

# PFIZER – fin des tests : 02 / 05 / 2023

Source : US National Library of Medicine – ClinicalTrials.gov

<https://clinicaltrials.gov/ct2/show/NCT04368728>

COVID-19 Information  
[Public health information \(CDC\)](#) | [Research information \(NIH\)](#) | [SARS-CoV-2 data \(NCBI\)](#) | [Prevention and treatment information \(HHS\)](#) | [Español](#)

U.S. National Library of Medicine  
**ClinicalTrials.gov**  
Find Studies | About Studies | Submit Studies | Resources | About Site | [PRS Login](#)

Home > Search Results > Study Record Detail  Save this study

## Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

ClinicalTrials.gov Identifier: NCT04368728

Recruitment Status **📌** : Recruiting  
First Posted **📌** : April 30, 2020  
Last Update Posted **📌** : May 31, 2021  
[See Contacts and Locations](#)

**Sponsor:**  
BioNTech SE

**Collaborator:**  
Pfizer

**Information provided by (Responsible Party):**  
BioNTech SE

[Study Details](#) | [Tabular View](#) | [No Results Posted](#) | [Disclaimer](#) | [How to Read a Study Record](#)

### Study Description

Go to

**Brief Summary:**

This is a Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in healthy individuals. The study consists of 2 parts: Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part. The study will evaluate the safety, tolerability, and immunogenicity of 3 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various different dose levels in Phase 1;
- As a booster;
- In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55 or >55 years of age]).

The candidate selected for efficacy evaluation in Phase 2/3 is BNT162b2 at a dose of 30 µg. Participants who originally received placebo will be offered the opportunity to receive BNT162b2 at defined points as part of the study. In order to describe the boostability of BNT162, and potential heterologous protection against emerging SARS-CoV-2 VOCs, an additional dose of BNT162b2 at 30 µg will be given to Phase 1 participants approximately 6 to 12 months after their second dose of BNT162b1 or BNT162b2. This will provide an early assessment of the safety of a third dose of BNT162, as well as its immunogenicity. The assessment of boostability will be further expanded in a subset of Phase 3 participants at selected sites in the US who will receive a third dose of BNT162b2 at 30 µg or a third and potentially a fourth dose of prototype BNT162b2VOC at 30 µg (BNT162b2s01, based upon the South African variant and hereafter referred to as BNT162b2SA). A further subset of Phase 3 participants will receive a third, lower, dose of BNT162b2 at 5 or 10 µg. To further describe potential homologous and heterologous protection against emerging SARS-CoV-2 VOCs, a new cohort of participants will be enrolled who are COVID-19 vaccine-naïve (ie, BNT162b2-naïve) and have not experienced COVID-19. They will receive BNT162b2SA given as a 2-dose series, separated by 21 days.

Condition or disease <b>📌</b>	Intervention/treatment <b>📌</b>	Phase <b>📌</b>
SARS-CoV-2 Infection	Biological: BNT162b1	Phase 2
COVID-19	Biological: BNT162b2 Other: Placebo Biological: BNT162b2SA	Phase 3

### Study Design

Go to

**Study Type **📌**** : Interventional (Clinical Trial)  
**Estimated Enrollment **📌**** : 43998 participants  
**Allocation:** Randomized  
**Intervention Model:** Parallel Assignment  
**Masking:** Triple (Participant, Care Provider, Investigator)  
**Primary Purpose:** Prevention

**Official Title:** A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

**Actual Study Start Date **📌**** : April 29, 2020  
**Estimated Primary Completion Date **📌**** : November 2, 2021  
**Estimated Study Completion Date **📌**** : May 2, 2023