## Department of Biotechnology supported GCLP Facility for Viral Immunogenicity Testing now open for operations

## National Facility at IRSHA, Bharati Vidyapeeth, Pune: A National Biopharma Mission supported Facility

Department of Biotechnology, Government of India has taken myriads of initiatives to increase investments in research and development (R&D) of affordable Biotech healthcare products. Establishment of National Biopharma Mission is one such endeavour to identify the needs and gaps of Biotherapeutics, Vaccine and Devices Industry and address those capacity bottlenecks.

Vaccine development requires extensive evaluation in humans to establish safety, immunogenicity and clinical efficacy. Centralised Viral and Bacterial clinical Immunogenicity labs meeting the stringent GCLP standards were therefore identified as a critical need for the vaccine Industry.

National Immunogenicity & Biologics Evaluation Center (NIBEC) for assessing clinical Immunogenicity of viral vaccines is established jointly by Bharati Vidyapeeth University through its constituent unit Interactive Research School for Health Affairs (IRSHA) and BIRAC-DBT, Government of India through National Biopharma Mission. The facility was inaugurated virtually by Dr Renu Swarup, Secretary, DBT, Government of India in an e-inauguration ceremony presided by Dr Vishwajeet Kadam, Minister of State; Government of Maharashtra.

NIBEC, having a dedicated area of about 10,000 sq ft, was established in a record time of just a year. It has state of the art one BSL-3+, 4 BSL-2 and 10 BSL-1 laboratories. Key immunogenicity evaluation tests like Plaque Reduction Neutralization Test (PRNT), Microneutralization assay, IgM and IgG ELISA have been developed, standardized and validated for Dengue, Chikungunya and SARS-CoV-2 viruses. The laboratory has already started associating closely with leading Indian vaccine manufacturing companies and National and International institutes engaged in vaccine developments.

Inaugurating the facility via video conference, Dr Renu Swarup, Secretary, DBT, said that she has very high expectations from NIBEC with regards to clinical immunogenicity testing of vaccine candidates specially with the COVID 19 vaccine pipeline in the country. She further elaborated that having domestic capabilities maintaining international standards in this space, will accelerate and fast track development of indigenous vaccines in the country.

Speaking on the subject, Dr Vishwajeet Kadam, Minister of State; Government of Maharashtra said that Government support for creation of such a facility at IRSHA is heart-warming. He acknowledged and thanked the support of DBT and BIRAC.

**About DBT**

The Department of Biotechnology (DBT), under the Ministry of Science & Technology, promotes and accelerates the development of biotechnology in India, including growth and application of biotechnology in the areas of agriculture, healthcare, animal sciences, environment and industry.

**About BIRAC:**

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

**About National Biopharma Mission:**

The Industry-Academia Collaborative Mission of Department of Biotechnology (DBT), Govt of India 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 Biotechnology Research Assistance Council (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.

**About IRSHA:**

Interactive Research School for Health Affairs (IRSHA) is a unique constituent unit of Bharati Vidyapeeth (Deemed to be University), totally dedicated to research. The institute was established in 2001. The institute is mandated to conduct research in priority areas of human health in co-ordination with other constituents of the university like Medical, Ayurveda, Homeopathy, Dental colleges, Rajiv Gandhi Institute of IT & BT, Environmental sciences etc. The core area of research includes Mother and child health, Cancer, Diabetes, Obesity, Osteoarthritis & Herbal medicine.

For more information, visit: <https://irsha.bharatividyapeeth.edu/>



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Press Information Bureau, 5 September, 2020