



## Background

In July 2020, a US biotech company selected Paratus Clinical to be involved in a Phase 1/2 randomized, observer-blinded, placebo-controlled trial of a COVID-19 vaccine in healthy adults 18-59 years of age. The ultimate goal of the Sponsor company was to allow rapid advancement during the current coronavirus pandemic.

Three of the Paratus Clinical sites were involved in this rapidly recruiting, multi-site study. The Sponsor's recruitment target was for 750 participants in Australia.

## Study highlights

Paratus was proud to be the first Australian site activated and to randomise the first participant in Australia for the Phase 2 portion of the study. Across the three Paratus sites, over 300 participants were screened and 205 participants were randomised in 5 weeks.

Quality participants were successfully recruited by the dedicated recruitment team utilizing multiple media advertising channels including radio, newspaper articles and an ABC News feature.

Site staff proved their flexibility and adaptability when Sponsor recruitment targets changed, sometimes on a daily basis. Paratus was often called upon to pick up recruitment numbers when other sites were below their target. The initial recruitment period of 2 weeks was extended multiple times which the Paratus team managed on an ongoing basis whilst also maintaining personable participant visits, daily CRA contact, hourly Sponsor updates and quality data entry.

The study requirement of 24 hour data entry posed a possible challenge with such a large volume of participants however devoted Study Coordinator's and Site Manager oversight ensured 100% of data was entered on time.

## Outcome

Paratus Clinical's quality of participants, flexibility and speed contributed to the quick development of the vaccine. The vaccine will be available to Australians by end of 2021/early 2022. Paratus is proud to have been involved in this paramount study and making a contributing difference in a global pandemic.



**DR JOSHUA KIM**  
Principal Investigator at  
Paratus Clinical, Central Coast

"It would be hard to forget the work we did on a Phase 1/2 COVID-19 Vaccine Study investigating a Nanoparticle Vaccine directed against the SARS-CoV-2 Spike Protein. Being part of the global effort to find a safe and effective solution for the pandemic always gives a great sense of pride - especially in appreciating the level of collaboration and commitment our teams demonstrated. Always brings warmth whenever I reflect on the dedication that each and every member of the Clinical Trial Process, including the Trial Participants, contributed and should be proud to represent."