

# DBT's Efforts to combat COVID-19



सत्यमेव जयते

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY  
GOVERNMENT OF INDIA**

**14<sup>th</sup> July, 2021**

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

**Overview**

Taking note of the unprecedented scenario of the COVID19 pandemic, the Department of Biotechnology (DBT) prepared a roadmap early on with a focus on diagnosis, treatment and most importantly, prevention. DBT, its Autonomous Institutions (AIs) and the Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC), have been working relentlessly over the past one year to develop effective interventions for combating the pandemic. Highlights of major activities include:

- Support for >100 projects in the thematic areas of vaccines, diagnostics and therapeutics.  
Enabling 7 vaccine candidates by industry and 8 candidates by academia
- 5 vaccine candidates, 19 clinical trial sites, 6 facilities for immunogenicity assays and animal challenge models, facility augmentation for Covaxin production, supported under Mission COVID Surksha.
- THSTI bio-assay laboratory recognized by Coalition for Epidemic Preparedness Innovations (CEPI), under their network of 7 global laboratories.
- Organized training programs for strengthening clinical trial capacities in neighboring countries under PACT initiative
- COVID 19 testing at 9 DBT AIs, approved as Hubs for their respective City/Regional clusters.
- Rapid scale-up of manufacturing of indigenous COVID-19 diagnostic kits with a production capacity of about 15 Lakh kits/day and deployment of nation's first infectious disease mobile laboratory in Haryana.
- Supporting genomic surveillance of emerging variants of SARS-CoV-2, through INSACOG initiative
- 5 COVID19 Biorepositories with ~57,000 samples available to academia and industry.
- Development of therapeutics from natural products in partnership with M/o AYUSH.
- Nearly 50 BIRAC supported start-ups have developed innovative products for COVID19.

A summary of the activities undertaken by DBT, DBT-AIs and BIRAC, in combating the pandemic is provided in the document. A brief on services / facilities offered by DBT AIs is enclosed as Annexure -I.

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

**COVID-19 – Delivering Solutions for Healthcare Challenges**

**I. Supporting COVID-19 research activities under DBT-BIRAC COVID-19 Research Consortium**

- The Department of Biotechnology (DBT) and its Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC), have published a "Request for Proposal (RFP) for COVID-19 Research Consortium" as part of the comprehensive efforts to facilitate development of indigenous research solutions to tackle COVID-19. A total of 103 proposals across academia, public funded research institutions and industry are being supported across the thematic areas of vaccines and supporting ecosystem (17); 33 diagnostics and facilities for scale-up (45); therapeutics, repurposing and supporting ecosystem (22); other biomedical interventions (23). The outcomes of the projects being supported are summarized in the respective sections.
- Continued support is being provided to the recommended projects for further development.

**II. Facilitating National efforts for COVID-19 vaccine development**

**a) Support for COVID-19 Vaccine development and manufacturing under Mission COVID Suraksha**

- ‘Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission’, was announced by Government of India (GOI) as part of the third stimulus package, Atmanirbhar 3.0, for promoting research and development of Indian COVID-19 vaccines. The Mission is led by the Department of Biotechnology (DBT) and is implemented by BIRAC, a Public Sector Undertaking (PSU) of DBT, at a total cost of Rs. 900 Cr. for 12 months. 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 the market for consideration of regulatory authorities and for introduction in public health systems.
- 5 vaccine candidates are being supported, including: mRNA platform-based vaccine by Gennova Biopharmaceuticals Ltd., Pune; Recombinant protein Subunit vaccine by Biological E; DNA Vaccine by Cadila Healthcare Limited; Novel intra nasal vaccine by Bharat Biotech International Limited; VLP vaccine candidate by Genique Life sciences Pvt. Ltd.
- 3 Immunogenicity Assay Laboratories for SARS-CoV-2 clinical immunogenicity studies are being supported at: IRSHA Pune; Syngene International Ltd, Bengaluru; THSTI, New Delhi. The assays being established include Total IgG measurement, pseudovirus neutralization assays, PRNT assays, microneutralization assay, cell free surrogate assays, ELISPOT and CMI assays. THSTI and IRSHA are already providing the services to vaccine developers.

