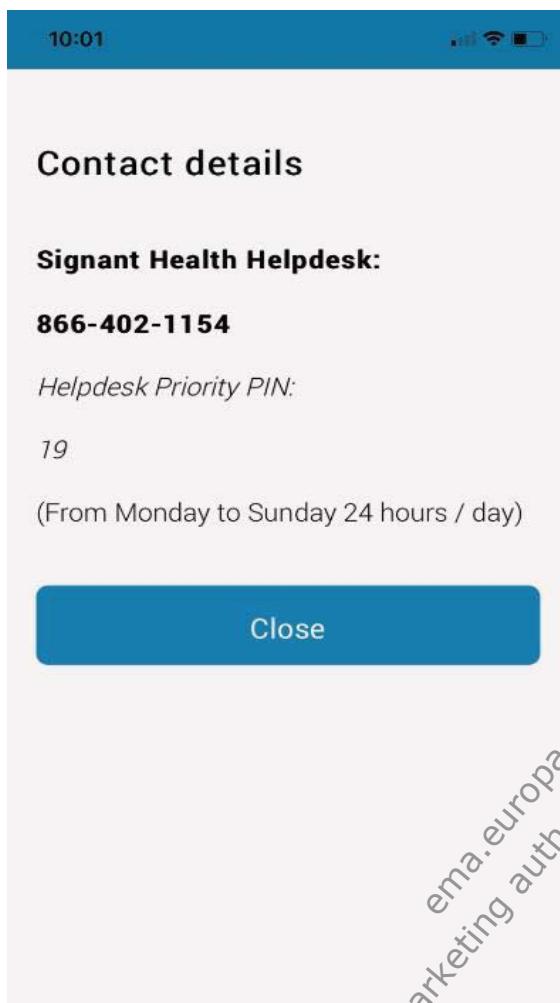
1      2      3  
4      5      6  
7      8      9  
0

Screen 11

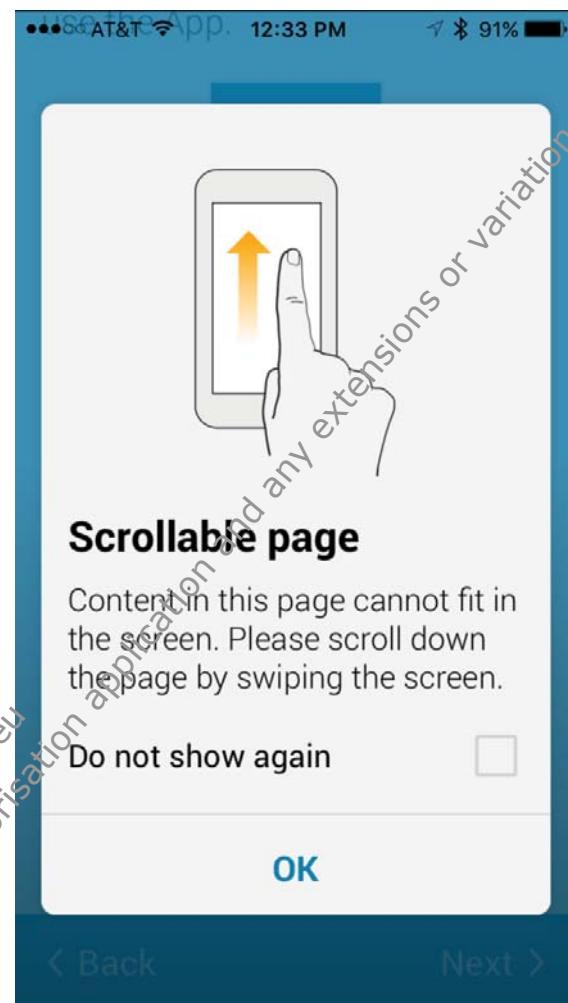
1      2      3  
4      5      6  
7      8      9  
0

