DBT’s RESPONSE TO COVID-19
S&T Interventions for COVID-19

PRODUCT DEVELOPMENT
- Medical Devices and Diagnostics
- Vaccines
- Biotherapeutics
- Botanicals

ECOSYSTEM SUPPORT
- Production Scaleup Facilities
- Fast Track Approvals
- Support To Startups
- Mentoring
COVID-19 Research Consortium

Develop biomedical tools for prevention, identification and treatment to combat the epidemic of COVID-19 through considering a holistic approach addressing critical roadblocks.

Testing
- Development of molecular and serological tests
- Development of novel diagnostics
- Testing Hubs
- Mobile I-Lab

Treatment
- Plasma therapy
- Monoclonal antibodies
- Drug re-purposing efforts
- DBT-AYUSH Phyto-pharmaceuticals

Genomics
- PAN-India 1000 SARS-COV-2 RNA genome sequencing successfully completed by DBT AI consortium
- Nasal microbiome study - Useful for epidemiological studies

Prevention
- BCG Trial
- Multiple vaccine platforms
- Assays and animal models
- Clinical Trial sites
- Immunoassay lab

Facilitating the Ecosystem
- 5 COVID-19 Bio-repositories
- Indigenization of Resources
- Validation Centres
- Rapid Regulatory Framework

Other interventions
- Scaling up of manufacturing - ventilators, PPE, Screening and monitoring devices, disinfection and sterilization platforms
Mission COVID Suraksha
the Indian COVID-19 Vaccine Development Mission

Bringing 5-6 vaccine candidates that are closer to licensure and introduction in the market within the next 12 months.

+ Announced as part of the Atmanirbhar Bharat 3.0 package
+ Mission led by DBT and implemented by BIRAC, a PSU of DBT
+ Rs. 900 Cr. for 12 months
## COVID Vaccines Portfolio

3 vaccine candidates received Emergency Use Authorization

<table>
<thead>
<tr>
<th>Vaccine Candidates</th>
<th>Preclinical Development</th>
<th>Clinical Phase I</th>
<th>Clinical Phase II</th>
<th>Clinical Phase III</th>
<th>EUA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covishield, SII-AZ</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Covaxin, BBIL-ICMR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputnik V, DRL-RDIF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNA Vaccine, Zydus Cadila</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein Subunit Vaccine, BioE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mRNA Vaccine, Gennova</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intranasal Vaccine, BBIL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabies Vector based Vaccine, BBIL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novel Active Virosome, Seagull</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adeno-associated virus [rAAV], Intas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCG Vaccine (repurposing), SII</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DBT supported COVID-19 Bio-Repositories

Institute of Life Sciences (ILS), Bhubaneswar
252 SAMPLES

Institute of Liver and Biliary Sciences (ILBS), New Delhi
~25000 SAMPLES

Institute For Stem Cell Science and Regenerative Medicine (InStem), Bangalore
121 SAMPLES

Translational Health Science and Technology Institute (THSTI) and
Regional Centre for Biotechnology (RCB), Faridabad
~16290 SAMPLES

National Centre for Cell Science, Pune
~127 SAMPLES

41790 clinical samples and 17 viral isolates collected; ~6000 biospecimens shared for > 30 requests
NABL Accredited Bioassay Laboratory at THSTI
Recognized by CEPI as one of the 7 global network of laboratories for harmonized assays for vaccine development.

Neutralization assay services provided for 6 manufacturers
CEPI validated assays for vaccine candidates from BioE, India & Medigen, Taiwan.

Immunogenicity Assay laboratories being supported at IRSHA, Pune; THSTI, Delhi and Syngene Bangalore.

THSTI and IRSHA already service providers.

Animal Challenge facilities at ILS Bhubneshwar NCBS/In-STEM, Bangalore; IISC, Bangalore, THSTI for SARS-CoV-2.

