Department of Biotechnology
Ministry of Science & Technology
Government of India

Mission COVID Suraksha

Background

'Mission COVID Suraksha- the IndianCOVID-19 Vaccine Development Mission', was announcedas part of the third stimulus package, AtmanirbharBharat3.0, for promoting research and development of Indian COVID-19 vaccines. Mission COVID Surakshais being led by the Department of Biotechnology (DBT) and is being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of DBT, at a total cost of Rs. 900 Cr. for 12 months.

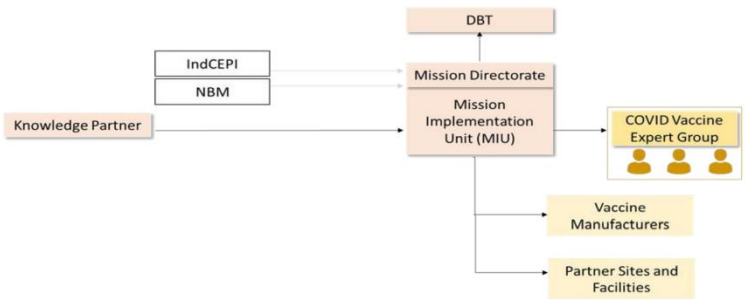
Mission Goal

The Mission has been intended to be a National Mission with a focus on bringing to the citizens of the country a safe, efficacious, affordable and accessible COVID-19 Vaccine, at the earliest with a focus on AtmaNirbharBharat.The goal of the Mission is to accelerate the development of at least 5-6 COVID-19 vaccine candidates and ensure that some of these are brought closer to licensure and introduction in themarket for consideration of regulatory authorities and for introduction in public health systems.

Mission Objectives

1. Accelerating pre-clinical & clinical development; licensure of COVID-19 vaccine candidates that are currently in clinical stages or ready to enter clinical stage of development.
2. Establishing clinical trial sites, and strengthening the existing immunoassay laboratories, central labs and suitable facilities for animal studies, production facilities and other testing facilities to support COVID-19 vaccine development.
3. Supporting trainings,regulatory submissions, to accelerate clinical development and licensure of COVID-19 vaccine candidates that have targets identified.
4. Supporting capabilities for process development, cell line development and manufacturing of GMP batches for animal toxicology studies and clinical trials.
5. Development of suitable Target Product Profile so that vaccines being introduced through the Mission have preferred characteristics applicable for India.

The Governance and Management Framework



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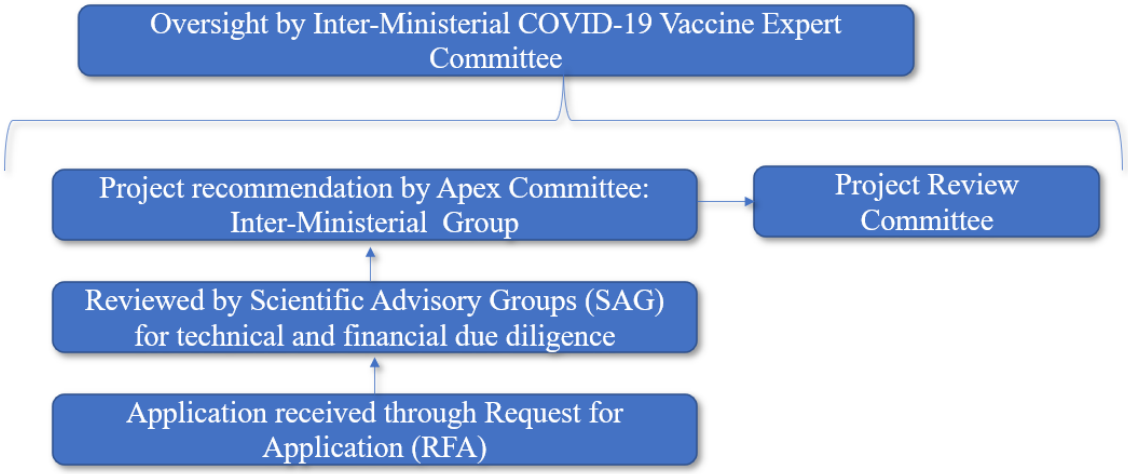
Implementation Mechanism