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

- 3 Animal Challenge facilities at ILS Bhubneshwar; NCBS / inStem, Bangalore; and IISc, Bangalore are being supported for: development of hamster models; generation of indigenous transgenic mice; maintenance and breeding of imported transgenic mice. 19 clinical trial sites are also being supported.
- Further, in order to enhance capacities for augmented vaccine production, support to BBIL and three Public Sector Enterprises (PSEs), (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, over the next 6-8 months. The Department of Biotechnology (DBT) is also facilitating technology transfer for 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.
- The process of technology transfer for COVAXIN production from BBIL to the PSEs is in progress, as part of the voluntary licensing process. The efforts are expected to boost the production capacity of COVAXIN from current 15-18 million/month to 80 million/month by year end.
- The Republic Day tableau for 2021, by the Department of Biotechnology depicting 'India's Fights against COVID-19' was adjudged the best tableau amongst the Ministries and Departments of Government of India.

**b) Support for Vaccine development under DBT-BIRAC COVID-19 Research Consortium**

- 17 proposals were supported under the DBT-BIRAC COVID-19 Research Consortium Call for vaccine development and research resources, with funding being routed through National Biopharma Mission and Ind-CEPI Mission. Seed funding was provided for pre-clinical development of vaccine candidates including: DNA vaccine candidate (ZyCoV-D by Zydus Cadila); mRNA vaccine candidate (HGCO19 by Gennova Biopharma); Vesiculovax platform (Aurobindo Pharma); Recombinant subunit vaccine (Biological E); Recombinant Adeno associated virus based vaccine (Intas Pharmaceuticals); Active virosome vaccine (Seagull Biosolutions Pvt Ltd); Intranasal Mucosal Vaccine for COVID-19 Infection (Institute of Chemical Technology) Virus Like Particle vaccine candidate by National Institute of Biomedical Genomics; repurposing of BCG vaccine for COVID-19; mRNA Vaccine candidate (CMC, Vellore). Additionally, projects encompassing development of animal models, pseudovirus platforms, devices for vaccine administration and large-scale manufacturing of Spike protein have also been supported.

**c) Upgradation of DBT's laboratories as Central Drug Laboratories (CDLs) for Vaccine Testing**

- Based on the recommendation of the Cabinet Secretariat, two DBT Autonomous Institutes - National Institute of Animal Biotechnology (NIAB), Hyderabad and National Centre for Cell Science (NCCS), Pune, have been identified for upgradation as Central Drug Laboratories (CDLs), for vaccine testing. Based on the Detailed Project Report (DPR) from

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

NIAB and NCCS, shared with MoHFW, in principle approval has been accorded by the PMO, whereby, the PM CARES Funds Trust has transferred Rs. 9,22,00,000/- and Rs. 11,19,60,000/- to the dedicated bank accounts of NIAB and NCCS, Pune, respectively, on March 6, 2021.

- The facility at NCCS, Pune, was notified as CDL, by MoHFW, on June 28, 2021 and is likely to be operational in by Mid-July, 2021. The Facility at NIAB likely to be operational from August 2021.

**d) Regulatory facilitation by DBT**

- The Department has proactively taken several steps to support researchers and industries involved in research on COVID-19 and issued Biosafety Regulations for COVID 19, in close coordination with CDSCO, for facilitating expedited approvals / clearances. The following Biosafety Regulations for COVID 19 have been provided by the Review Committee on Genetic Manipulation (RCGM) and Drugs Controller General of India (DCGI):
  - Rapid Response Regulatory Framework: to provide expedited regulatory approvals for all diagnostics drugs and vaccines
  - Regulations and Guidelines for recombinant DNA Research & Biocontainment- Interim Guidelines of laboratory biosafety to handle COVID 19 specimens for R & D purpose
  - A Rapid Response Regulatory Framework for COVID 19 Vaccine development.
  - Also, the Department of Biotechnology has worked with the NITI Aayog to provide Guidelines for sharing of Bio-specimen & Data for Research on COVID-19.