THSTI is offering Hamster Challenge services to vaccine manufacturers; K-18 hACE2 transgenic mice Breeder pairs available for redistribution at inStem.
Field Sites for Clinical Trials
DBT’s Resource of Indian Vaccine Epidemiology Network (DRIVEN)

PAN-India 53 sites including 36 hospital sites
Augmenting Vaccine Manufacturing Capacities

- Financial support to Bharat Biotech International Ltd. (BBIL) and 3 Public Sector Undertakings (PSUs) to scale-up production capacity of Covaxin.

- Covaxin production to increase from the current 10 million doses/month to 100 million doses/month.

- Upgradation of DBT’s laboratories at National Institute of Animal Biotechnology (NIAB), Hyderabad and National Centre for Cell Science (NCCS), Pune as Central Drug Laboratories (CDLs).

- Interim facility at NIAB and NCCS to be operational from May 2021.
Global Partnerships

- Partnership with Ministry of External Affairs (MEA) and Indian Missions abroad for strengthening of clinical trial capacity in neighbouring countries.

- THSTI’s Bioassay laboratory supported under the Ind-CEPI Mission selected by as one of the 06 global network of laboratories for centralized assessment of COVID-19 Vaccines.

- DBT as the focal point for the R&D and manufacturing as part of the ACT accelerator

India’s Engagement in ACT Accelerator

DBT’s Response to COVID - 19
India - PACT - Programme (Partnerships for Accelerating Clinical Trials)

National Partners

International Partners

Implemented by
Training Program to Strengthen the Clinical Trial Research Capacity in Neighbouring Countries

Successfully completed 2 training series of 4 E-Courses between Sep-Dec 2020 and Feb-Apr 2021.

Organised by DBT India and BIRAC, through their Ind-CEPI Mission along with MEA and Missions abroad.

Participation from Afghanistan, Bahrain, Bhutan, Bangladesh, Gambia, Kenya, Myanmar, Maldives, Mauritius, Oman, Nepal, Somalia, Sri Lanka, Vietnam
Achieved 100 % self-sufficiency in indigenous diagnostic kit production

MTM and NAE kits – Huwel

Ag & Ab -detection
LFA – Dhiti

IgG/IgM detection
LFA – Ubio

Patho Detect RT-PCR Kit MyLab
Promoting Indigenous Biomanufacturing of COVID-19 Diagnostic Kits and Reagents

NBRIC is a ‘A Make in India’ initiative for Biomedical research and innovative products, promoting import substitution and exports.

+ 200+ Indian Manufacturers registered under the consortium for the manufacturing of 15 major components/ reagents.
PAN-India 1000 Genome Sequencing & INSACOG: Indian SARS-CoV-2 Genomics Consortium

Inter-ministerial consortium of 10 public funded research institutions

Ascertain Status of new SARS-Cov-2 variants

501Y.V1, 501Y.V2 and 20J/501Y.V3 variants identified

DBT AIs have generated about 2562 sequences so far

Temporal and spatial analyses reveal clustering pattern

A2a halotype dominating other lineages

More than 20000 samples sequenced

PAN-India 1000 SARS CoV-2 RNA Genome Sequencing Consortium
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.

Phase II clinical trials of Anti-dengue botanical drug (AQCH) (developed jointly by ICGEB, CSIR-IIIM and Sun Pharma) for COVID-19, in progress across 10 centres in India covering 200 patients.

DBT network project with Ministry of AYUSH for screening of 15 medicinal plants and 8 traditional Ayurvedic formulation for anti- SARS-CoV-2 activity.

**Biosafety Regulation for COVID-19**

RCGM/DCGI

- Rapid Regulatory Response Mechanism.
- Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens
- A Rapid Regulatory Pathway for COVID Vaccine developed to facilitate Vaccine Trials.
- A Guidance Document for COVID 19 Vaccine Clinical Trial released by DCGI.
COVID-19 Consortium:
BIRAC
Support to Startups

1000+
Identification

3
Funding Initiatives

35+ Funding*
200+ Regulatory
100+ Network
Supported

*In Progress

WEBINARS
+ Fund raising.
+ Business mentoring.
+ Regulatory Guidance
+ Re-Strategize business

200+
Webinars for mentoring
+ Business mentoring.
+ Regulatory Guidance (FIRST HUB, RFIC).
+ Re-Strategize business to sustain in difficult phase of Covid and post Covid.

