



बायोटेक्नोलॉजी विभाग  
DEPARTMENT OF BIOTECHNOLOGY  
MINISTRY OF SCIENCE & TECHNOLOGY  
GOVERNMENT OF INDIA



# Scientific Chronicles During COVID times

*DBT-BIRAC Efforts*

॥ आत्मनिर्भरता की ओर ॥







## डॉ० जितेन्द्र सिंह

राज्य मंत्री (स्वतंत्र प्रभार),  
विज्ञान एवं प्रौद्योगिकी मंत्रालय;  
राज्य मंत्री (स्वतंत्र प्रभार) पृथ्वी विज्ञान मंत्रालय;  
राज्य मंत्री, प्रधान मंत्री कार्यालय;  
राज्य मंत्री कार्मिक, लोक शिकायत एवं पेंशन मंत्रालय;  
राज्य मंत्री परमाणु ऊर्जा विभाग तथा  
राज्य मंत्री अंतरिक्ष विभाग  
भारत सरकार



## Dr. JITENDRA SINGH

Minister of State (Independent Charge)  
of the Ministry of Science and Technology;  
Minister of State (Independent Charge)  
of the Ministry of Earth Sciences;  
Minister of State in the Prime Minister's Office;  
Minister of State in the Ministry of Personnel,  
Public Grievances and Pensions;  
Minister of State in the Department of Atomic Energy and  
Minister of State in the Department of Space  
Government of India



### Message

India's journey on developing COVID vaccines has been remarkable. I congratulate Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC) for their efforts in the fight against COVID-19.

India's efforts through Mission COVID Suraksha led by DBT, Government of India and implemented by BIRAC has not only strengthened AtmaNirbhar Bharat but also has bolstered India's status as a worldwide vaccine development and manufacturing center showcasing the strength of Science and Technology. It is a matter of pride for all of us as a nation.

With Mission COVID Suraksha, we had aimed at bringing out a safe, efficacious, affordable and accessible indigenous COVID 19 vaccines not only for India but for the world. We stuck to a strong public-private partnership (PPP) model to deliver the vaccine and it gives me immense pleasure to point out that India has developed four indigenous vaccines in just two years. The Department of Biotechnology, DBT, through 'Mission COVID Suraksha', has delivered four vaccines, augmented the manufacturing of Covaxin, and created the necessary infrastructure for the smooth development of future vaccines. These vaccines are ZyCoV-D, CORBEVAX, GEMCOVAC, and iNCOVACC.

This COVID 19 Vaccine Development Mission has proved to be pivotal in establishing clinical trial sites, development of common harmonized protocols, regulatory submissions along with strengthening the existing immunoassay laboratories, central laboratories and suitable facilities for animal studies, production facilities and other testing facilities to strengthen India's vaccine manufacturing ecosystem.

DBT and BIRAC have been instrumental in catalyzing the change in the Indian Biotech Innovation Ecosystem. This Coffee table booklet will highlight the science behind combating COVID-19 and the efforts by DBT and its Autonomous Institutes and Public Sector Undertakings.

(Dr. Jitendra Singh)

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Dr. RAJESH S. GOKHALE



Foreword

सचिव  
भारत सरकार  
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DEPARTMENT OF BIOTECHNOLOGY  
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Biotechnology is emerging as the next frontier of technology revolution that will conjure products as diverse as organs for transplant, tolerogenic plants, consumer chemical products and cleaner renewable fuels. It is thus poised to change our lives and deliver effective and affordable solutions in areas of medicine, healthcare, agriculture, energy, industry, and others.

The Department of Biotechnology (DBT) has over the last 3 decades focused on building coherence and connectivity between Biology, Engineering and Medicine disciplines to build scientific temper. The framework consisting of academic research, entrepreneurial culture, start-ups, building national and international research collaborations/partnerships, establishment of incubation centres and innovation parks, and promoting industry-academia partnerships; catalyzed accelerated development of preventive solutions during COVID-19 pandemic. DBT coordinated Indian SARS-CoV-2 Genomic Consortium (INSACOG) has effectively tracked dynamics of virus evolution by sequencing more than 3 lakh viral genomes, as part of multiagency consortium.