**e) Cooperation with Russia for clinical development of the Russian vaccine Sputnik V**

- Based on discussions of Government of India with Russian Direct Investment Fund (RDIF), a Confidentiality Disclosure Agreement (CDA) was signed between Biotechnology Industry Research Assistance Council (BIRAC)- a Public Sector Undertaking (PSU) of DBT and RDIF, for advancing the development of Sputnik V in India.
- Dr. Reddy's Laboratories Ltd. (DRL) has been identified to undertake late-stage clinical trials of Sputnik V in India. DRL has partnered with BIRAC for advisory support on clinical trials and Translational Health Science and Technology Institute (THSTI), an Autonomous Institute of DBT, has been identified to provide immunological assessment for the clinical trials of Sputnik V.
- Emergency Use Authorisation for Sputnik V, in India, was approved in April, 2021.
- To expand the manufacturing capacity of Sputnik V in India, 6 Indian manufacturers have been identified including Hetero Biopharma, Virchow Biotech, Stelis Biopharma, Gland Pharma, Panacea Biotec and Shilpa Medicare. Technology transfer by Russian Direct Investment Fund (RDIF) is in process. The domestic production of Sputnik V is expected to begin by August, 2021.

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

**f) Efforts for vaccine development by DBT- Autonomous Institutes**

<b>S.No.</b>	<b>Institute</b>	<b>Platform</b>	<b>Current status</b>
1.	National Institute of Immunology (NII), New Delhi	Protein-based subunit	<ul style="list-style-type: none"> <li>Developed a novel indigenous RBD based candidate vaccine using E.coli. The process of evaluating the efficacy of protein-based subunit vaccine in animal model is being studied.</li> <li>CDA with Cadila Pharma signed for pre-clinical development.</li> </ul>
2.	National institute of Biomedical genomics (NIBMG), Kalyani	Virus Like Particle (VLP)	<ul style="list-style-type: none"> <li>Novel baculovirus expressed VLP based vaccine candidate being developed. VLP characterization has been completed; preliminary immunogenicity study is started; Generation of VLPs incorporating mutations pertaining to emerging variants is being undertaken.</li> <li>Provisional patent application underway.</li> </ul>
3.	International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi	VLP	<ul style="list-style-type: none"> <li>Developing yeast-expressed RBD-VLP based COVID-19 vaccine candidate; pre-clinical studies in progress.</li> </ul>
4.	Translational Health Science and Technology Institute (THSTI), Faridabad	Self-amplifying mRNA	<ul style="list-style-type: none"> <li>Pre-clinical studies underway</li> </ul>

**III. International Partnerships for accelerating COVID-19 vaccine development**

**a) Participation of the Government of India in the ACT -Accelerator (ACT-A)**

- The Access to COVID-19 Tools (ACT) Accelerator is a collaborative taskforce launched by World Health Organization (WHO) to promote the development, production and equitable distribution of vaccines, diagnostics and therapeutics for COVID-19.
- The key partners in this initiative are WHO, Coalition for Epidemic Preparedness Innovations (CEPI), Bill & Melinda Gates Foundation (BMGF), Wellcome Trust and Global Alliance for Vaccines and Immunizations (GAVI).

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

- The ACT accelerator has three verticals, one each for Vaccines, Therapeutics and Diagnostics. In June, 2020, the intent of Government of India to partner in this alliance was conveyed, whereby, DBT was identified as the focal point for the R&D and manufacturing.
- The ACT-Accelerator is represented by Dr Vinod Paul, Member (Health), NITI Aayog; Professor K. Vijay Raghavan, Principal Scientific Adviser to the Government of India; Dr.Renu Swarup, Secretary DBT and Sh. Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare.
- The ACT-A Facilitation Council (FC) has been constituted to provide oversight and review the progress of the accelerator, mobilize resources and engage with stakeholders. The Government of India has nominated Sh. Lav Agarwal, Joint Secretary, Ministry of Health and Family Welfare, as national focal point from India for ACT-A Facilitation Council.
- So far six meetings of the ACT-A FC have been held and a high-level finance ministries' meeting were held. The meetings are intended to help the international community address key strategic, policy and financial issues relating to development, production, procurement and distribution of vaccines, therapeutic and diagnostic equipment.
- The 'Vaccine Pillar' of the ACT Accelerator is known as COVAX and is co-led by Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi (The Vaccine Alliance). The COVAX facility aims to get 2 billion doses of COVID vaccine by the end of 2021 and assures the participating countries for vaccine doses to cover 20% of their country's population.
- In the G7 Leaders' summit held on 13<sup>th</sup> June,2021, a commitment of 870 million doses of COVID vaccines was made for COVAX facility, for the years 2021 and 2022, with the aim to deliver at least half the doses, by the end of 2021. As of 25th June, 2021, a commitment of USD 17.7 billion was received by the ACT-A.
- Through a communication to Government of India, CEO Gavi, confirmed that India is eligible to receive official development assistance (ODA) support through the COVAX AMC, to receive doses of COVID-19 vaccines through the COVAX Facility.

