

DCGI approves Serum Institute for Phase II+III trials of Oxford University vaccine

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The Drugs Controller General of India (DCGI) has given approval to Serum Institute of India, Pune to conduct Phase II+III clinical trials of Oxford University-Astra Zeneca COVID-19 vaccine (COVISHIELD) in India.

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"We will begin with the trials for the vaccine in India. In addition, we will soon start manufacturing the vaccine in large volumes", said Adar Poonawalla, CEO, Serum Institute of India.

Oxford and AstraZeneca are collaborating with clinical partners around the world as part of a global clinical programme to trial the Oxford vaccine. The global programme is made up of a Phase III trial in the US enrolling 30,000 patients, a paediatric study, as well as Phase III trials in low-to-middle income countries including Brazil and South Africa which are already underway.

AstraZeneca remain committed to fulfilling their commitment for broad and equitable access to the vaccine, should late-stage clinical trials prove successful. So far, commitments to supply more than 2 billion doses of the vaccine have been agreed with the UK, US, Europe's Inclusive Vaccines Alliance (IVA), the Coalition for Epidemic Preparedness (CEPI), Gavi the Vaccine Alliance and Serum Institute of India.