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.

**Vaccines**

**Therapeutics**

**Diagnostics**

**Other Interventions**

**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
## Accelerating COVID-19 vaccine development and Building vaccine development ecosystem

### Vaccine Candidates
- ZyCoVD, Zydus Cadila - Received EUA
- Corbevax, Biological E - Phase III
- BBV 154, Bharat Biotech - Phase II
- HGCO-19, Gennova Biopharmaceuticals - Phase II
- VLP Vaccine, Genique Lifesciences - Advanced Pre-clinical

| Rs. 406.47 Cr. |

### Enhancement of Capacities
- 05 animal challenge facilities working on transgenic mice and Hamster Challenge models; supporting vaccine manufacturers
- 03 Immunoassay laboratories being supported.
- THSTI lab recognized as global CEPI network lab with expertise in T-cell immunoassays
- Services being provided to vaccine manufacturers

| Rs. 52.8163 Cr. |

### Clinical Trial Sites
- 19 PAN India GCP Compliant Clinical Trial Sites
- Access to a cohort of about 50000 – 100000 healthy volunteers

| Rs. 31.82163 Cr. |

### Facility augmentation for COVAXIN manufacturing
- Support to BBIL and 03 PSEs to scale-up production of COVAXIN.
- Facilitating technology transfer for Covaxin production to Gujarat COVID Vaccine Consortium (GCVC)

| Rs. 220.00 Cr. |
## COVID Vaccines Portfolio - India

5 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>
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</thead>
<tbody>
<tr>
<td>Covishield, SII-AZ</td>
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<td>Covaxin, BBIL-ICMR</td>
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<td>Sputnik V, DRL-RDIF</td>
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<tr>
<td>ZyCoVD, DNA Vaccine, Zydus Cadila</td>
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<td>Covovax, SII/Novavax</td>
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<td>Corbevax, Protein Subunit Vaccine, BioE</td>
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<td>HGC019, mRNA Vaccine, Gennova</td>
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<tr>
<td>BBV154, Intranasal Vaccine, BBIL</td>
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<tr>
<td>Novel Active Virosome, Seagull</td>
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<tr>
<td>Adeno-associated virus [rAAV], Intas</td>
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<tr>
<td>VLP Vaccine (Genique)</td>
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<tr>
<td>BCG Vaccine (repurposing), SII</td>
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</tbody>
</table>

DBT's Response to COVID - 19

No CT conducted in India
# COVID Vaccines Portfolio

## Pre-clinical Stage

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Development Stage</th>
<th>Company/Research Institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>VLP Vaccine Candidate</td>
<td>Advanced Pre-clinical</td>
<td>Genique Life Sciences</td>
</tr>
<tr>
<td>Attenuated rVSV-Vector Vaccine</td>
<td>Advanced Pre-clinical</td>
<td>Aurobindo Pharma</td>
</tr>
<tr>
<td>rAAV Based Genetic Vaccine</td>
<td>Early Pre-clinical</td>
<td>Intas Pharmaceuticals Ltd.</td>
</tr>
<tr>
<td>Non-Replicating Measles Virus Vector Active Virosome Platform</td>
<td>Early Pre-clinical</td>
<td>Seagull Bio Solutions</td>
</tr>
<tr>
<td>Self-Amplifying mRNA</td>
<td>Early Pre-clinical</td>
<td>THSTI</td>
</tr>
<tr>
<td>Tamarind Seed Polysaccharide (TSP) Intranasal Mucosal Nano Vaccine</td>
<td>Early Pre-clinical</td>
<td>Institute of Chemical Technology (ICT), Mumbai</td>
</tr>
<tr>
<td>SARS-CoV-2 Virus Like Particle (VLP)</td>
<td>Early Pre-clinical</td>
<td>National Institute of Biomedical Genomics</td>
</tr>
<tr>
<td>Lipid Encapsulated mRNA Vaccine Candidate</td>
<td>Early Pre-clinical</td>
<td>CMC, Vellore</td>
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</table>
DBT supported COVID-19 Bio-Repositories

Institute of Life Sciences (ILS), Bhubaneswar
287 SAMPLES

Institute of Liver and Biliary Sciences (ILBS), New Delhi
~40000 SPECIMENS

Institute For Stem Cell Science and Regenerative Medicine (inStem), Bangalore
573 SAMPLES

Translational Health Science and Technology Institute (THSTI) and
Regional Centre for Biotechnology (RCB), Faridabad
~15000 SAMPLES

National Centre for Cell Science, Pune
~127 SAMPLES

> 53000 clinical samples and 27 viral isolates collected;
~16000 biospecimens shared with industry and academia
Building Vaccine Development Ecosystem

- 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.
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.

- DBT-BIRAC is also facilitating tech transfer for Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), comprising of Hester Biosciences, OmniBRx Biotechnologies Pvt Ltd, and Gujarat Biotechnology Research Centre (GBRC)

- 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).

