

COVAXIN™ clinical trials cross 23,000 subjects, and forges ahead, India's largest Phase III trials

The product development and clinical trial data thus far has generated 5 publications, 4 of which have been accepted by international peer reviewed journals and will be published soon.

The publication of phase II trial data is undergoing the peer review process. As a part of our regulatory guidelines, all data has been submitted to the DCGI and CDSCO.

Hyderabad, January 02, 2021: Bharat Biotech has announced successful recruitment of 23,000 volunteers, and continued progress towards achieving the goal of 26,000 participants for Phase-3 clinical trial of COVAXIN™ across multiple sites in India.

The Phase III human clinical trials of COVAXIN™ began mid-November, targeted to be done in 26,000 volunteers across India, this is India's first and only Phase III efficacy study for a COVID-19 vaccine, and the largest phase III efficacy trial ever conducted for any vaccine in India. COVAXIN™ has been evaluated in approximately 1000 subjects in Phase I and Phase II clinical trials, with promising safety and immunogenicity results, with acceptance in international peer reviewed scientific journals.

COVAXIN™, India's indigenous COVID-19 vaccine by Bharat Biotech is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). This indigenous, inactivated vaccine is developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) bio-containment facility, one of its kind in the world.

COVAXIN™ is a highly purified and inactivated 2 dose SARS-CoV2 vaccine, manufactured in a Vero cell manufacturing platform with an excellent safety track record of more than 300 million doses.

Ms. Suchitra Ella, Joint Managing Director of Bharat Biotech said, *"We thank every volunteer who has taken the time to participate in this trial. Their volunteering spirit is a great morale boost for India and the world. We thank all the Principle Investigators, Doctors, medical staff & the hospitals for their cooperation & support in taking the phase III trials forward in 26,000 volunteers in India. We continue our progress towards achieving the goal of 26,000 participants for Phase-3 clinical trials of COVAXIN™"* **Mrs. Ella added.**

COVAXIN™ Publications: 5 publications in 8 months.

<https://www.medrxiv.org/content/10.1101/2020.12.21.20248643v1>

<https://www.medrxiv.org/content/10.1101/2020.12.11.20210419v1>

<https://www.biorxiv.org/content/10.1101/2020.09.09.285445v2>

<https://www.researchsquare.com/article/rs-76768/v1>

<https://www.researchsquare.com/article/rs-65715/v1>

About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 140 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 116 countries and WHO Pre-qualifications.

Located in Genome Valley, the hub for the global biotech industry, the company has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

The company is proficient in conducting extensive multi-centre clinical trials, having completed more than 75 trials enrolling more than ~ 700,000 participants globally. Our commitment to global social innovation programs and public-private partnerships resulted in the introduction of path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC® and Typbar TCV® combating Polio, Rotavirus and Typhoid infections respectively. Bharat Biotech has successfully partnered with NIV-ICMR having developed JENVAC®, a licensed Japanese Encephalitis vaccine.

The 2019 acquisition of Chiron Behring (CHIRORAB®), has positioned Bharat Biotech as the largest Rabies vaccine manufacturer in the world.

To learn more about Bharat Biotech visit www.bharatbiotech.com

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