The Mission "COVID Suraksha" enabled the country to produce new indigenously developed vaccines. Relentless efforts of DBT and Biotechnology Industry Research Assistance Council (BIRAC) has leveraged the country's ability to establish India both as a world class vaccine developer and manufacturer. This programme delivered four vaccines, -ZyCoV-D- world's first DNA vaccine, CORBEVAX™ - India's first protein subunit vaccine, GEMCOVAC™.19 - temperature stable mRNA vaccine and INCOVACC - India's first intranasal vaccine for COVID-19. While investment, collaboration and coordination have been the key, DBT's autonomous institutions Translational Health Science & Technology Institute (THSTI) and National Institute of Immunology (NII) directly participated in vaccine development.

During the next two decades Biotechnology holds promise for bringing 'GREEN GROWTH' by fostering Biomanufacturing and developing an integrated approach towards promoting circular economy towards green, clean and prosperous India. The Department aims not only to promote technical excellence, but also foster equity, ethics, dialogue and social responsibility in how the fruits of biotech research are deployed to make BIOTECH sector a "broad and inclusive enterprise" with the focus on Atmanirbhar Bharat and for the world's happiness cooperation and peace.

(Dr. Rajesh S. Gokhale)

**डा. अलका शर्मा**  
वैज्ञानिक "एच" / वरिष्ठ सलाहकार  
**Dr. ALKA SHARMA**  
Scientist 'H' / Senior Advisor



भारत सरकार  
विज्ञान और प्रौद्योगिकी मंत्रालय  
बायोटेक्नोलॉजी विभाग  
GOVERNMENT OF INDIA  
MINISTRY OF SCIENCE & TECHNOLOGY  
DEPARTMENT OF BIOTECHNOLOGY  
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Lodhi Road, New Delhi-110003



The Department of Biotechnology (DBT) has set up Biotechnology Industry Research Assistance Council (BIRAC) as its industry-academia interface agency for creating and strengthening the biotech innovation ecosystem to undertake strategic research, promote innovation, and address nationally relevant product development needs.

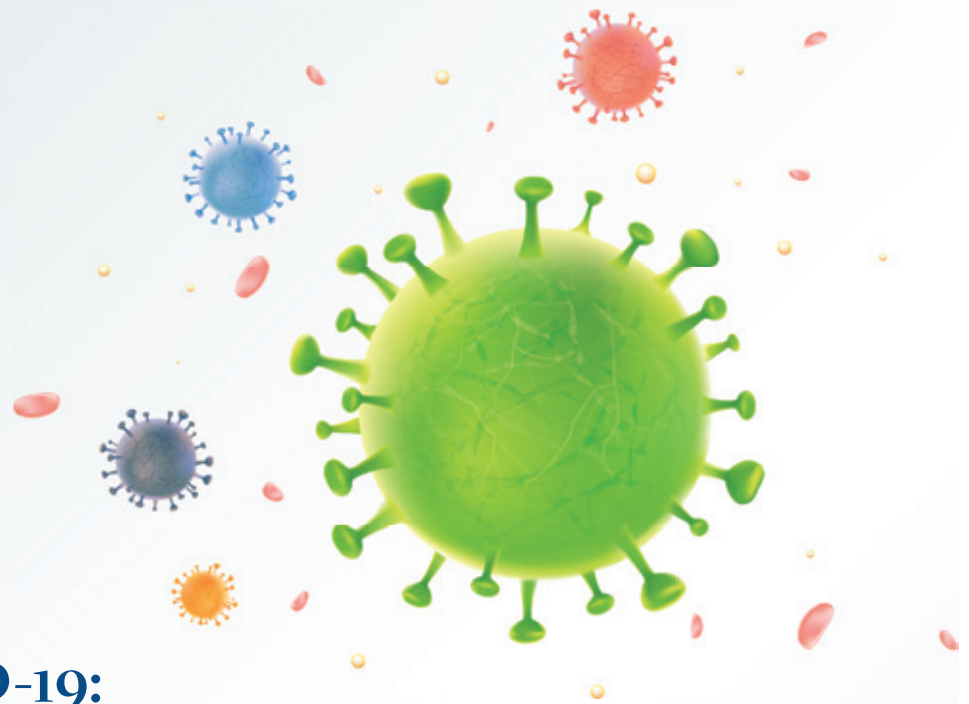
The last two years were all about the global health pandemic that caused widespread disruptions. Our Government at different levels took several measures to address the challenges posed by the pandemic. The DBT along with its Autonomous Institutes (AIs) and its industry-academia interface agency, BIRAC worked relentlessly to mitigate the COVID-19 crisis through development of diagnostics, vaccines, monoclonals, novel protection equipment, facilitating and supporting biotech Start ups activities, scaling up of diagnostic capacity and rapid regulatory response.