**b) Participation of DBT in the Quad partnership**

- The Quad Cooperation is an alliance between four countries including the United States, Australia, India, and Japan to accelerate the global COVID-19 response and to build longer term global health security.
- A major focus was on international cooperation to ensure equitable access to COVID-19 vaccines. Considering India's strengths in vaccine manufacturing, India has been identified to provide manufacturing support.
- DBT participated in the first Quad Leaders' Summit held in March, 2021, whereby, it was proposed that a Quad Vaccine Expert Group (VEG) may be constituted to execute Quad partnership activities to improve availability and delivery of COVID-19 vaccines globally and within the Indo-Pacific region. 03 meetings of the Quad VEG have been held so far.
- As an outcome of the Summit, Biological E has agreed to work with the US Development Finance Corporation (DFC) to enhance production of Johnson & Johnson's COVID-19 vaccine candidate. Further, DBT is closely coordinating with MEA on strengthening the manufacturing capacities in India as a part of Quad Initiative.

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

**c) India-PACT-Programme (Partnerships for Accelerating Clinical Trials)**

- The Partnerships for Advancing Clinical Trials (PACT) programme is a science diplomacy initiative of the Department of Biotechnology, implemented by BIRAC and Clinical Development Services Agency (CDSA).
- The national partners include Ministry of External Affairs, Ministry of Health and Family Welfare, Indian Council of Medical Research (ICMR), Central Drugs Standard Control Organisation (CDSCO), and the international partners include Coalition for Epidemic Preparedness Innovations (CEPI), World Health Organization (WHO) and National Institute of Health (NIH).
- The programme is aimed at advancing vaccine development activities in neighbouring countries and conducting training programmes to strengthen clinical trial capacity in neighbouring countries. The trainings envisaged an in-depth coverage of ‘Good Clinical Practice; Ethical considerations in clinical research; Good Clinical Laboratory Practice; Novel vaccine development and immunization policy in a pandemic’.
- Series 1 of the PACT training program was held during Sep-Dec 2020 wherein, a total of 771 candidates from Afghanistan, Bangladesh, Bhutan, Maldives, Mauritius, Nepal and Sri Lanka., participated in the 10 sessions.
- The 2nd E-course series was held during Feb-Apr, 2021, whereby, 1758 candidates participated across the 10 sessions of from Afghanistan, Bahrain, Bhutan, Gambia, Kenya, Myanmar, Nepal, Oman, Somalia, Vietnam and USA.

**IV. Efforts for COVID-19 Testing and Diagnostics**

**a) Testing for COVID-19**

- DBT has identified 21 City /Regional clusters to scale up covid testing as a part of the Hub and Spoke model. Nine Autonomous Institutes (AIs) of DBT have been approved as testing centres for COVID-19 diagnosis. These DBT AIs have also been identified as hubs for their respective regions.
- For the July-Dec 2020 duration, 12 hubs/spokes performing COVID tests have been supported by the Department for the manpower component. For Jan-June 2021 duration, 3 hubs/spokes have been supported, for the manpower and consumable component.
- The information pertaining to testing activity for the 15 city/regional clusters in the week from July 02, 2021 to July 08, 2021 is given below:

S.No	Title of the activity	KPIs	Disaggregation level	Numbers
1	COVID-19 Responses	No. of tests performed	Telangana (Hyderabad)	780
			Kerala (Thiruvananthapuram)	513
			Odisha (Bhubaneswar)	8061
			UP (Lucknow)	17218

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

		Delhi (NCR)*	933
		Karnataka (Bangalore)	5594
		Maharashtra (Mumbai)	154
		Maharashtra (Nagpur)	31247
		Tamil Nadu (Chennai)	1646
		UP (Banaras)	25692
		North East (Mizoram)	7607
		Madhya Pradesh (Bhopal)	1598
		Himachal Pradesh (Palampur)	1221
		Delhi City	2073
		Punjab (Mohali)	47

\*\*464 samples were tested in Faridabad region by the Mobile testing I-Lab.