Screen 12

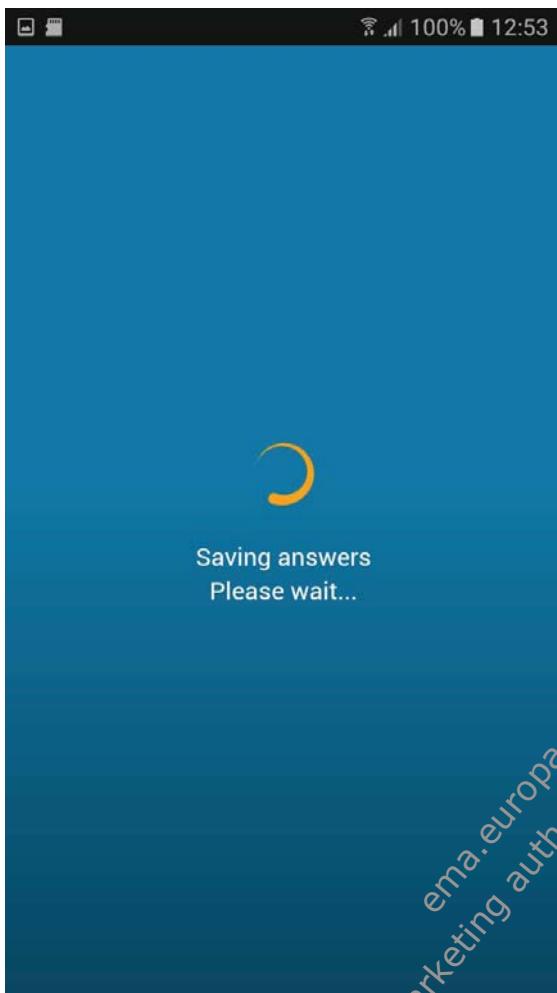




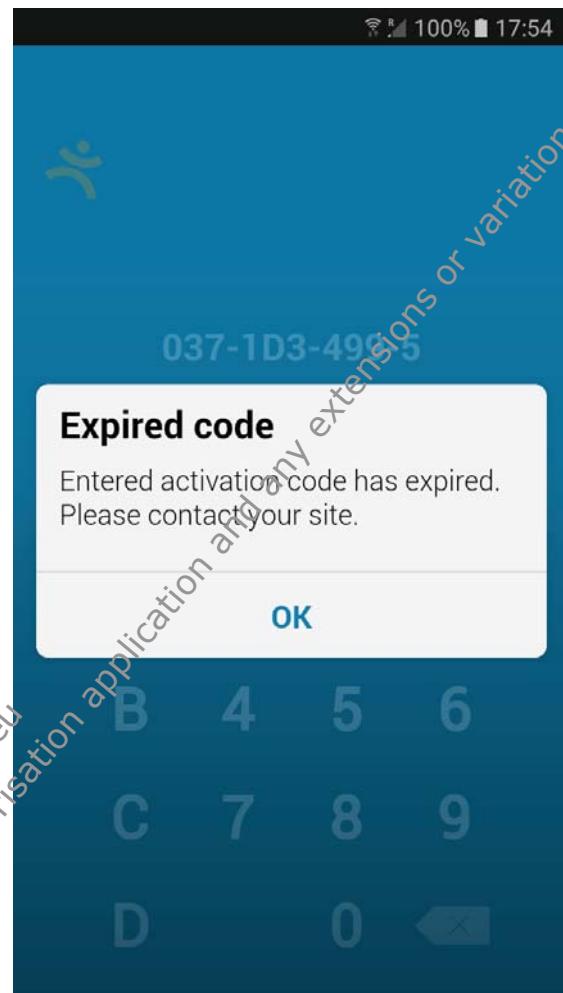
Screen 15



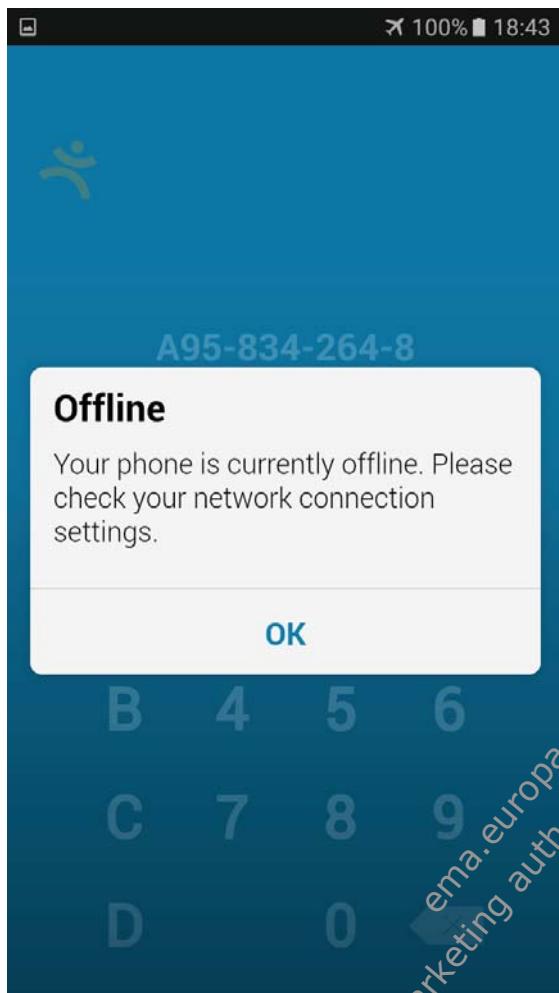
Screen 16



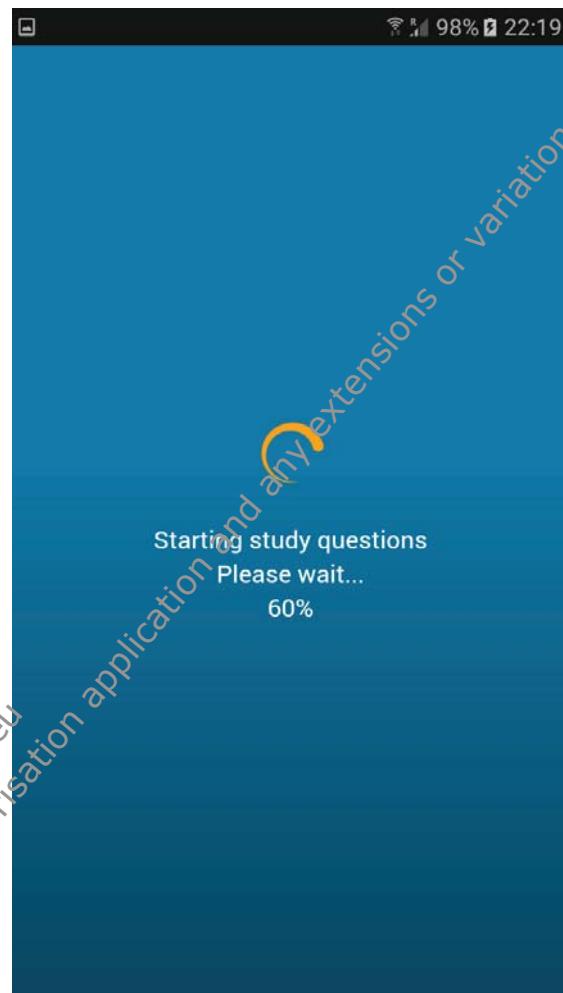
Screen 17



Screen 18

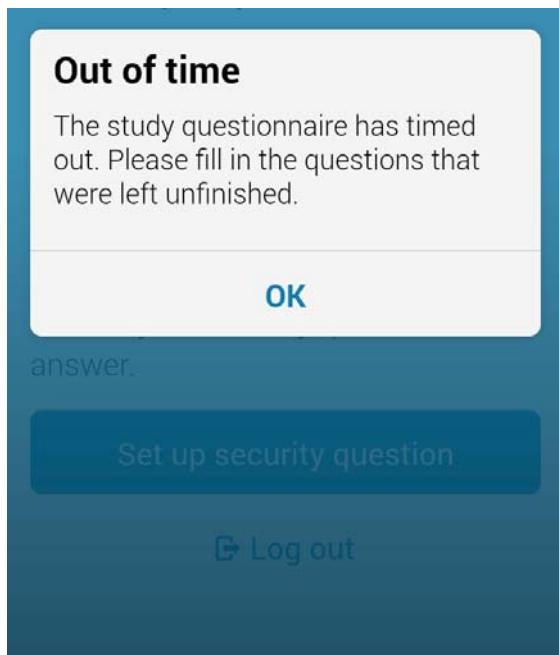


Screen 19



Screen 20

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Screen 21



Language: English (US)



TrialMax App

Go to App Store, and install the study app.

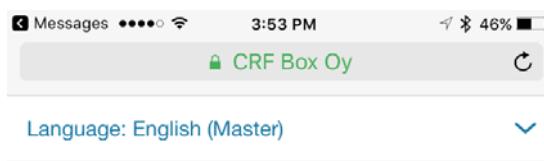
After installation, open the app.