A multi-pronged research strategy was formulated by DBT alongwith its Autonomous Institutions and its industry-academia interface agency, BIRAC for building an ecosystem for development and manufacturing of vaccines. This includes: setting up of bio-repositories, facilities for development of animal models and immunoassays and establishment of clinical trial sites, and facilities augmentation. Two vaccine testing facilities have been set up at DBT-NIAB, Hyderabad and DBT-NCCS, Pune with PM-CARES Funds support for testing and batch release of vaccines.

'Mission COVID Suraksha' was launched under AatmaNirbhar Bharat. This was led by DBT and implemented by BIRAC with the goal of bringing safe, efficacious, affordable and accessible indigenous COVID-19 vaccines not only for India but also for the world. Four vaccines supported under Mission COVID Suraksha have received Emergency Use Authorisation. Clinical trial sites, immunoassay labs, and animal challenge facilities were also established. Facility augmentation support was also provided under this Mission.

The enabling biotech innovation ecosystem created across the country including regulatory reforms have boosted the overall growth of the biotech sector. This has also facilitated a large number of innovators to pursue entrepreneurship and converted themselves from Job seekers to Job creators.

**Dr. Alka Sharma**  
Senior Adviser, DBT &  
Managing Director, BIRAC



Response to COVID-19:

# *Creating National and Global Impact*



The World Health Organization (WHO) declared the Novel Coronavirus COVID-19 outbreak as a Pandemic in March, 2020.



Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India, proactively evolved a comprehensive research strategy and action plan with a focus on *'testing, treatment and prevention'*.

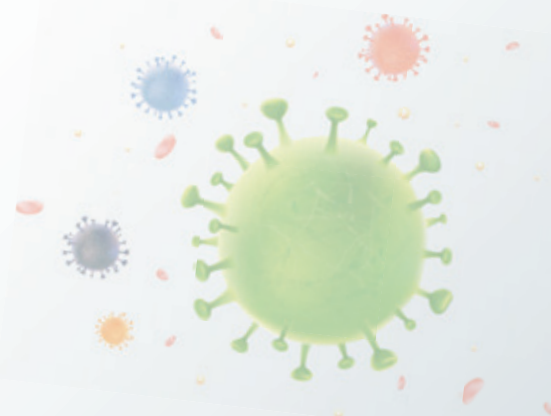


❁ DBT-BIRAC COVID-19 Research Consortium was launched, as early as March, 2020 to facilitate development of effective biomedical solutions and interventions. ***'Mission COVID Suraksha-The Indian COVID-19 Vaccine Development Mission'*** was initiated under Atmanirbhar Bharat 3.0, to accelerate Indian COVID-19 vaccine development efforts.

❁ Innovative solutions were delivered in a timely manner by start-up community supported by the Public Sector Undertaking (PSU) Biotechnology Industry Research Assistance Council (BIRAC).

❁ The Autonomous Institutions (AIs) of DBT, equipped with cutting-edge infrastructure, are contributing to ramping up COVID-testing efforts; offering critical services such as anti-viral testing and animal challenge studies for therapeutic and vaccine development.

❁ The comprehensive multipronged efforts of DBT, AIs and BIRAC are being continued and taken forward with renewed vigour and commitment.



# DBT-BIRAC COVID-19 *Research Consortium*

Multi-pronged research strategy with DBT's Autonomous Institutions & BIRAC; Nodal institutes identified; Focus on thematic areas



## Vaccine Development

- Multiple vaccine platforms
- Scaling up manufacturing
- Setting up of Central Drug Laboratories
- Studying vaccine induced immune responses





### Ecosystem Facilitation

- Immunoassay labs and animal challenge facilities
- Clinical Trial Sites
- COVID -19 Bio-repositories
- Rapid Regulatory Framework



### Diagnostics and Testing

- Development of novel diagnostics
- Testing Hubs
- Mobile I-Lab



### Therapeutics

- Pegylated Interferon (Virafin)
- Monoclonal antibodies
- DBT-AYUSH - Plant based pharmaceuticals