- 1,04,384 samples were tested in the 15 city/regional clusters during the past one week. Total samples tested so far through this hub and spoke model since 15th April, 2020 are 53,08,821.
  - Andhra Pradesh Med Tech Zone (AMTZ) is a common shared facility to manufacture diagnostic kits and ventilators. AMTZ is operationalizing indigenous manufacturing of kits and reagents for testing. COVID-19 related activities were taken up by AMTZ under the DBT-BIRAC-AMTZ-COMMAND (COVID Medtech Manufacturing Development) strategy.
  - Andhra Med Tech Zone (AMTZ) has achieved a production capacity of >10 Lakh RT-PCR COVID-19 diagnostic tests/day and >1 Lakh VTM/day. AMTZ has so far manufactured the following: RT-PCR tests – 150 lakh tests, Viral Transport Medium – 8 lakh units, IR Thermometers – 2500 units, Ventilators – 3950 units, Pulse – Oximeters 200 units.
  - AMTZ also developed the Nation's first first I-lab (infectious disease diagnostic lab) to ramp up the Covid testing in rural and inaccessible areas. The first I-Lab is attached to the THSTI hub. A total of 22399 tests have been performed by the mobile lab from Faridabad region.
- b) Constitution of National Biomedical Resource Indigenization Consortium (NBRIC)**
- The Department of Biotechnology (DBT) constituted NBRIC in a Public Private Partnership mode to foster indigenous innovation focused on developing reagents, diagnostics, vaccines and therapeutics for COVID19.
  - NBRIC is led by ABLE (Association of Biotechnology Led Enterprises) and CII (Confederation of Indian Industry), and is hosted by C-CAMP (Centre for Cellular and Molecular Platforms).
  - More than 300 Indian Manufacturers registered under the consortium for the manufacturing of nearly 15 major components/ reagents. 8 NBRIC members have developed, manufactured and deployed novel, low-cost, gold standard RT-PCR test kits, ELISA rapid antibody testing kits and enzymes/reagents key to running these test kits.

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

**c) Support for development of diagnostics under DBT-BIRAC COVID-19 Research Consortium call**

- 45 projects are being supported through DBT-BIRAC COVID-19 Research Consortium Call for production of PCR and serology-based diagnostic kits at mass scale and indigenous development of good quality primers and probes.
- First Indigenous kit for diagnosis of COVID-19 developed by a BIRAC supported start up (MyLab) in Pune, is producing nearly one lakh kits per week. More than 90 lakh kits manufactured till date.
- Ubio Biotechnology Systems and Dhiti Life Sciences developed indigenous Antibody and Antigen detection kits are in market. Apart from this, Molecular Transport Medium (MTM) and Nucleic acid extraction kits developed by HuwelLifesciencs are also available in market.
- The number of products manufactured till date by DBT-BIRAC supported companies are mentioned below:
  - Mylab: RT PCR - 36 Lakhs and Antigen detection test 54 Lakhs
  - Ubio Biotechnology Systems: Antibody detection test: 80000, Antigen detection test: 2000000 and RT-PCR tests: 500000
  - Dhiti Life Sciences: 35 lakhs Ag detection test, 3 Lakhs Antibody detection tests

**d) Efforts for development of diagnostics by DBT Autonomous Institutes**

S.No.	Institute	Current status
1.	Translational Health Science and Technology Institute (THSTI), Faridabad	<ul style="list-style-type: none"> <li>• Developed a panel of Aptamers for diagnosing Coronavirus disease</li> <li>• DNAzyme Visual detection-based method developed</li> </ul>
2.	International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi	<ul style="list-style-type: none"> <li>• Developed an indigenous total antibody test kit called 'COVID-19 [IgM, IgG, IgA] MICROLISA' test</li> <li>• MoU established between ICGEB and J Mitra &amp; Co and efforts underway for the development of an antigen test for COVID-19.</li> </ul>
3.	Rajiv Gandhi Centre for Biotechnology (RGCB), Trivandrum	<ul style="list-style-type: none"> <li>• Developed COVID-Anosmia Checker: A rapid and low-cost alternative tool for mass screening of COVID-19</li> </ul>
4.	Institute for Stem Cell Science and	<ul style="list-style-type: none"> <li>• Combinatorial sensing protocol algorithm validated by scientists at inStem</li> </ul>

