



# mRNA COVID-19 Vaccine

BIONTECH

Randomised Placebo-Controlled Clinical Trial

**Phase 3 Started:** Aug 2020 [US & Global]

**Clinical Trial End Date:** Jun 2021

**Safety & Efficacy End Date:** Dec 2022

**Participants:** 43.5K **Healthy Only** [50% placebo]

## What the Study is testing for:

## mRNA Vaccine Tech

Experimental vaccine technology injects modified RNA that **instructs cells to produce the SARS-CoV2 Spike Protein** and present it outwards, initiating an immune response - hopefully with sustained neutralising B & T Cell memory.

No mRNA Vaccine has ever had regulatory approval. **Uncharted territory.**

Immediate Adverse Reactions

COVID-19 Infection Prevention

Neutralising Antibody Production

Serious COVID-19 Infection Prevention

Long Term Vaccine Injury (2YR)

## Independent Interim Analysis:

**39K Healthy** Individuals received 2nd Dose

**94 COVID-19 Cases** (PCR +ve & 1+ Symptom)

**~1 month** Median time after 2nd Dose

**~85**  
people  
**Placebo**

**~9**  
people  
**Vaccinated**

**90%**  
of infections in  
**placebo group**

This interim analysis could have been produced in Oct. However, in October, team decided to NOT test samples for SARS-CoV2 with FDA. Then, on 4th Nov, they decided to commence sample testing. They met on Sunday 8th Nov - once the president-elect was announced by the media. Announced 9th Nov.

## Next Steps:

No further interim analysis will be performed. By 3rd week of November there will be a median of 2 months of Safety data, and an **EUA** can be applied for from the FDA - with approval expected in **December**.

## What is Not Known

- **Adverse Reactions** data (*aches, fever etc - supposedly worse than Pfizer's Flu vaccine*)
- Neutralising **Antibody & T Cell** Data (*were they measured before trial?*)
- Will vaccine-induced Immunity **wane?**
- Prevention of **Serious COVID-19 cases**
- Long term **vaccine-induced injuries**
- Does vaccine prevent **carrying and shedding** SARS CoV2? (*v. unlikely*)
- Are **mRNA vaccines** a good idea?