If the installation fails, ask the Study Personnel for assistance or call the Helpdesk.

[Go to App Store](#)

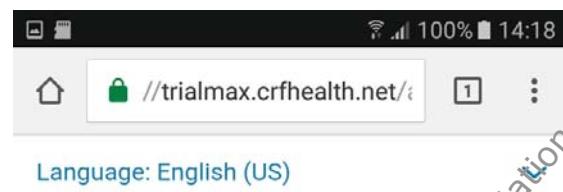


Screen 22



Unfortunately this device cannot run the study app.

Please inform the Study Personnel / contact your site.



TrialMax App

Go to Play Store and install the study app.

After installation, open the app.

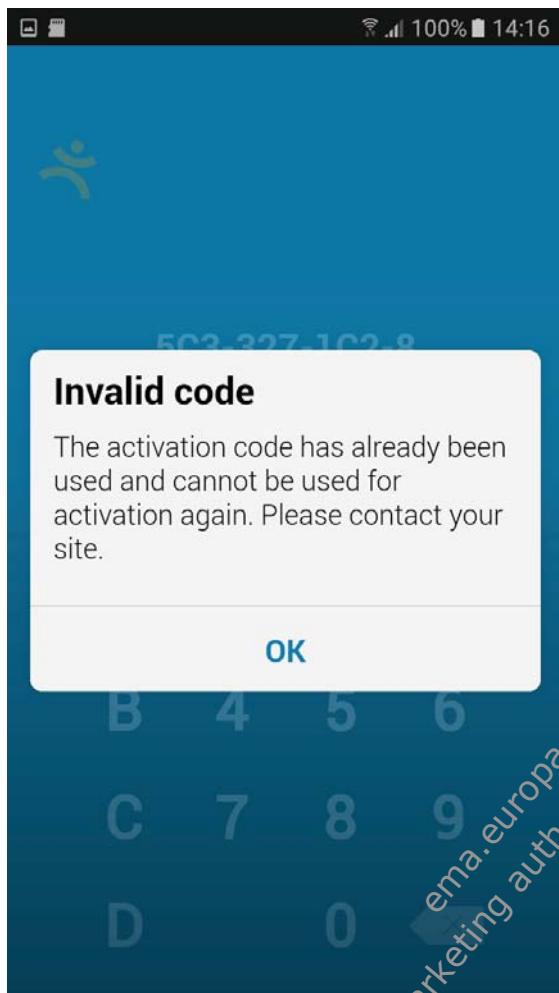
If the installation fails, ask the Study Personnel for assistance or call the Helpdesk.

[Go to Play Store](#)