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

	Regenerative Medicine (InStem), Bangalore	<ul style="list-style-type: none"> <li>Partnering with CCAMP in the InDxprogramme to review quality and quantity of indigenously developed kits.</li> </ul>
5.	National institute of Animal Biotechnology (NIAB), Hyderabad	<ul style="list-style-type: none"> <li>Developed a sensitive potentiostat based biosensor for detection of surface antigen of novel corona virus in clinical sample upto femto molar range.</li> <li>Developed a low cost, fluorescence based direct assay for sensitive detection of SARS-CoV-2</li> </ul>
6.	National Agri-food Biotechnology Institute (NABI), Mohali	<ul style="list-style-type: none"> <li>Developed lateral flow assay (LFA) strip; using aptamers against nucleocapsid peptide molecules and citrate gold nanoparticles to enhance detection limit.</li> </ul>
7.	National Institute of Immunology (NII), New Delhi	<ul style="list-style-type: none"> <li>A low cost point-of-care serology test (Hemagglutination (HAT) assay) for measuring IgG, IgM and IgA</li> </ul>

**V. Facilitating research efforts for COVID-19 Therapeutics**

**a) Support for development of therapeutics under DBT-BIRAC COVID-19 Research Consortium call**

- 22 projects are being supported under DBT-BIRAC COVID-19 Research Consortium call for development of novel indigenous therapeutic interventions for COVID-19. Commercial scale purification and clinical trials of immunoglobulin G (IgG) from convalescent individuals, manufacturing equine hyper immunoglobulin against COVID 19 infection and development of 3D Lung Organoid models are noteworthy.
- Virchow Biotech, supported under National Biopharma Mission, was approved by the Drug Controller General of India for conducting Phase II Randomised controlled multicentric Clinical Trials to evaluate safety and efficacy of COVID-19 Hyper-immunoglobulin in COVID-19 patients.
- DBT-BIRAC supported anti-viral drug - Virafin (pegylated interferon alpha-2b) by Zydus Cadila has been approved for emergency use for moderate COVID-19 infection.
- DBT-BIRAC supported Eystem Research Pvt. Ltd. has developed human iPSC derived lung airway and alveolar epithelial cells for disease modelling and for testing potential therapeutics against COVID-19.

**b) Development of COVID-19 Therapeutics by DBT Autonomous Institutes**

S.No.	Institute	Current status
-------	-----------	----------------

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

1.	Institute of Life Sciences (ILS), Bhubaneswar	<ul style="list-style-type: none"> <li>• Immuno-profiling of COVID-19 positive patients using combination of approaches employing ELISA, Bioplex and mass cytometry to study immune response</li> </ul>
2.	Institute for Bioresource and Sustainable Development (IBSD), Manipur	<ul style="list-style-type: none"> <li>• Preparation of several extracts of NER medicinal plants with anti-viral properties</li> <li>• Monograph on medicinal plants of North-East Region prepared and is available on the DBT portal.</li> <li>• Project entitled “Sub-Network 1: Studies on anti-SARS-CoV-2 activity of selected medicinal plants and formulations in cell culture model of virus infection” under “DBT-AYUSH Network on R&amp;D Activities related to SARS-CoV-2 Virus and COVID-19 Disease” to be implemented and work is under progress.</li> </ul>
3.	National Centre for Cell Sciences (NCCS), Pune	<ul style="list-style-type: none"> <li>• Generation of virus-neutralizing human monoclonal antibodies against SARS-CoV-2: positive B cell clones secreting RBD-specific antibodies selected and neutralization efficacy studies underway. Almost 10 clones showed neutralization with the real virus, which are being characterized further. Four more clones were obtained, which yielded antibodies that bind strongly to the RBD. Their supernatants will be sent to BBIL to test for neutralization.</li> <li>• Developed Peptide-based therapeutics using machine learning to identify possible therapeutics for COVID-19</li> </ul>
4.	National Institute of Plant Genome Research (NIPGR), New Delhi	<ul style="list-style-type: none"> <li>• Potential flavonoids have been purified and their antiviral activity is being tested, two flavonoids have shown significant viral inhibition in cell culture experiment. The 7-point IC50 determination of the selected flavonoids to check the minimal inhibitory concentration is going on.</li> <li>• Glucosinolates, glucomoringin (<i>Moringaoleifera</i>) and glucoraphanin (<i>Brassica</i> species) purified and efficacy of these molecules is being tested in animal cell line infected with SARS CoV2. Out of six tested biomolecules, one glucosinolate has shown significant viral inhibition in the cell culture experiment.</li> </ul>
5.	International Centre for Genetic Engineering and Biotechnology, Delhi	<ul style="list-style-type: none"> <li>• Phase-2 trials on AQCH, a phyto-pharmaceutical drug as potential treatment for COVID-19 patients were initiated</li> <li>• Generated over 100 productive monoclonal antibody clones</li> <li>• Developing a cell-based assay for screening of chemical libraries for identifying new drugs/leads</li> </ul>

