

DCGI approves Ph 3 trial of US-based Inovio's DNA vaccine candidate for COVID-19

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Authorization to conduct INNOVATE Phase 3 trial in India builds on recent regulatory authorizations from Brazil, Philippines, Mexico and Colombia



US-based Inovio Pharma has received authorization from the Central Drugs Standard Control Organization (CDSCO)'s Drug Controller General of India (DCGI) to proceed with the Phase 3 segment of INOVIO's global Phase 2/3 trial, **INNOVATE (INOVIO INO-4800 Vaccine Trial for Efficacy)**, in India for INO-4800, its DNA vaccine candidate for COVID-19.

Inovio is partnering with Advaccine Biopharmaceuticals Suzhou Co., Ltd. (Advaccine) to conduct the INNOVATE Phase 3 segment in multiple countries in Latin America, Asia, and Africa. Regulatory authorization in India follows authorizations from health authorities in Brazil, Philippines, Mexico and Colombia.

The global Phase 3 segment of INNOVATE will evaluate the efficacy of INO-4800 in a two-dose regimen (2.0 mg per dose), administered one month apart, in a 2-to-1 randomization in men and non-pregnant women 18 years of age and older. The primary endpoint of this case-driven Phase 3 trial is virologically confirmed symptomatic COVID-19.

As one of the only nucleic-acid based vaccines that is stable at room temperature for more than a year, at 37°C for more than a month, has a five-year projected shelf life at normal refrigeration temperature and does not need to be frozen during transport or storage, INO-4800 is anticipated to be well-positioned for a primary series immunization as well as a booster.