### Genomic Surveillance

- Indian SARS-CoV-2 Genome Consortium (INSACOG)

# DBT's Autonomous Institutions and BIRAC : *COVID-19 Activities*

*Facilitating Development of COVID-19  
Vaccines, Diagnostics and Therapeutics*

## COVID-19 Testing

THSTI, NII, ICGB, ILS,  
CDFD, inStem, RGCB, IBSD,  
NIBMG



## COVID Biorepositories

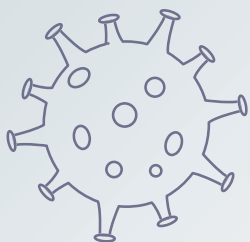
THSTI, RCB, ILS, inStem,  
NCCS



## INSACOG Network

NIBMG, ILS, CDFD, inStem,  
RGCB, NCCS, IBSD



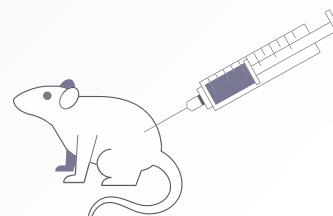


### **Immuno-assay Labs**

THSTI, ILS, NII, inStem

### **Animal Challenge Facilities**

THSTI, ILS, inStem, NII



### **Antiviral Screening**

RCB, ILS, inStem,  
ICGEB, RGCB, NIAB

### **Vaccine Testing Facilities**

NIAB, NCCS



# VACCINE *Development*



# Enabling *COVID-19* *Vaccine* Development

DBT identified as central coordinating agency by PMO constituted Vaccine Task Force



Proof of concept and pre-clinical studies of nearly 14 candidates



Diverse state-of-the-art platforms



Initial seed funding under DBT and BIRAC's National Biopharma Mission and Ind-CEPI Mission\*



Mission COVID Suraksha accelerated development of promising indigenous COVID-19 vaccines



Focused efforts towards product development and ecosystem strengthening



\*CEPI: Coalition for Epidemic Preparedness Innovations

04 vaccine  
*candidates* successfully  
completed the *journey* from  
Proof-of-Concept to *human use*



# *COVID-19 Vaccines:* Emergency Use Authorization Granted



World's 1<sup>st</sup> and India's  
indigenously developed  
DNA Vaccine, ZyCoV-D

Protein subunit  
vaccine, CORBEVAX™



mRNA vaccine  
GEMCOVAC™-19



Intranasal  
COVID-19 Vaccine  
(iNCOVACC)

# *ZyCoV-D: World's First & India's Indigenously Developed Plasmid DNA Vaccine for COVID-19*



The plug and play technology of the Plasmid DNA platform allows rapid generation of newer versions to tackle variants. ZyCoV-D is safe for human use. The Pharmajet system enables painless needle-free intradermal delivery. The vaccine is stable at 25° C for three months, enabling easy transportation and storage.



# ***CORBEVAX<sup>TM</sup>***

## **DBT-BIRAC supported protein subunit vaccine for COVID-19**

CORBEVAX<sup>TM</sup> is India's first recombinant protein subunit vaccine based on Receptor Binding Domain (RBD) of SARS-CoV-2 spike protein, adjuvanted with CpG 1018 and Alum.

CORBEVAX<sup>TM</sup> has been approved for use in children (5 years and above) and as a heterologous booster (18 years and above). Translational Health Science and Technology Institute, an Autonomous Institute of DBT, provided immunogenicity data for the Phase II/ III trials of Corbevax.





# GEMCOVAC™-19 India's first mRNA based Vaccine



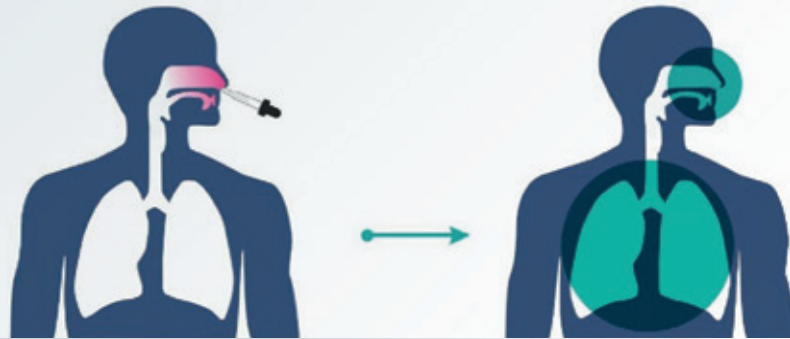
GEMCOVAC™-19 is India's first mRNA-based vaccine and world's first and only mRNA vaccine that is stable at 2 - 8° C making it deployable globally.