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

		<ul style="list-style-type: none"> <li>• SARS-CoV-2 Mpro protease was purified and novel inhibitors screened using Surface Plasmon Resonance kinetics and a 96-well format Enzyme inhibition assay</li> <li>• SARS-CoV-2 viral infections in VERO-E6 cell line were established</li> </ul>
6.	National Institute of Immunology (NII), New Delhi	<ul style="list-style-type: none"> <li>• T-cell assays have been developed for studying the T-cell correlates-of-protection in COVID-19 and measuring the vaccine efficacy.</li> <li>• Provided the evidence for existing T-cell immunity in around 70% of the Indian population</li> </ul>
7.	Regional Centre for Biotechnology, Faridabad	<ul style="list-style-type: none"> <li>• Screened the in vitro antiviral activity of 15 plant extracts; Tulsi, Kalmegh and Kalonji showed maximum antiviral activity</li> </ul>
8.	Center of Innovative and Applied Bioprocessing (CIAB), Mohali	<ul style="list-style-type: none"> <li>• Polypyrrollic photosensitizers and their nanoformulations for antiviral photodynamic therapy</li> <li>• Natural garlic essential oil as an ACE 2 protein inhibitor for preventing SARSCoV-2 invasion.</li> <li>• A provisional patent has been filed on 31/3/-2021 entitled 'Lignin based polypyrrolenanoformulations as highly effective antiviral agents against SARS-CoV-2'.</li> </ul>
9.	Translational Health Science and Technology Institute (THSTI), Faridabad	<ul style="list-style-type: none"> <li>• Preclinical and Pharmacokinetics Evaluations of select AYUSH Herbal Extracts/Formulations for mitigating SARS-CoV2 Associated Pathologies</li> <li>• Collaboration Agreement with Eystem Research Private Limited for proprietary Anti-SARS-CoV-2 screening platform using iPSC derived lung progenitors to screen whether lung lineage iPSC cells can be infected with SARS-CoV-2.</li> <li>• Project entitled “Sub-Network 2: Preclinical and pharmacokinetics evaluation of selected AYUSH herbal extracts / formulations for mitigating SARS-CoV2 and associated pathologies” sanctioned under “DBT-AYUSH Network on R&amp;D Activities related to SARS-CoV-2 Virus and COVID-19 Disease”</li> <li>• An MoU for in-vivo studies of plant extracts signed between DBT and National Medicinal Plants Board (NMPB), Ministry of AYUSH to explore the anti-SARS-CoV-2 effect of oral ayurvedic formulations</li> </ul>

**VI. Research efforts on SARS-CoV-2 genomics**

**a) PAN India 1000 genome sequencing initiative**

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

- The Department of Biotechnology had launched PAN- India 1000 SARS--CoV-2 RNA Genome Sequencing programme in May, 2020.
- The consortium coordinated by National Institute of Biomedical Genomics (NIBMG-Kalyani), West Bengal and Five other National clusters including: ILS-Bhubaneswar; Centre for DNA Fingerprinting and Diagnostics (CDFD)-Hyderabad;inStem- National Centre for Biological Sciences (NCBS)-IISc-Bangalore; NCCS-Pune.Other National Institutes and hospitals have also collaborated in this effort.
- As on date, the Consortium has successfully completed its initial goal of completing the sequencing of 2000 SARS-CoV-2 genomes with samples across 10 states covering different zones. Multiple lineages of SARS-CoV-2 were observed to be circulating in India, with a predominance of the A2a haplotype (20A/B/C) with D614G mutation.