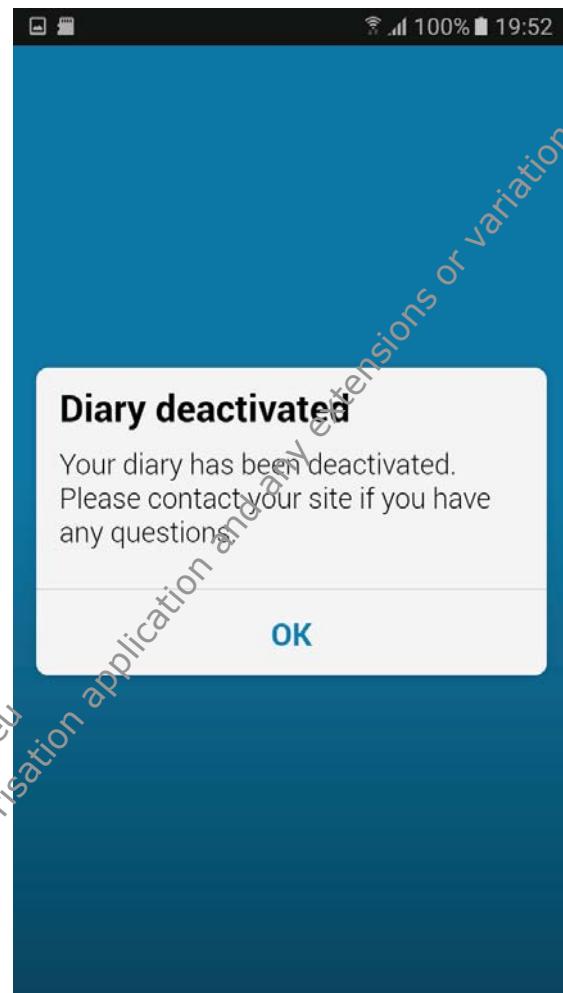


Screen 23

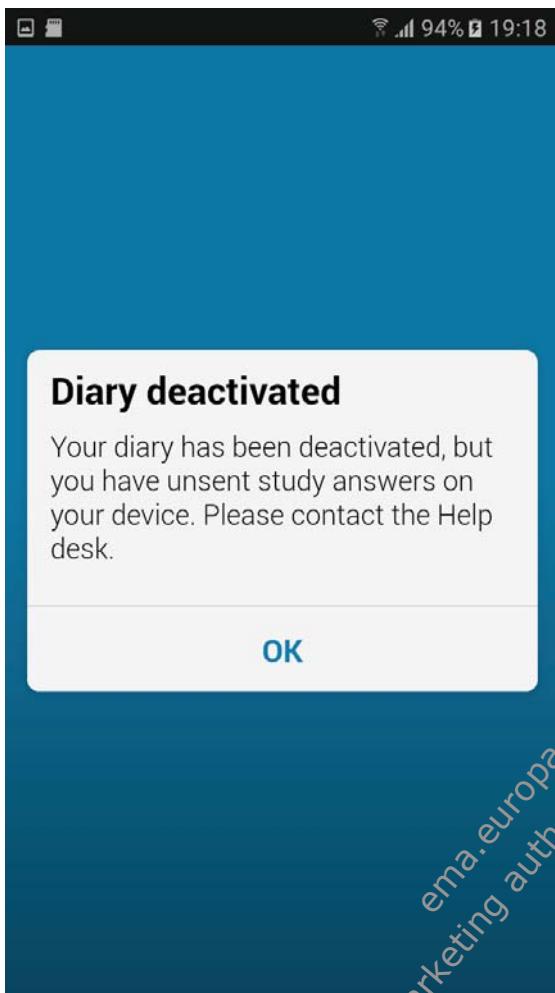
Screen 24



Screen 25



Screen 26

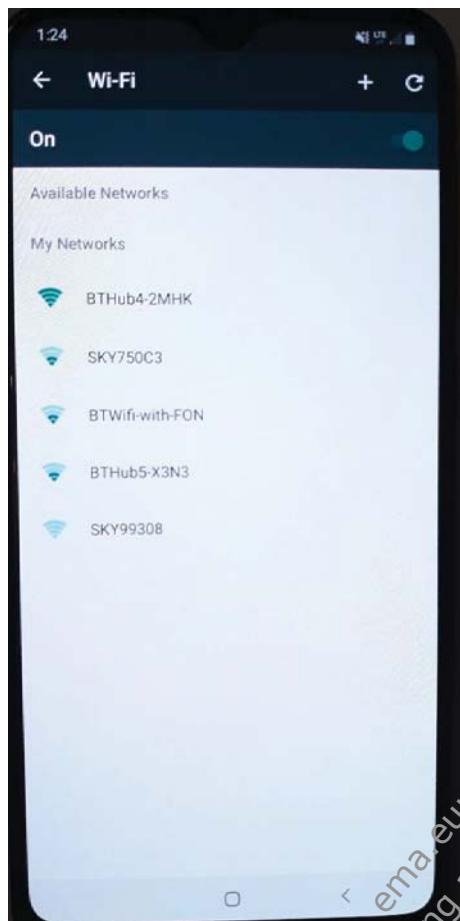


Screen 27



Screen 28

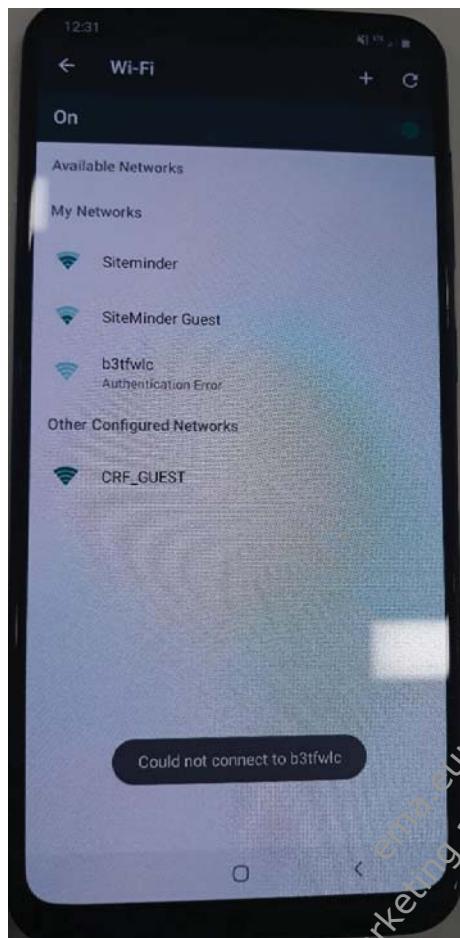
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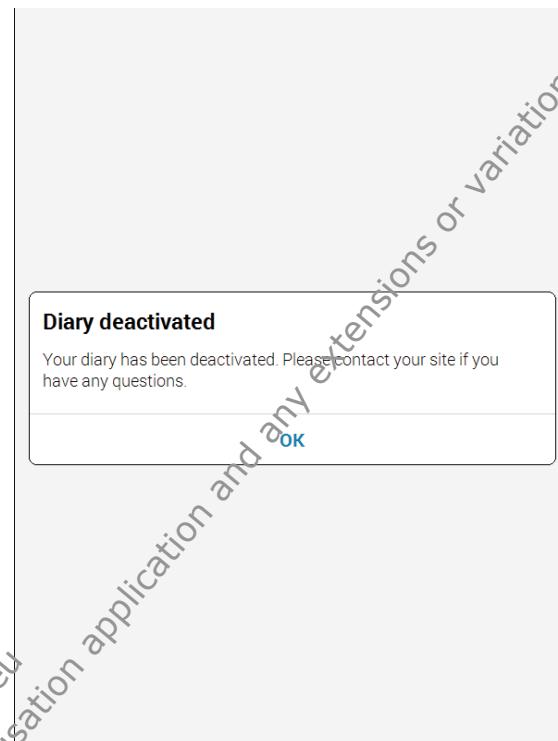
Screen 29



Screen 30



Screen 31



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

Vaccination Diary	
[Computed]	
< Exit	Next >

Screen 1

Confirm	
Do you really want to exit without saving?	
No	Yes

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} more day(s)."

{1} Will display a date

{2} Will display a number of days.

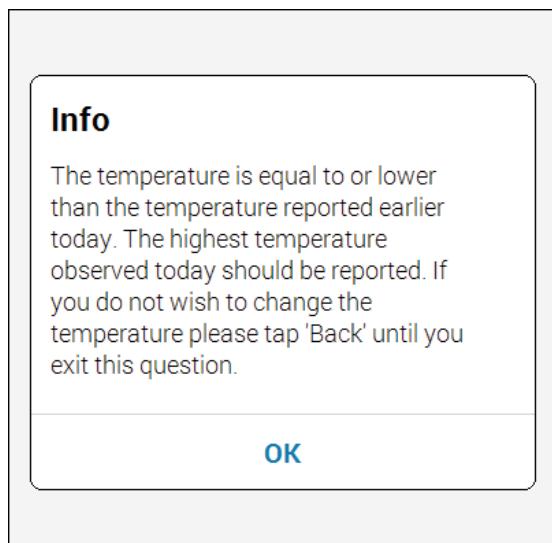
Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 more day(s).

Vaccination Diary																					
Please record your highest temperature today in degrees Fahrenheit.																					
<table border="1" style="margin-left: auto; margin-right: auto;"> <tr><td>○</td><td>○</td><td>○</td><td>○</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> </table>		○	○	○	○	9	9	9	9	0	0	0	0	1	1	1	1	2	2	2	2
○	○	○	○																		
9	9	9	9																		
0	0	0	0																		
1	1	1	1																		
2	2	2	2																		
Back	Next >																				