The vaccine has been approved for use in adults (18 years and above).





iNCOVACC: India's First  
*Intranasal* COVID-19  
*Vaccine*



iNOVACC is based on replication-deficient chimpanzee adenovirus vector expressing Spike protein of SARS-CoV-2. The vaccine has been approved for use as a heterologous booster (18 years and above). iNOVACC® is administered through the nose offering advantage of needle free delivery.





# ECOSYSTEM *Facilitation*



Translational Research Ecosystem established under focused Missions of the Department like NBM and Ind-CEPI were leveraged

Animal challenge facilities and immunoassay laboratories established for offering services to vaccine manufacturers

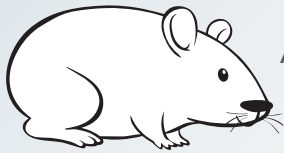


GCP compliant clinical trial sites set up to undertake regulatory clinical trials.

Biorepositories supported for archiving COVID-19 biospecimens



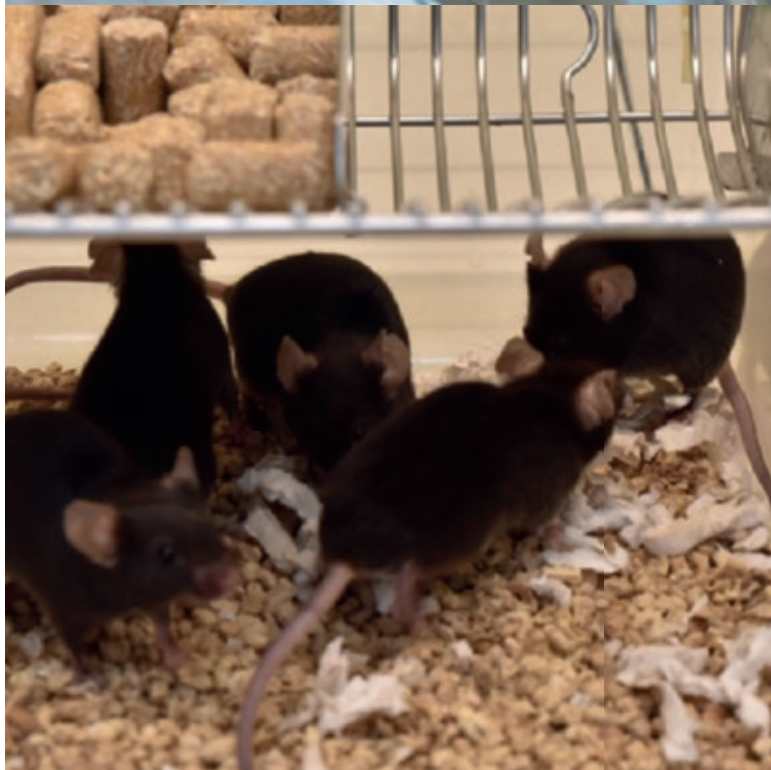
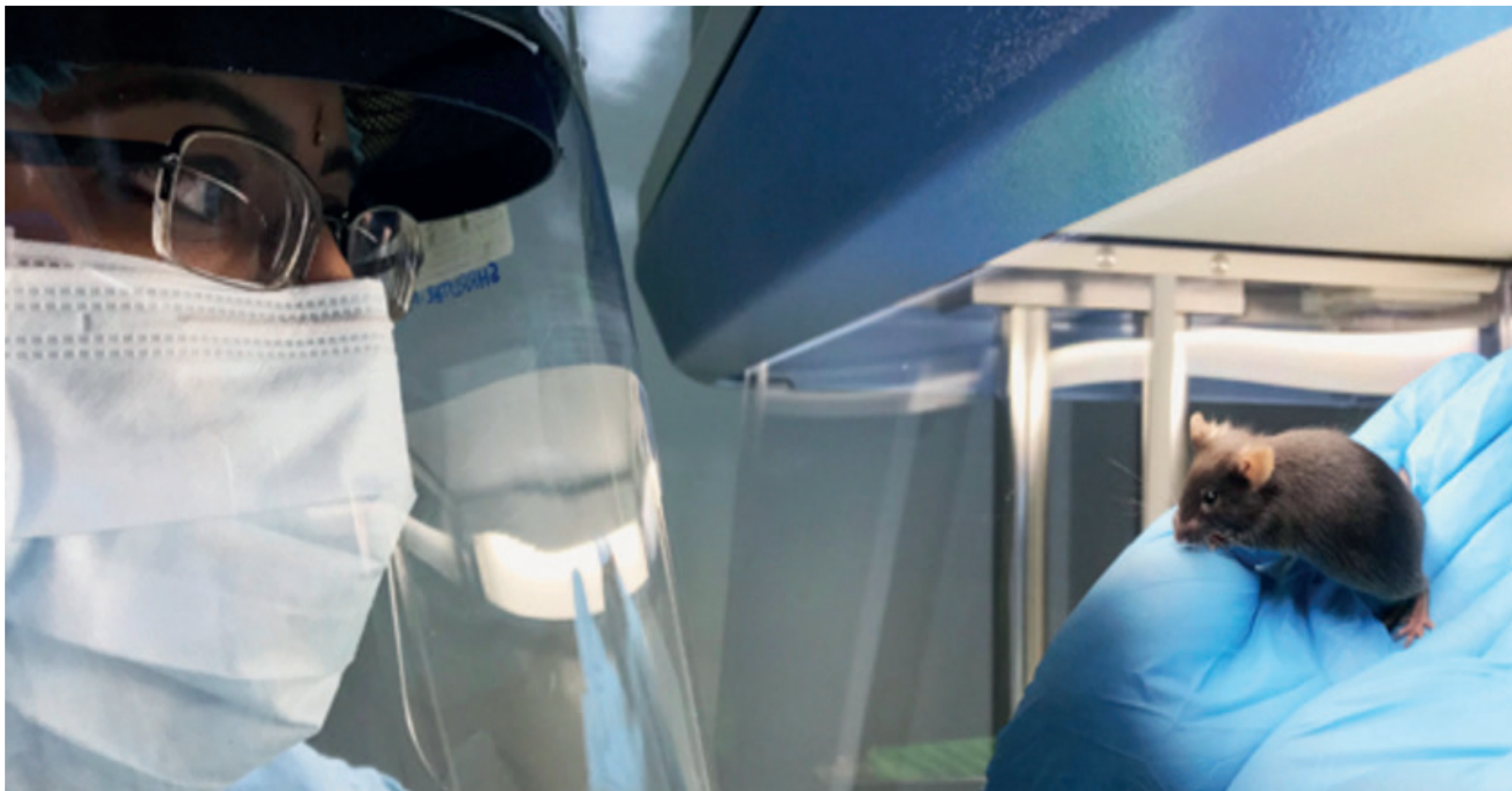
# Animal *Challenge* Facilities



Animal challenge facilities established at Institute of Life Sciences, Bhubaneshwar; Indian institute of Science, Bengaluru National Centre for Biological Sciences, Bengaluru, Institute for Stem Cell Biology and Regenerative Medicine, Bengaluru, and Translational Health Science and Technology Institute (THSTI).

THSTI Hamster Facility is the first of its kind in the nation. These facilities offered services to vaccine manufacturers.





DBT's Resource of  
Indian Vaccine Epidemiology  
Network (DRIVEN)  
*GCP Compliant  
Clinical Trial Sites*