25000+
Startups/Researchers/Entrepreneurs/Stakeholders reached

125+
Startup solutions offered specifically for COVID 19 crisis

200+
BioNEST incubators waived off rentals for Startups from 25 – 100% for 3 months.

20,925
Startups, entrepreneurs, stakeholders reached

125+
Covid solutions supported through BIRAC’s Incubator network

PRODUCTS UNDER VALIDATION OR READY FOR DEPLOYMENT

Virus inhibition Coatings - Reinste
ZeBox to Arrest Infection Spread - Biomoneta
Sanitation System - Nuverse and Pinktech
Artificial Respiratory System - PGIMER Chandigarh
Mechanical ventilator - Nocca

DBT’s Response to COVID - 19
# Research Efforts by DBT Autonomous Institutes (AIs) for COVID-19 Support

## Vaccine Development Efforts

<table>
<thead>
<tr>
<th>Institute</th>
<th>Platform</th>
<th>Current status</th>
</tr>
</thead>
</table>
| National Institute of Immunology (NII), New Delhi       | Protein-based subunit     | + 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.  
+ CDA with Cadila Pharma has been signed for pre-clinical development. |
| National institute of Biomedical genomics (NIBMG), Kalyani | VLP                       | Working on development of novel baculovirus expressed VLP based vaccine candidate. VLP characterization has been completed; preliminary immunogenicity study is started; Generation of VLPs incorporating mutations pertaining to emerging variants is being undertaken. |
| International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi | VLP                       | Developing yeast-expressed RBD-VLP based COVID-19 vaccine candidate.                                                                                                                                              |
| Translational Health Science and Technology Institute (THSTI), Faridabad | Self-amplifying mRNA      | -                                                                                                                                                                                                            |
## Efforts for Development of COVID-19 Diagnostics