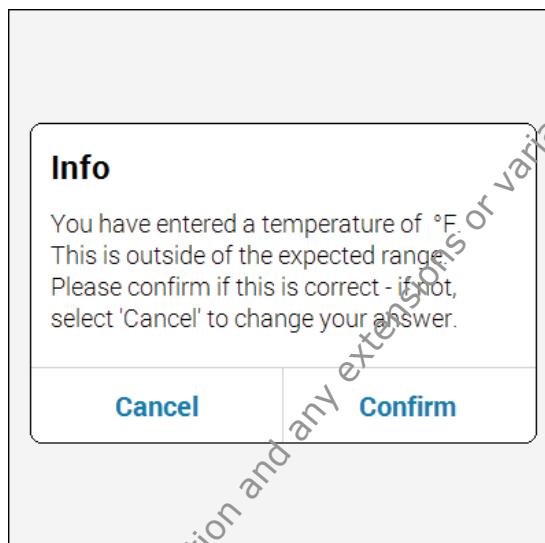
Screen 2

Info	
Please answer the required question(s).	
OK	

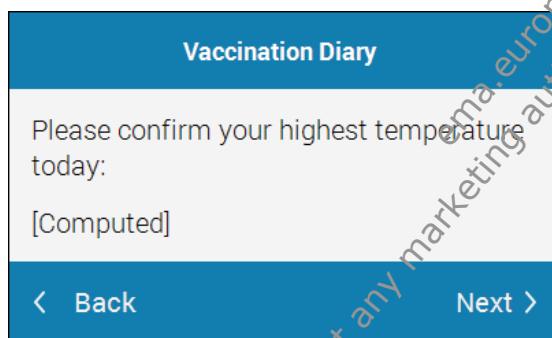
Message 1



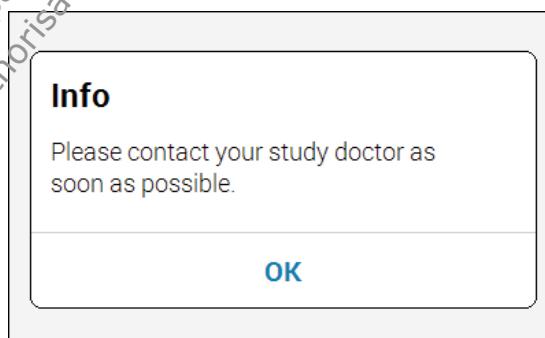
Message 2



Message 3



Screen 8



Message 1

[Computed] will display the temperature selected on Screen 2.

**Vaccination Diary**

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

Yes

No

< Back Next >

Screen 4

**Info**

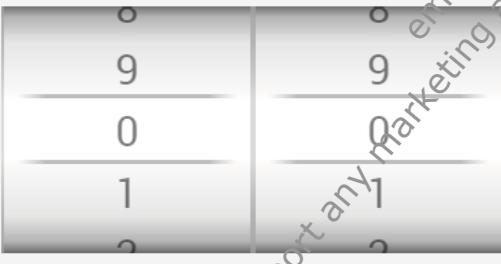
The value you reported is the same as previously reported. If you do not wish to change the response please tap 'Back' until you exit this question.

**OK**

Message 2

**Vaccination Diary**

Please tap on the number from the measuring device for redness.



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

< Back Next >

Screen 5

**Info**

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

**OK**

Message 2

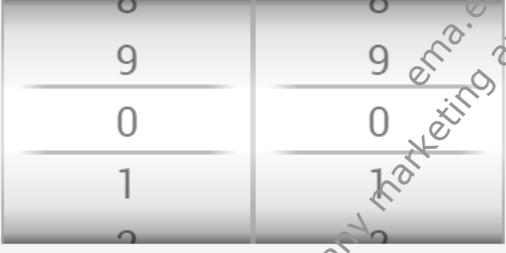
Vaccination Diary
Please confirm the number from the measuring device for redness:  [Computed]
<b>&lt; Back</b> <b>Next &gt;</b>

Screen 6

[Computed] will display the number selected on Screen 5.

Vaccination Diary
Today, have you had any swelling at the injection site?
Yes <input type="radio"/>
No <input type="radio"/>
<b>&lt; Back</b> <b>Next &gt;</b>

Screen 7

Vaccination Diary
Please select the number from the measuring device for swelling.  
If your swelling was greater than 21, please select 21.
<b>&lt; Back</b> <b>Next &gt;</b>

Screen 8

Vaccination Diary
Please confirm the number from the measuring device for swelling:  [Computed]
<b>&lt; Back</b> <b>Next &gt;</b>

Screen 9

Vaccination Diary	
Today, have you had any pain at the injection site?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 10

Vaccination Diary	
<b>Pain at the injection site definitions:</b>	
Mild = Does not interfere with activity	
Moderate = Interferes with activity	
Severe = Prevents daily activity	
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a>	<a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>

Screen 11

Vaccination Diary	
Please indicate whether the pain at the injection site was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 12

Info	
Severe = Prevents daily activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.	
<a href="#" style="color: inherit; text-decoration: none;">No</a>	<a href="#" style="color: inherit; text-decoration: none;">Yes</a>

Message 2

**Info**

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

**OK**

**Vaccination Diary**

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

Yes

No

< Back **Next >**

Screen 13

Message 4

**Vaccination Diary**

Today, have you experienced fatigue (tiredness)?

Yes

No

< Back **Next >**

Screen 14

**Vaccination Diary**

Fatigue (tiredness) definitions:

Mild = Does not interfere with activity

Moderate = Some interference with activity

Severe = Prevents daily routine activity

< Back **Next >**

Screen 15

**Vaccination Diary**

Please indicate whether the fatigue (tiredness) was:

Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

< Back      Next >

Screen 16

**Info**

Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No	<input type="radio"/>
Yes	<input checked="" type="radio"/>

Message 2

**Vaccination Diary**

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

Yes	<input type="radio"/>
No	<input type="radio"/>

< Back      Next >

Screen 17

**Vaccination Diary**

Today, have you experienced headache?

Yes	<input type="radio"/>
No	<input type="radio"/>

< Back      Next >

Screen 18

Vaccination Diary
<b>Headache definitions:</b>  Mild = Does not interfere with activity  Moderate = Some interference with activity  Severe = Prevents daily routine activity
<a href="#">Back</a> <a href="#">Next &gt;</a>

Screen 19

Vaccination Diary
Please indicate whether the headache was:
Mild <input type="radio"/>
Moderate <input type="radio"/>
Severe <input type="radio"/>
<a href="#">Back</a> <a href="#">Next &gt;</a>

Screen 20

Vaccination Diary
Did you go to the ER or were you hospitalized for this reaction?
Yes <input type="radio"/>
No <input type="radio"/>
<a href="#">Back</a> <a href="#">Next &gt;</a>

Screen 21

Vaccination Diary
Today, have you experienced vomiting?
Yes <input type="radio"/>
No <input type="radio"/>
<a href="#">Back</a> <a href="#">Next &gt;</a>

Screen 23

**Vaccination Diary**

**Vomiting definitions:**

Mild = 1 to 2 times in 24 hours

Moderate = More than twice in 24 hours

Severe = Requires intravenous hydration

< Back      Next >

Screen 23

**Vaccination Diary**

Please indicate whether the vomiting was:

Mild

Moderate

Severe

< Back      Next >

Screen 24

**Info**

Severe = Requires intravenous hydration.  
If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No	Yes
----	-----

Message 2

**Vaccination Diary**

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

Yes

No

< Back      Next >

Screen 25

**Vaccination Diary**

Today, have you experienced diarrhea?