- Facilities at NIAB and NCCS notified as CDLs on 28th June and 17th August, 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 07 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.

+ Member of the Quad Alliance to strengthen vaccine manufacturing for global equitable access.
India - PACT - Programme (Partnerships for Accelerating Clinical Trials)
**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 with ~2400 participants across 14 neighboring and friendly countries

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

- **Good Clinical Practice:**
  - 4 Session E-Course
- **Ethical Considerations in Clinical Research:**
  - 2 Session E-Course
- **Good Clinical Laboratory Practice:**
  - 2 Session E-Course
- **Large Vaccine Field Trials:**
  - 2 Session E-Course

Participation from Afghanistan, Bahrain, Bhutan, Bangladesh, Gambia, Kenya, Myanmar, Maldives, Mauritius, Oman, Nepal, Somalia, Sri Lanka, Vietnam
COVID-19 Medical Devices Portfolio

Achieved 100 % self-sufficiency in indigenous diagnostic kit production

Products in market

MTM and NAE kits – Huwel

Ag & Ab-detection
LFA – Dhiiti

IgG/IgM detection
LFA – Ubio

Antigen detection
LFA – Ubio

Patho Detect RT-PCR Kit MyLab

DBT's Response to COVID - 19
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.

+ 300+ 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

Indo-American Science and Technology Park (IASP) - Government of India

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

PAN-India 1000 SARS COV-2 RNA Genome Sequencing Consortium

DBT AIs have generated about 2562 sequences so far

Temporal and spatial analyses reveal clustering pattern

A2a halotype dominating other lineages

More than 82000 samples sequenced
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.

Human iPSC derived lung airway and alveolar epithelial cells for disease modelling and testing potential therapeutics against COVID by Eyestem research Pvt. Ltd.
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

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

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

200+

Startups / Researchers / Entrepreneurs / Stakeholders reached

125+

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

200+

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

20,925

Startups, entrepreneurs, stakeholders reached

125+

Covid solutions supported through BIRAC’s Incubator network

DBT’s Response to COVID - 19
## Vaccine Development Efforts

<table>
<thead>
<tr>
<th>Institute</th>
<th>Platform</th>
<th>Current Status</th>
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</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>
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</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), New Delhi** | + 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. |
| **Rajiv Gandhi Centre for Biotechnology (RGCB), Trivandrum** | Developed COVID-Anosmia Checker: A rapid and low-cost alternative tool for mass screening of COVID-19. |
| **Institute for Stem Cell Science and Regenerative Medicine (InStem), Bangalore** | + 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. |
| **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 molar range.  
+ Developed a low cost, fluorescence based direct method for sensitive detection assay. |
| **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 |
## Development of Therapeutics for COVID-19

<table>
<thead>
<tr>
<th>Institute</th>
<th>Current Status</th>
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<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>
<tr>
<td>Institute for Bioresource and Sustainable Development (IBSD), Manipur</td>
<td>+ Preparing several extracts of NER medicinal plants with anti-viral properties and monograph preparation is in final stage.</td>
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<td>+ 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.</td>
</tr>
<tr>
<td>National Centre for Cell Sciences (NCCS), Pune</td>
<td>+ 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.</td>
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<td>+ 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.</td>
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<td>+ 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.</td>
</tr>
<tr>
<td>National Institute of Plant Genome Research (NIPGR), New Delhi</td>
<td>+ Phase-2 trials on AQCH, a phyto-pharmaceutical drug as potential treatment for COVID-19 patients were initiated.</td>
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<td>+ Generated over 100 productive monoclonal antibody clones.</td>
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<td>+ Developing a cell-based assay for screening of chemical libraries for identifying new drugs/leads.</td>
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<td>+ SARS-CoV-2 Mpro protease was purified and novel inhibitors screened using Surface Plasmon Resonance kinetics and a 96-well format Enzyme inhibition assay.</td>
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<td>+ SARS-CoV-2 viral infections in VERO-E6 cell line were established.</td>
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<tr>
<td>International Centre for Genetic Engineering and Biotechnology, Delhi</td>
<td>+ T-cell assays have been developed for studying the T-cell correlates-of-protection in COVID-19 and measuring the vaccine efficacy.</td>
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<td>+ Provided the evidence for existing T-cell immunity in around 70% of the Indian population.</td>
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<td>National Institute of Immunology (NII), New Delhi</td>
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<td>Institute</td>
<td>Current status</td>
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<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. + Polypyrrollic photosensitizers and their nanoformulations for antiviral photodynamic therapy. + Natural garlic essential oil as a ACE 2 protein inhibitor for preventing SARS-CoV-2 invasion.</td>
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<tr>
<td>Translational Health Science and Technology Institute (THSTI), Faridabad</td>
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<td>Institute</td>
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<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>
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<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>
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