



## Mission COVID Suraksha

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### Why in News

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The Government of India has announced the **stimulus package of Rs. 900 crore** for the **Mission COVID Suraksha**, the Indian Covid-19 Vaccine Development Mission, which will **help the development process of the vaccine candidates**.

### Key Points

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- **About:**

- Mission COVID Suraksha is India's **targeted effort to enable the development of indigenous, affordable and accessible vaccines** for the country and will complement the ongoing mission of **Atmanirbhar Bharat**.
- The Centre had announced this package during the **third economic stimulus**.
- The Mission with its **end-to-end focus from preclinical development through clinical development and manufacturing and regulatory facilitation for deployment**, would consolidate all available and funded resources towards accelerated product development.

- **Grant:**

- Phase-I of the Mission has been allotted **Rs. 900 Crore for a period of 12 months**.
- The grant will be provided to the **Department of Biotechnology (DBT)** for Research and Development (R&D) of Indian **Covid-19** vaccines.

- **Stakeholders:**

- It will be **led by DBT** and implemented by a dedicated **Mission Implementation Unit** at the **Biotechnology Industry Research Assistance Council** (BIRAC).
- The existing activities under **National Bio Pharma Mission** (NBM) and **Ind-CEPI Mission** will provide complementary strengths to this Mission.
  - The DBT is supporting the implementation of the Ind-CEPI Mission, “Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the **Coalition for Epidemic Preparedness Innovations** (CEPI)”.
  - The Ind-CEPI Mission was approved in **March 2019**.

- **Objectives:**

- Accelerating pre-clinical and clinical development.
- Licensure of Covid-19 vaccine candidates that are currently in clinical stages or ready to enter the clinical stage of development.
- Establishing clinical trial sites.
- Strengthening the existing central laboratories and suitable facilities for animal studies, production facilities and other testing facilities to support the vaccine development.
- Supporting the development of common harmonized protocols, training, data management systems, regulatory submissions, internal and external quality management systems and accreditations.
- Supporting capabilities for process development, cell line development and manufacturing of GMP batches for animal toxicology studies and clinical trials.
- Developing suitable **Target Product Profile** so that vaccines being introduced through the mission have preferred characteristics applicable to India.

- **Vaccine Candidates:**

A total of **10 vaccine candidates** have been supported by DBT so far at both academia and industry and as on date and **5 vaccine candidates are in human trials.**

- **Covishield:** The **Serum Institute of India** (SII) is conducting the **phase-3** trial of the **Oxford-Astrazeneca** Covid-19 vaccine.
- **Covaxin:** The indigenously developed **Bharat Biotech** and the **Indian Council of Medical Research** (ICMR) vaccine has already started the phase III clinical trial.
- **ZyCoV-D:** Indigenously developed vaccine by **Zybus Cadila** has completed the phase-2 clinical trial in the country.
- **Sputnik V:** The combined phase 2 and 3 clinical trials of the **Russian Covid-19 vaccine** Sputnik V in India are about to get started.
- **BNT162b2:** India is focusing on training for conducting phase II and III human clinical trials of the **Pfizer's Covid-19 vaccine candidate** along lines of India's regulatory mechanism.

## **Clinical Trials**

- It is a **systematic study to generate data for discovering or verifying the clinical and pharmacological profile** (including pharmacodynamic and pharmacokinetic) or **adverse effects** of a new drug on humans.
- It is the **only way of establishing the safety and efficacy** of any drug before its introduction in the market for human use and is preceded by animal trials where the efficacy and side effects are observed in animals and an estimated drug dose is established.
- Clinical trials of drugs developed in India **have to undergo all four phases of trials in India.**
  - Phase I or clinical pharmacology trials or “first in man” study.
  - Phase II or exploratory trials.
  - Phase III or confirmatory trials.
  - Phase IV trials or post-marketing phase.

**Source: PIB**