Yes	<input type="radio"/>
No	<input type="radio"/>

< Back      Next >

Screen 26

**Vaccination Diary**

**Diarrhea definitions:**

Mild = 2 to 3 loose stools in 24 hours

Moderate = 4 to 5 loose stools in 24 hours

Severe = 6 or more loose stools in 24 hours

< Back      Next >

Screen 27

**Vaccination Diary**

Please indicate whether the diarrhea was:

Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

< Back      Next >

Screen 28

**Info**

Severe = 6 or more loose stools in 24 hours. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No	Yes
----	-----

Message 2

Vaccination Diary	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 29

Vaccination Diary	
Today, have you experienced chills?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 30

Vaccination Diary	
<b>Chills definitions:</b>	
Mild = Does not interfere with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 31

Vaccination Diary	
Please indicate whether the chills were:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 32

<b>Vaccination Diary</b>	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 33

<b>Vaccination Diary</b>	
Today, have you had new or worsened muscle pain (other than at the injection site)?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 34

<b>Vaccination Diary</b>	
Muscle pain definitions:	
Mild = No interference with activity	
Moderate = Some interference with activity	
Severe = Prevents daily routine activity	
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 35

<b>Vaccination Diary</b>	
Please indicate whether the new or worsened muscle pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 36

**Info**

Severe = Prevents daily routine activity. If this is correct tap 'Yes' to go forward or 'No' to change your answer.

No	Yes
----	-----

Message 2

**Vaccination Diary**

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

Yes	<input type="radio"/>
No	<input type="radio"/>

< Back      Next >

Screen 37

**Vaccination Diary**

Today, have you had any new or worsened joint pain?

Yes	<input type="radio"/>
No	<input type="radio"/>

< Back      Next >

Screen 38

**Vaccination Diary**

**Joint pain definitions:**

Mild = No interference with activity

Moderate = Some interference with activity

Severe = Prevents daily routine activity

< Back      Next >

Screen 39

<b>Vaccination Diary</b>	
Please indicate whether the new or worsened joint pain was:	
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 40

<b>Vaccination Diary</b>	
Did you go to the ER or were you hospitalized for this reaction?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 41

<b>Vaccination Diary</b>	
Today, have you taken any medication to treat fever or pain?	
Yes	<input type="radio"/>
No	<input type="radio"/>
<a href="#" style="color: inherit; text-decoration: none;">&lt; Back</a> <a href="#" style="color: inherit; text-decoration: none;">Next &gt;</a>	

Screen 42

<b>Info</b>	
You have reported taking medication to treat fever or pain. Is your answer correct?	
<b>No</b>	<b>Yes</b>

Message 2

Vaccination Diary	Vaccination Diary
<p>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'.</p> <p>If your symptoms worsen today, please select 'Update Symptoms' from the main menu to update your symptoms.</p> <p>[Computed]</p>	<p>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'.</p> <p>If your symptoms worsen again today, please select 'Update Symptoms' from the main menu to update your symptoms.</p> <p>[Computed]</p>
Save	Save
< Back	< Back

Screen 43

Screen 44

[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).

[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: Patient Main Menu

Welcome,

Thank you for taking part in this Study. There are a few things you need to do before you can start filling in your daily diary.

First you need to set up a security question in case you lose your PIN.

Then you will learn how to complete your daily diary using a training diary.

Tap 'Set up security question' to choose your security question and answer.

**Set up security question**

 Log out

Screen 1

**Log out?**

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

No

Yes

Message 1

**Thank you,**

Your security question and answer have been saved.

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

**Go to training diary**

 Log out

Screen 2

**Log out?**

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

No

Yes

Message 1

## Reminder time changed

The daily 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

## Hello,

[Computed]

[Computed]

Report Medication Taken to treat  
Fever or Pain

⌚ Training and review

⚙️ Settings

✖️ Log out

Screen 4

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

[Computed] text below Hello, will either display:  
"There are no Vaccination Diaries expected",  
"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  
Vaccination Diary before midnight". The  
[Computed] text within the button will read  
"Update Symptoms" or "Vaccination Diary"

<p><b>Info</b></p> <p>You can only fill in your Vaccination Diary between 06:00:00 PM and 11:59:59 PM.</p> <p style="text-align: center;"><b>OK</b></p>	<p><b>Info</b></p> <p>Have any of your symptoms become worse?</p> <table border="1" style="width: 100%;"><tr><td style="width: 50%; text-align: center;">No</td><td style="width: 50%; text-align: center;">Yes</td></tr></table>	No	Yes
No	Yes		

Message 1

Message 2

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

Vaccination Diary

Update Symptoms

Temperature

Redness

Swelling

Injection site pain

Fatigue (tiredness)

