



# INFORMATION ABOUT THE PFIZER/BIONTECH VACCINE FOR COVID-19

Pfizer and BioNTech are jointly developing a vaccine for Coronavirus (COVID-19). If the vaccine is proven to be safe and effective, and is approved for use, it will be available in Australia from early 2021 as part of the Australian Government's COVID-19 Vaccine and Treatment Strategy.

The vaccine doses purchased by the Australian Government will be manufactured in the United States, Belgium and Germany.

Status	Type	Developer	Likely doses
Phase 3 clinical trials	mRNA-based vaccine	Pfizer/BioNTech	Two



## Testing Process

All vaccines must pass different stages of research trials to prove they are safe and effective.

Preclinical results in animal studies announced by Pfizer and BioNTech showed immunisation prevented infection with COVID-19 in the lungs and nose. These findings will be submitted to a research journal for peer review.

Preliminary results of the Phase 1 clinical trial, published in the New England Journal of Medicine in October 2020, showed the vaccine generated a strong immune response.

Early (Phase 1/2) human clinical trials are being completed in the United States, Germany and Japan.

Large-scale human clinical trials (Phase 2/3), involving 44,000 participants, are underway in the United States, Germany, Argentina, Brazil and South Africa.

The vaccine is being tested in adults 18-54 years of age, 55-85 years of age and adolescents 12-18 years of age. The Pfizer/BioNTech vaccine is the first COVID-19 vaccine to be tested in adolescents.



## Doses for Australia

Before the Pfizer/BioNTech COVID-19 vaccine is approved for use in Australia it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes.

This includes assessment of its safety, quality and effectiveness. The TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world. In October 2020, the TGA granted a provisional determination to Pfizer for this vaccine candidate. This means that it is now eligible to apply for provisional registration on the Australian Register of Therapeutic Goods.

If the Pfizer/BioNTech vaccine is successful:

- 10 million doses will be available from early 2021
- These doses will be manufactured offshore.