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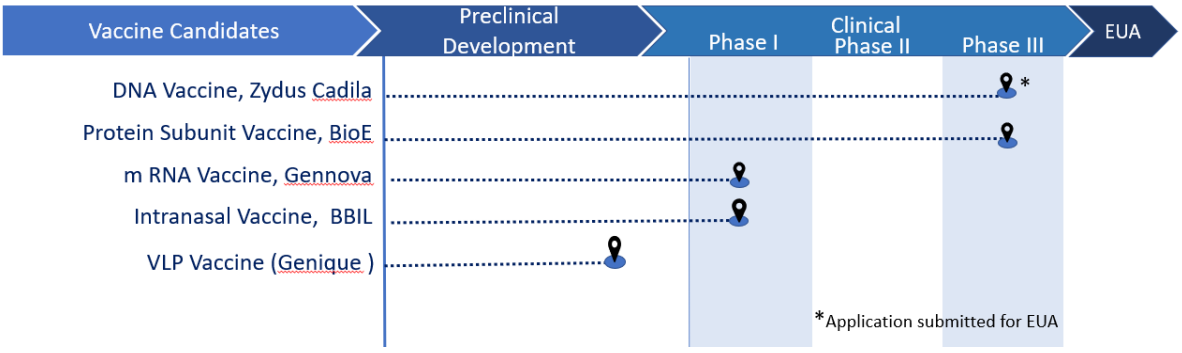
Current Status of the Mission

3 Requests for Expression of Interest (REOIs) were issued for receipt of proposals. A total of 66 applications have been received across all the 3 REOIs, whereby, following due scientific and technical due diligence, 30 applicants have been shortlisted for support.Financial support under the Mission is being provided for public funded research institutes; State and Central PSEs; Public and private hospitals; industrial organizations. An amount of Rs. 710 Cr. has been committed till date, to support these activities.Detailed information is as under:

i. REOI-1 Development of COVID-19 vaccine candidate(s")

Support under this REOI is being provided to industry for regulatory toxicology studies of the vaccine candidates and for clinical development of the vaccine candidates. Support is being provided to the development of five vaccine candidates including:



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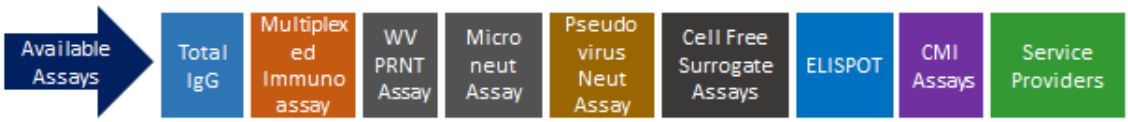
ii. REOI-2 Enhancement of Capacity to support COVID-19 vaccine development

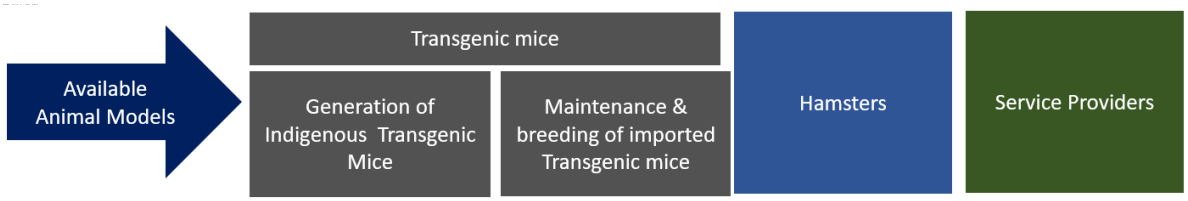
In order to strengthen indigenous capabilities for vaccine development, the REOI has been issued to support (a) establishment of facilities for Animal Challenge Studies and (b) establishment of laboratories for performing Clinical Immunogenicity Assays.

Three Immunogenicity Assay Laboratories for SARS-CoV-2 clinical immunogenicity studies are being supported at: IRSHA Pune; Syngene International Ltd, Bengaluru; THSTI, New Delhi. THSTI and IRSHA are already providing the services to vaccine developers.The details of assays being established is provided below:



Institutes									
IRSHA, Pune	√		√	√	√	√	√	√	√
THSTI, Delhi	√		√		√		√	√	√
Syngene, Bangalore	√	√			√	√	√		Not yet

Three Animal Challenge facilities at ILS Bhubneshwar; NCBS / inStem, Bangalore; IISc, Bangalore; are being supported for: development of hamster models; generation of indigenous transgenic mice; maintenance and breeding of imported transgenic mice. The details on the Animal Challenge Model is as follows:

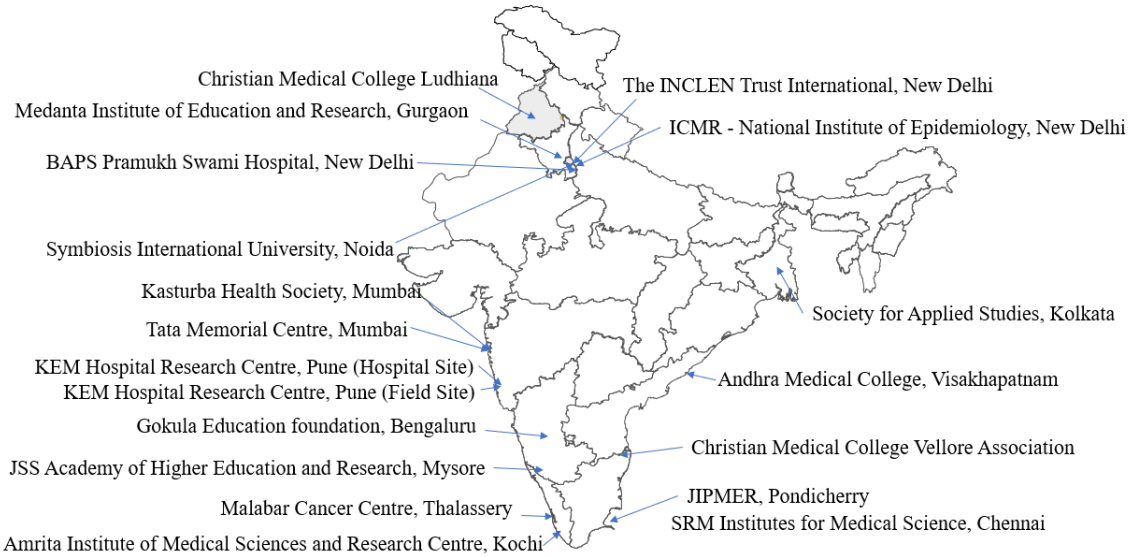


Institutes				
ILS, Bhubaneshwar		√	√	Colonies of mouse infection models established
NCBS/In-STEM, Bangalore	√			Breeder pairs available for redistribution
IISC, Bangalore		√	√	Hamster models being developed

iii. REOI-3 Enhancing capacity for conduct of Human clinical trials for COVID-19 Vaccine candidates

The REOI has been issued for enhancing and strengthening the institutional capacity for conduct of Phase I/II/III clinical trials for COVID-19 vaccine candidates. 19 hospital based

clinical trial sites are being supported under the Mission. The list of clinical trial sites being supported is below:



iv. Facility augmentation for Covid 19 Vaccine manufacturing

In accordance with the directives received, to address the urgent need for making available sufficient vaccine doses to meet the existing requirements, efforts have been made to support scale-up of vaccine production, under Mission COVID Suraksha. Accordingly, support for one private industry (Bharat Biotech, Hyderabad) and three public sector manufacturing facilities (Indian Immunologicals, Hyderabad; Haffkine Biopharmaceuticals, Mumbai; Bharat Immunologicals and Biologicals, Bulandshar), is being provided to make them ready with enhanced capacities to support augmented production of Covaxin. The Department of Biotechnology (DBT) is also facilitating technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), comprising of Hester Biosciences, OmniBRx Biotechnologies Pvt Ltd, and Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat.Through these efforts, it is expected that the current manufacturing of Covaxin of about 1 crore doses/ month will be enhanced in the next few months.

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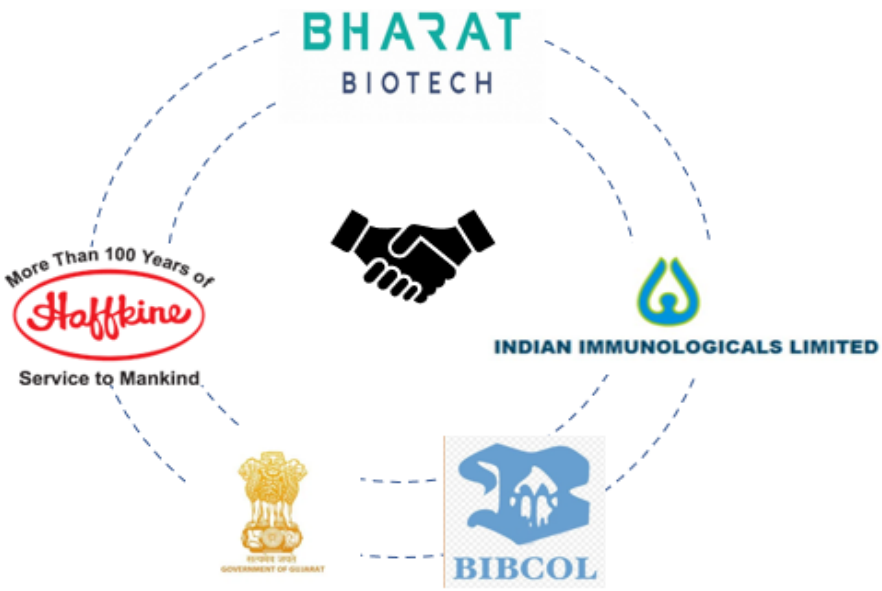

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