

Efficacy Trial of BCG Vaccine

July 28, 2020

Serum Institute of India Pvt Ltd (SIIPL) has been supported under the Department of Biotechnology's National Biopharma Mission for conduct of a multisite randomized double-blinded placebo-controlled phase III **clinical trial of recombinant BCG vaccine candidate, VPM1002.**

Recombinant BCG Vaccine

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 administered routinely to all newborn babies as a part of the **National childhood immunization programme to prevent tuberculosis** (TB), 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 recombinant Bacillus Calmette-Guerian (rBCG) can boost immunity to fight against the virus.

BIRAC

Biotechnology Industry Research Assistance Council is a **not-for-profit Section 8, Schedule B, Public Sector Enterprise,** set up by the Department of Biotechnology (DBT) as an interface agency to strengthen and **empower the emerging biotech enterprise** to undertake strategic research and innovation, addressing nationally relevant product development

needs.

National Biopharma Mission

The **Industry-Academia Collaborative Mission of DBT** for accelerating discovery research to early development for biopharmaceuticals approved by the Cabinet for a total cost US\$ 250 million and **50% co-funded by the World Bank** is being **implemented at BIRAC**. This program is dedicated to deliver affordable products to the nation with an aim to improve the health standards of India's population. Vaccines, medical devices and diagnostics and biotherapeutics are few of its most important domains, besides, strengthening the clinical trial capacity and building technology transfer capabilities in the country.

SI IPL

It is the **world's largest vaccine manufacturer by number of doses produced and sold globally** which includes Polio vaccine as well as Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines. Vaccines manufactured by the Serum Institute are accredited by the World Health Organization, Geneva and are being used in around 170 countries across the globe in their national immunization programs, saving millions of lives throughout the world.