Department of Biotechnology
Ministry of Science & Technology
Government of India

COVID-19 Research for Diagnostics, Vaccines and Therapeutics

The first reports of Coronavirus disease (COVID-19)from Wuhan, China surfaced initially on 31 December 2019, following which, on 30 January, 2020, the World Health Organization (WHO) has declared the novel coronavirus COVID-19 outbreak as a Public Health Emergency of International Concern (PHEIC).

Furthermore, in the‘ Global research and innovation forum: towards a research roadmap for novel coronavirus’, organised by the WHO at Geneva on 11th and 12th February, 2020, two of the key recommendations were (i) Accelerated research on the evaluation of investigational therapeutics and vaccines and (ii) Mobilize research on rapid point of care diagnostics.

Taking note of the same and recognizing the necessity for a readiness plan towards R&D activities during epidemics, several meetings have been convened at the Department of Biotechnology to develop a Research strategy for preparedness against COVID-19. Accordingly, a **Research strategyhas been evolved at theDepartment of Biotechnology (DBT) for immediate response and long-term preparedness to combat COVID-19 infection**.

Furthermore, as per the latest ‘Strategy of COVID-19 testing in India (17.03.2020)’, released by ICMR, the laboratories of the**11 Autonomous Institutes of DBT** would be engaged as diagnostic testing laboratories as part of the expansion process. Rajiv Gandhi Centre for Biotechnology, Kerala has already been validated for the same. In addition, 5 autonomous institutes of DBT (Instem, NCCS, ILS, NIBMG and THSTI) are assessing their capability to initiate diagnosis of COVID-19 at the earliest.

In view of the above, detailed information regarding the (i) Research strategy evolved by DBTand (ii) Support for Research Consortia is mentioned below:

1. **Research Strategy for immediate response and long-term preparedness to combat COVID-19 infection**

    a) **Diagnostics:**A Network of DBT Autonomous Institutes (AIs) namely, THSTI (NCR Cluster), NIBMG, CDFD, ILS, RGCB to co-ordinate and develop preparedness with respect to diagnostics; a priority for a populous nation. Diagnostic reagents in accordance with CDC protocols to be made available so that the assays could be validated. Translational assay lab being supportedat THSTI, under Ind-CEPI, to take a lead inthis direction and provide training. Potential industry partners could be identified. These could be from those funded by DBT and BIRAC for development of diagnostic devices ready to be used.

    b) **Vaccines:**DBT has been pro-active in responding to the emerging situation to support advancement of vaccine candidates and related technologies, by actively partnering with CEPI, through the DBT supported Ind-CEPI Mission. DBT would be actively supporting the Indian component of the applicants

selected in response to the call (i) 'Proven vaccine technologies, applicable for large scale manufacturing,(ii) Rapid response against novel Coronavirus, 2019-nCoV' issued by CEPI.

Department is actively engaged in discussion with a number of Indian industries for vaccine development and trial.

c) **Therapeutics:**A therapeutic approach could be based on selecting neutralizing antibodies againstviruses, using B cells from infected, but recoveredpatients, and making use of single cell sorting and antibody cloning technologies.These technologies have been in use for more than 10 years and areconstantly evolving.Also. the application ofsuch technologies for obtaining desired neutralizing antibodies against2019-nCoV has been demonstrated.

2. COVID-19Research consortia

In line with the research strategy, and recognizing the urgent need for accelerated development of vaccines and therapeutics against novel coronavirus, DBT along with its Public Sector undertaking, BIRAC, is publishing a "Request for Proposal (RFP) for COVID-19 Research Consortium".

The theme of the current RFP is:"*Developing Diagnostics, Vaccines, novel Therapeutics and repurposing of drugs for SARS-CoV-2".* The scope of the RFP is inclusive of and not exhaustive of the following areas:

Diagnostics:

- To develop technologies/Assays for diagnosis of coronavirus including diagnostic methods such as ELISA, Lateral Flow assay, Molecular diagnostics (PCR, Real Time PCR), colorimetric tests, Chemiluminescence, Immunoassays,cell culture

Vaccines:

- Vaccine technology platforms, novel vaccine manufacturing technologies, vaccine candidates and enabling disciplines for corona virus
- Type of candidate vaccine can be DNA, RNA, Live Attenuated Virus, Non-Replicating Viral Vector, Protein Subunit, Replicating Viral Vector at any stage of development
- In-licensing technology for optimization, scale-up and manufacturing

Novel Therapeutics

- To develop in-vitro assay/animal models and standardize challenge studies
- Screen existing libraries (Biologicals and Chemicals) and identify potential hits for development
- Novel methods of B-cell isolation/ monoclonal antibody development

Repurposing of Drugs

- Develop prophylaxis clinical studies and prioritize in healthcare workers
- Evaluate existing marketed drugs under a standard protocol in patients of COVID-19

3. Rapid Response Regulatory Framework

A meeting was held on 16th March, 2020 under the Chairpersonship of Secretary,Department of Biotechnology jointly with DCGI to discuss rapid responses for Regulatory approval to deal with epidemics / outbreaks of COVID-19. The Drugs Controller General (India), CDSCO and Chairman Review Committee oon Genetic Manipulation participated in the meeting along with other officials and experts.

It was decided to constitute a Committee Chaired by DCGI and Co-chaired by Chairman, Review Committee for Genetic Manipulation (RCGM) with experts in the field of toxicology, virology, diagnostics, vaccine development & clinical trials to facilitate and guide applicants for all regulatory requirements related to development of diagnostics, prophylactics and therapeutics for COVID-19.

It was also agreed that both the authorities will work together and reduce the timelines for approval of various permissions with respect to development of diagnostics, prophylactics and therapeutics for COVID-19.