Headache

Vomiting

Diarrhea

Chills

Muscle pain

Joint pain

< Back

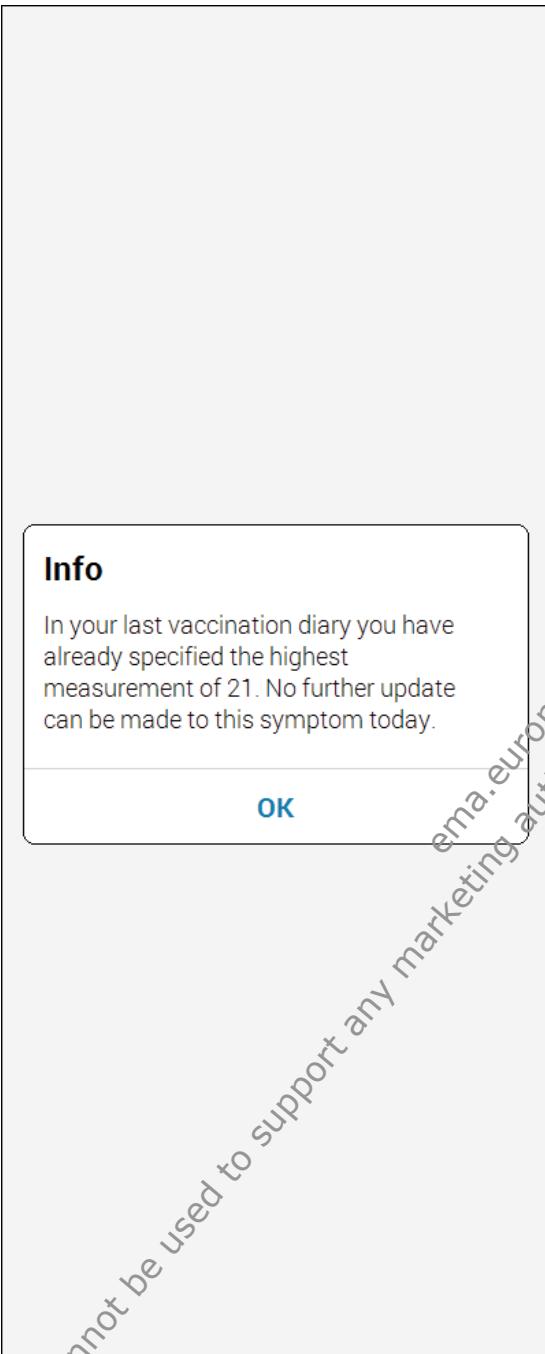
Screen 5

Info

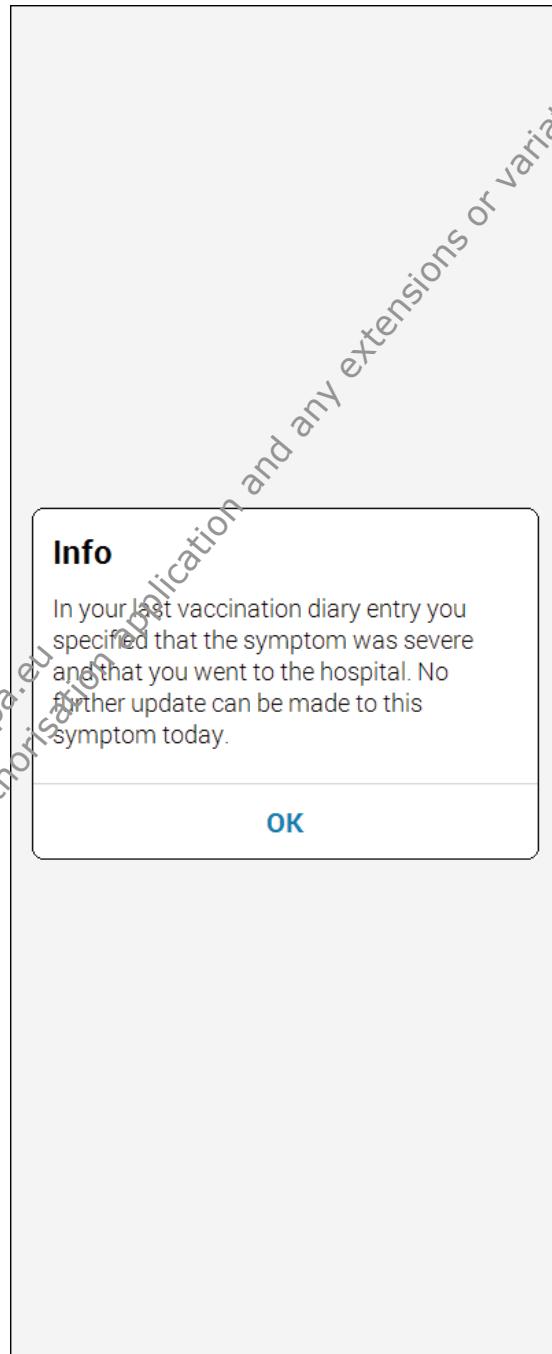
In your last vaccination diary entry you have already specified a temperature of 110.0 °F. No further update can be made to this symptom today.

OK

Message 2



Message 4



Message 8

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## 5 Form: Subject training diary

**Training**



## Welcome to the Training!

Here you will learn:

- About the app
- How to fill in your diary

Use the '**Next >**' button below to move through the Training. Use the '**< Back**' button to go back.

**Let's get started!**

**< Back**      **Next >**

Screen 1

**Confirm**

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

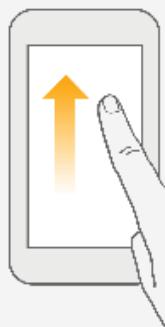
**No**      **Yes**

Message 1

**Training**

## About scrolling

Some pages have more content than can fit onto one screen. Swipe the screen upwards to scroll to the rest of the page.



You will be shown a pop-up guide whenever the page is scrollable.

Tap 'Next >' to continue

< Back

Next >

Screen 2

**Training**

## Logging in with your PIN

You need to log in every time you use the app.



If you forget your PIN, please call the Helpdesk. More information about the Helpdesk will follow.

Do not share your PIN with anyone else, not even your Study doctor or nurse.

Tap 'Next >' to continue

< Back

Next >

Screen 3

**Training**



## Diary reminder

A daily notification has been set up to remind you to fill in your diary.

[Computed]

You may change the reminder time in the Settings page.

Tap 'Next >' to continue

**< Back** **Next >**

Screen 4

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

**Training**



## Sending your answers

Your answers will be sent automatically every time you log in or complete a questionnaire.

You can use the app and fill in your diary offline, but please remember to use the diary online when you can.

Tap 'Next >' to continue

**< Back** **Next >**

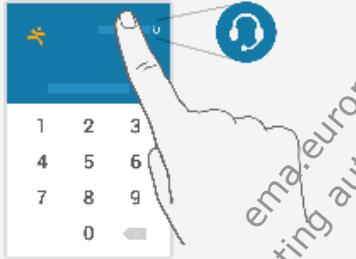
Screen 5

**Training**



## The Helpdesk

We hope you find the app easy to use. If you do have problems, the Helpdesk is always there for you.



You can find the Helpdesk number by tapping the 'Contact info' button on the login screen. The number is also available in your Quick Reference Guide.