<table>
<thead>
<tr>
<th>Institute</th>
<th>Current status</th>
</tr>
</thead>
</table>
| Translational Health Science and Technology Institute (THSTI), Faridabad   | + Developed a panel of Aptamers for diagnosing Coronavirus disease.  
+ DNAzyme Visual detection-based method developed.                            |
| International Centre for Genetic Engineering and Biotechnology (ICGEB),   | + Developed an indigenous total antibody test kit called ‘COVID-19 [IgM, IgG, IgA] MICROLISA’ test.  
+ MoU established between ICGEB and J Mitra & Co and efforts are underway for the development of an antigen test for COVID-19. |
| New Delhi                                                                  |                                                                                                                                                                                                               |
| Institute for Stem Cell Science and Regenerative Medicine (InStem),       | + The combinatorial sensing protocol algorithm validated by scientists at inStem.  
+ Partnering with CCAMP in the InDx programme to review quality and quantity of indigenously developed kits.                                                                                           |
| Bangalore                                                                 |                                                                                                                                                                                                               |
| National institute of Animal Biotechnology (NIAB), Hyderabad              | + Developed a sensitive potentiostat based biosensor for detection of surface antigen of novel corona virus in clinical sample upto femto molarrange.  
+ Developed a low cost, fluorescence based direct method for sensitive detection assay.                                                                                                               |
<p>| National Agri-food Biotechnology Institute (NABI), Mohali                 | Developed lateral flow assay (LFA) strip; using aptamers against nucleocapsid peptide molecules and citrate gold nanoparticles to enhance detection limit.                                                                 |
| National Institute of Immunology (NII), New Delhi                        | A low cost point-of-care serology test (Hemagglutination (HAT) assay) for measuring IgG, IgM and IgA                                                                                                            |</p>
<table>
<thead>
<tr>
<th>Institute</th>
<th>Current status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institute of Life Sciences (ILS), Bhubaneshwar</td>
<td>Carried out immuno-profiling of 90 COVID-19 positive patients using combination of approach using ELISA, Bioplex and mass cytometry to study immune response.</td>
</tr>
</tbody>
</table>
| Institute for Bioresource and Sustainable Development (IBSD), Manipur | + Preparing several extracts of NER medicinal plants with anti-viral properties and monograph preparation is in final stage.  
 + 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&D Activities related to SARS-CoV-2 Virus and COVID-19 Disease” to be implemented and work is under progress. |
| National Centre for Cell Sciences (NCCS), Pune | + Generation of virus-neutralizing human monoclonal antibodies against SARS-CoV-2: positive B cell clones secreting RBD-specific antibodies has been selected and their neutralization efficacy study is underway.  
 + Developed Peptide-based therapeutics using machine learning to identify possible therapeutics for COVID-19. |
| National Institute of Plant Genome Research (NIPGR), New Delhi | + 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.  
 + Glucosinolates, glucomoringin (Moringa oleifera) and glucoraphanin (Brassica species purified and efficacy of these molecules is being tested in animal cell line infected with SARS-CoV-2. |
| International Centre for Genetic Engineering and Biotechnology, Delhi | + Phase-2 trials on AQCH, a phyto-pharmaceutical drug as potential treatment for COVID-19 patients were initiated.  
 + Generated over 100 productive monoclonal antibody clones.  
 + Developing a cell-based assay for screening of chemical libraries for identifying new drugs/leads.  
 + SARS-CoV-2 Mpro protease was purified and novel inhibitors screened using Surface Plasmon Resonance kinetics and a 96-well format Enzyme inhibition assay.  
 + SARS-CoV-2 viral infections in VERO-E6 cell line were established. |
| National Institute of Immunology (NII), New Delhi | + T-cell assays have been developed for studying the T-cell correlates-of-protection in COVID-19 and measuring the vaccine efficacy.  
 + Provided the evidence for existing T-cell immunity in around 70% of the Indian population. |
<table>
<thead>
<tr>
<th>Institute</th>
<th>Current status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional Centre for Biotechnology, Faridabad</td>
<td>Screened the in vitro antiviral activity of 15 plant extracts; Tulsi, Kalmegh and Kalonji showed maximum antiviral activity.</td>
</tr>
<tr>
<td>Center of Innovative and Applied Bioprocessing (CIAB), Mohali</td>
<td>+ Polypyrrollic photosensitizers and their nanoformulations for antiviral photodynamic therapy.</td>
</tr>
<tr>
<td></td>
<td>+ Natural garlic essential oil as a ACE 2 protein inhibitor for preventing SARS-CoV-2 invasion.</td>
</tr>
<tr>
<td>Translational Health Science and Technology Institute (THSTI), Faridabad</td>
<td>+ Preclinical and Pharmacokinetics Evaluations of select AYUSH Herbal Extracts/Formulations for mitigating SARS-CoV2 Associated Pathologies.</td>
</tr>
<tr>
<td></td>
<td>+ Collaboration Agreement with Eyestem 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.</td>
</tr>
<tr>
<td></td>
<td>+ 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”.</td>
</tr>
<tr>
<td></td>
<td>+ 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.</td>
</tr>
<tr>
<td>Institute</td>
<td>Type of kits validated</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>THSTI, Faridabad</td>
<td>+ RT-PCR and RT LAMP&lt;br&gt;+ TrueNAT&lt;br&gt;+ CRISPR&lt;br&gt;+ Antigen&lt;br&gt;+ Antibody&lt;br&gt;+ RNA Cartridge&lt;br&gt;+ VTM</td>
</tr>
<tr>
<td>RGCB, Trivandrum</td>
<td>+ Antigen&lt;br&gt;+ ELISA&lt;br&gt;+ Extraction kit&lt;br&gt;+ LAMP assay&lt;br&gt;+ RT-PCR</td>
</tr>
</tbody>
</table>