**b) Indian SARS-CoV-2 Genomics Consortium (INSACOG)**

- The Indian SARS-CoV-2 Genomics Consortium (INSACOG) is a consortium of 28 Regional Genome Sequencing Laboratories (RGSLs) established with the overall aim is to sequence SARS-CoV2 from Covid-19 infections in India to monitor the emergence and community circulation of viral variants and variants of concern (VOC).
- A datahub for centralized storage, analysis and management of SARS-CoV-2 sequences from different Indian institutes has been established at NIBMG and IGIB.
- As on 2<sup>nd</sup> July, INSACOG partner institutions have sequenced 50,521 samples and the line list with Pangolin lineage information for 39,124 sequences have been submitted to NCDC. Till date, 32593 viral genome sequences from India shared in the global repository of sequences, GISAID. Of these 32593 viral genome sequences, 23967 are shared with INSACOG Tag in GISAID.
- INSACOG activities have been expanded covering the various aspects for sentinel surveillance, targeted sampling (Surge, Vaccine-breakthrough etc.), Hospital network samples sequencing for clinical correlation, and environmental surveillance (sewage samples etc.). This will allow good representative sampling to be done and also clinical cohort to be connected to understand the virus mutation epidemiologically.
- Discussions are underway to further expand the sequencing network as a 'Hub and Spoke' model, whereby, inclusion of private sequencing laboratories in INSACOG is being explored.

**VII. COVID-19 solutions supported by BIRAC's BioNEST network**

- 50 BioNEST incubators spread across the country have responded to the Covid situation and collectively this network has nurtured 100+ Startup solutions for Covid.
- BIRAC recognizing the efforts has considered co-funding requests from two of the BioNEST Incubator Partners
  - (i) IKP Knowledge Park for I-Co Fund to support upto 15 Startup solutions and
  - (ii) C-CAMP for C-CIDA to support upto 10 Startups.

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

- 200+ Webinars have been conducted for business mentoring, Fund raising, Industry Connect, Legal advice and how to sustain in the Covid and post-Covid times. Over 20,000 Startups, Entrepreneurs, Researchers, Stakeholders have been reached.
- Regulatory facilitation of 250+ Startups through FIRST HUB and RIFC was done.
- BioNEST Incubators recognizing Startups difficult financial situation, have waived off 25-100% of incubation rentals for 3 months.
- A new mask with germicidal fabric “G-fab” that traps and destroys microbes including COVID-19 has been manufactured by C-CAMP incubatee, M/s Color Threads Pvt. Ltd. The technology was developed by scientists at DBT-inStem.
- CCAMP COVID-19 Accelerator (CCIDA) supported Dozee Health was awarded the Economic Times Innovation Award under New product/ Service innovation category, for their contactless health monitoring device, that can remotely monitor symptoms of COVID-19 even when asleep.

**VIII.DBT-BIRAC support to Start-ups and Co-funding Partners**

- In view of a need to identify and provide fast track support to Health-Tech Startup solutions for immediate deployment (0-3 months) to address challenges of COVID-19, a Fast track Internal Review Committee was constituted at BIRAC to review and recommend the proposals that can be supported under COVID fund.
- Funding has been disbursed to 7 Startups till now:
  - Aarna Biomedical Products,
  - Alpha Corpuscles,
  - MicroGO,
  - Ubicare Health
  - Ayu Devices
  - Health Sensei
  - DNA Xperts Private Limited
- Two of the start-ups supported under the BIRAC’s Fast Track Internal Review Initiative- Aarna Biomedical Products and MicroGO LLP got a privilege to interact and present their product details before Hon’ble PM Shri Narendra Modiji at the DPIIT International Summit-Prarambh organized on 15<sup>th</sup> Jan 2021.
- Additionally, BIRAC has also approved support to two Co-funding partners IKP and CCAMP for co-funding upto 25 Startups under the BIRAC’s mandate to foster market deployment of innovative solutions addressing Covid-19 challenges.
- CCAMP supported start-up Shanmukha's mobile COVID testing lab Mitr, with ability to test 300 samples per day was launched in Uttarakhand.
- Two of BIRAC supported Startup technologies - Blackfrog and Alfa corpuscles, were showcased to Secretary Pharma Dept. for evaluation and possible adoption for Immunization program based on merit.
- C-CAMP COVID-19 Innovations Deployment Accelerator’s (CCIDA) start-upCoeoLabsdeveloped a novel, multimodal & portable Continuous Positive Airway

**DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY**

Pressure (CPAP) respirator that has been deployed in multiple hospitals across India Efforts are on to incorporate automation in the device, to enhance functionality.