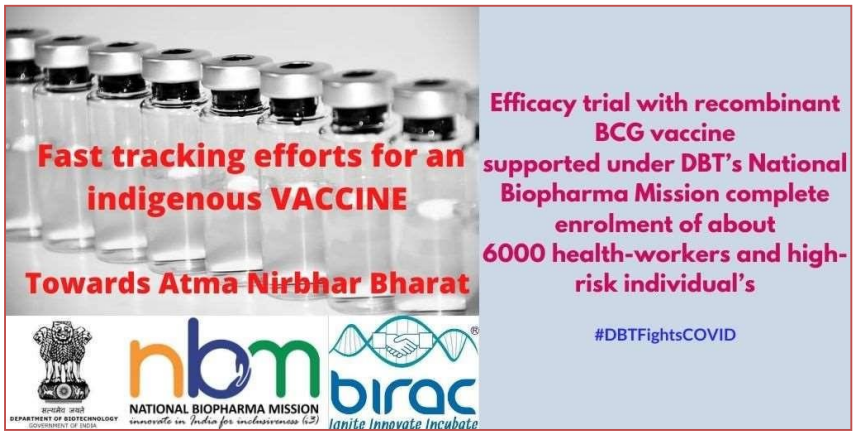
Efficacy trial with recombinant BCG vaccine completed the enrolment of about 6000 health-workers and high-risk individuals

The Biotechnology Industry Research Assistance Council (BIRAC), a New Delhi based Govt of India Enterprise, funded the Serum Institute of India Pvt Ltd (SIIPL) under Department of Biotechnology's National Biopharma Mission for conduct of a multisite randomized double-blinded placebo-controlled phase III clinical trial of a recombinant Bacille Calmette-Guerian (rBCG) vaccine candidate (VPM1002).



The objective of this trial is to evaluate the ability of VPM1002 in reducing infection incidence and severe disease outcomes of COVID- 19 among high risk persons of advanced age or co-morbidities and high-exposure healthcare workers.

The BCG vaccine is given routinely to all new born babies as a part of the National childhood immunization programme to prevent tuberculosis, an infection caused by bacteria that mainly affects the lungs. It has beneficial heterologous effects and proven antiviral and immune modulatory properties that protect against infectious diseases through induction of trained innate immunity and heterologous adaptive immunity.

About 6,000 health workers and high-risk individuals including those in close contact of COVID patients have been enrolled in a clinical trial to determine if the rBCG can boost immunity to fight against the virus. The trial began in May and has completed enrolment of subjects in almost 40 hospitals across the country.

There is an urgent need to ensure the safety and health of HCWs who are on the forefront fighting the epidemic, household contacts of COVID positive patients and all other people

residing or working in COVID-19 hotspots/outbreak areas where there is a high risk of transmission of COVID-19 infection. Similar trials with rBCG are also approved by Paul Ehrlich Institute (PEI), and Health Canada.