Tap 'Next' to continue

**< Back** **Next >**

Screen 6

**Training**



## Your turn to practice!

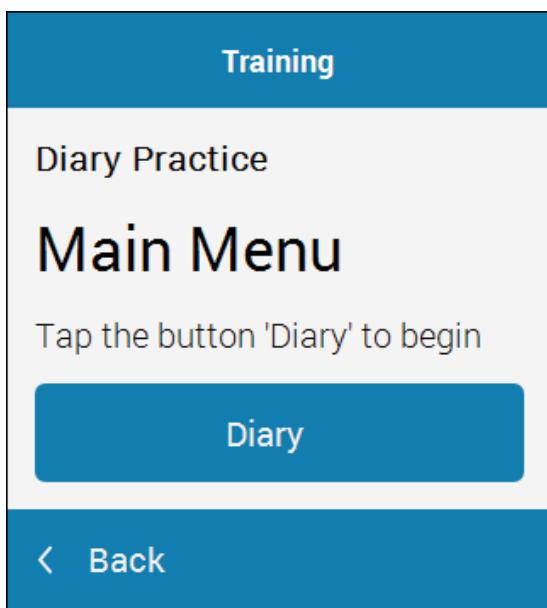
You are about to see a page that we call the 'Main Menu'.

Tap the button 'Diary' to start practicing.

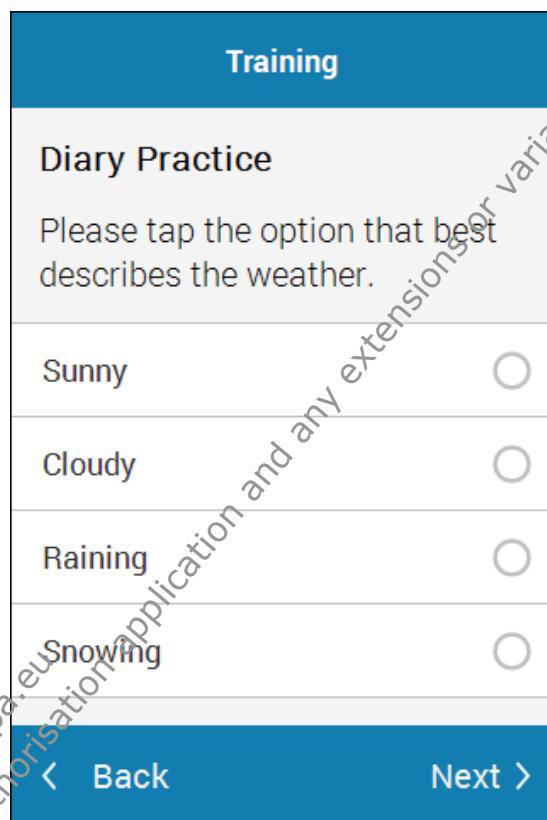
The answers you give during this training session will not be saved.

**< Back** **Next >**

Screen 7



Screen 8



Screen 9

**Info**

Please answer the required question(s).

**OK**

**Training**

**Diary Practice**

Please enter the hours you thought about the weather last week.

0	9
9	0
0	1
1	2
2	3

**Back** **Next >**

Message 1

Screen 10

090177e194d02327\Approved\Approved On: 02-Sep-2020 17:58 (GMT)

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Page 206

Training
<p><b>Diary Practice</b></p> <p>When completing your diary, you will be asked to save your answers at the end. If you exit without selecting save, your answers will not be saved.</p> <p>Please press the 'Save' button below to continue.</p> <p style="text-align: center;"><b>Save</b></p>
<p>&lt; Back</p>

Screen 11

Training

<p><b>Well done!</b></p> <p>Thank you for completing the Training diary. Now you are ready to start using your App.</p> <p>If you would like to repeat the Training later, just tap the 'Training review' button in the Main Menu.</p> <p>Tap '<b>Next &gt;</b>' to continue to the 'Main menu'.</p> <p>&lt; Back      <b>Next &gt;</b></p>

Screen 12

## 6 Form: Settings

**Reminder time**

The current reminder time of the diary is displayed below.

---

**Set Time** >

Tap the time if you want to change the reminder time. Only times from 6:00 PM to 10:00 PM are allowed.

---

< Back

Screen 1

A digital clock interface titled "Set Time". It displays the time as 10:59 AM. The interface consists of three columns: the first column has numeric inputs for hours (10, 11, 12, 01, 02) and minutes (00, 01, 02); the second column shows the current values 10 and 59; the third column shows AM and PM. At the bottom are "Cancel" and "Set" buttons.

Popup input 1

## 7 Form: Security question

Security question	
<p>Choose your security question. The answer should have only two digits. Your question and answer will be needed if you forget your PIN.</p>	
[Computed]	<input type="radio"/>
<p>Then tap the 'Next &gt;' button</p>	
<b>&lt; Back</b>	<b>Next &gt;</b>

Screen 1

**Info**

Please select a suitable question.

**OK**

Message 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)'

	<p style="text-align: center;"><b>Security question</b></p> <p>[Computed]</p> <p>Tap below to select the two digit answer to your question:</p> <p style="text-align: right;">Set Value &gt;</p> <p>After successfully selecting the digits, you can see them above.</p> <p>If you want to change your security question, tap the '<b>Back</b>' button on the lower left corner to go back.</p> <p>Please save your question and answer by tapping the '<b>Save</b>' button. Once saved, you will not be able to come back to change your selections.</p> <p style="text-align: center;"><b>&lt; Back</b> <b>Save</b></p>
Screen 2	

Message 2

[Computed] will display

'Your question:&lt;br/&gt;&lt;br/&gt;&lt;b&gt;&lt;i&gt;{1}&lt;/i&gt;&lt;/b&gt;'

{1} will show the question selected on Screen 1

<b>Set Value</b>									
<table border="1"><tr><td>9</td><td>9</td></tr><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr></table>		9	9	0	0	1	1	2	2
9	9								
0	0								
1	1								
2	2								
<b>Cancel</b>	<b>Set</b>								

Popup input 1

<b>Info</b>
Please select the two digit answer to your security question by tapping 'Set Value' and selecting the digits.
<b>OK</b>

Message 1

# SCREEN REPORT APPROVAL

## Content for Approval

Language	English for United States		
Site Screen Report	PPD	SR_enUS_v2	Version 2 Date 03-Apr-2020

## CUSTOMER

Approval			
Name and Title:	PPD	Signature:	
Company:	Pfizer	Date:	DocuSigned by: PPD PPD
03-Apr-2020   21:11 EDT			

## SIGNANT HEALTH

Approval			
Name:	PPD	Signature:	
Title:	PPD	Date:	DocuSigned by: PPD PPD
03-Apr-2020   21:10 EDT			