

Johnson & Johnson Covid-19 vaccine trial commences in South Africa

The first South African participants in the Johnson & Johnson Phase 3 [Ensemble trial](#) for a Covid-19 vaccine were dosed last week, as part of an international clinical study which also includes participants in the US, Brazil, Chile, Colombia and Argentina.



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The Phase 3 Ensemble study is a randomised, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a single vaccine dose - known as Ad26.COV2-S - versus placebo in up to 60,000 adults of 18 years old and older, including significant representation from those that are over the age of 60. The trial will also include those with and without comorbidities associated with an increased risk for progression to severe Covid-19.

The initiation of the Ensemble trial followed positive interim results from the company's Phase 1/2a clinical study, which demonstrated that the safety profile and immunogenicity after a single vaccination were supportive of further development. These results were published on [medRxiv](#) on 25 September 2020.

Johnson & Johnson aims to achieve broad representation of participants, including older adults and ethnically diverse populations, in the implementation of its Covid-19 Phase 3 trial programme. In South Africa, the study will take place across approximately 31 trial sites, in locations with a high incidence of Covid-19. Site locations will include Gauteng, North West, Eastern Cape, Western Cape, Limpopo, Mpumalanga, and the Free State. The locations of sites were determined in close collaboration with local health authorities, taking into account current disease prevalence, population demographics and regulatory authorities' requirements.

Manufacturing agreement

Meanwhile, the international pharmaceutical company has entered into a preliminary agreement with Aspen Pharmacare Limited for the technical transfer and proposed commercial manufacture of the vaccine candidate.

Aspen Pharmacare will perform formulation, filling and secondary packaging of the vaccine for supply to Johnson & Johnson at its existing sterile facility in Port Elizabeth, South Africa. The company has invested in excess of R3bn in the facility together with the high technology equipment and systems that will be used to manufacture state-of-the-art sterile drugs and vaccines, packaged into vials, ampoules and pre-filled syringes. The production area where it is intended that the vaccine candidates will be manufactured has capacity to produce more than 300-million doses per annum.

This agreement is still subject to the successful completion of the relevant technology transfer activities and finalisation of certain commercial manufacturing terms.

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