Christian Medical College -  
Ludhiana

Maulana Azad Medical  
College - New Delhi

Society for Applied Studies-  
New Delhi

The INCLEN Trust  
International, Palwal

BAPS Pramukh Swami  
Hospital, Surat

Symbiosis, Mulshi

KEMHRC, Pune

Tata Memorial Centre,  
Mumbai

IRSHA, Pune

KEMHRC, Manchar

JSS Academy of Higher  
Education & Research, Mysore

Gokula Education Foundation

Malabar Cancer Centre

Amrita Institute of Medical  
Sciences, Cochin

Medanta Institute of Education  
and Research

Dr Dang's Lab, New Delhi

THSTI, Faridabad

The INCLEN Trust  
International, Shillong

ICMR - RMRC, Bhubaneswar

Andhra Medical  
College-Visakhapatnam

SHARE India, Medchal

JIPMER Pondicherry

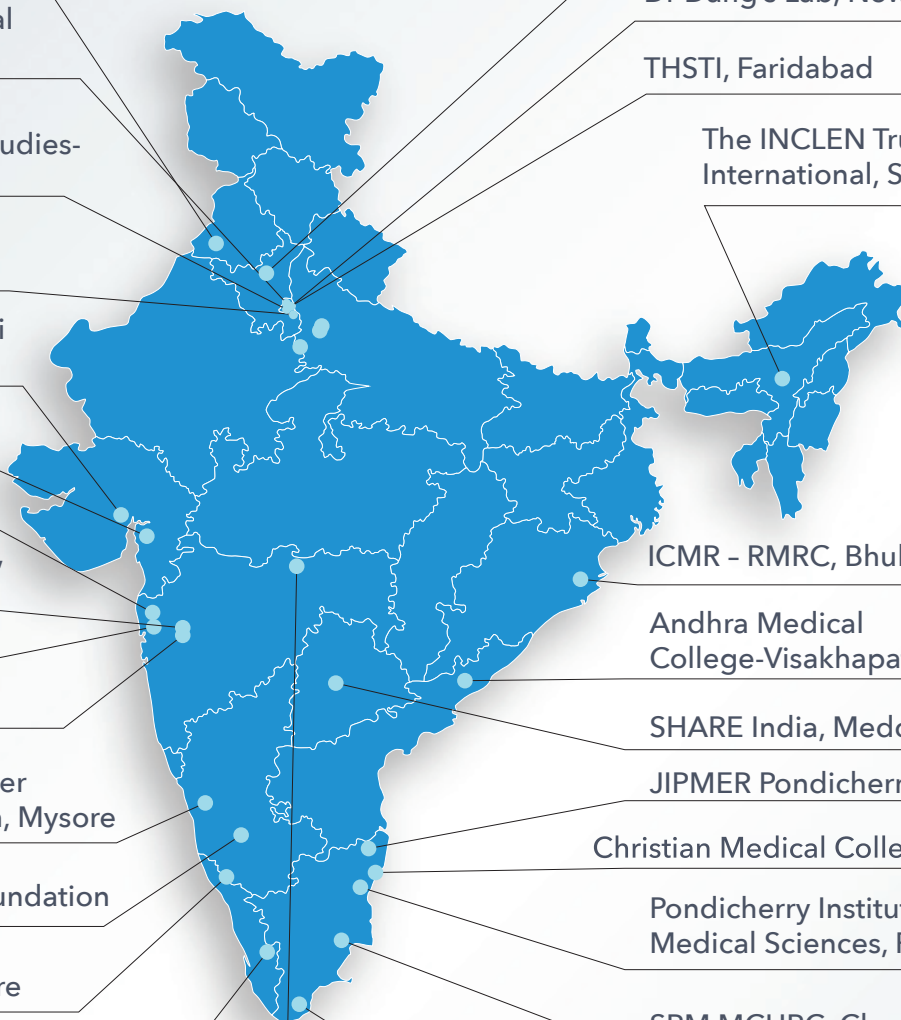
Christian Medical College, Vellore

Pondicherry Institute of  
Medical Sciences, Puducherry

SRM MCHRC, Chengalpattu

ICMR-NIE, Tirunelveli

Kasturba Health Society, Sewagram



# Glimpses of *DBT-BIRAC* supported Clinical Trial Sites



- DBT-BIRAC supported a PAN-India network of 54 GCP compliant clinical trial sites, with electronic data capture on a centralized platform. Of these 24 sites facilitated clinical trials for several COVID-19 vaccines and therapeutics.



# *Clinical Immunogenicity* Facilities

Immunogenicity assays are crucial to characterize vaccine efficacy. 06 immunogenicity assay labs at: Interactive Research School for Health Affairs Pune; Syngene International Ltd, Bengaluru; Translational Health Science and Technology Institute, Faridabad; Institute of Life Sciences, Bhubaneswar; Mazumdar Shaw Medical Foundation, Bengaluru and JNCASR, Bengaluru.





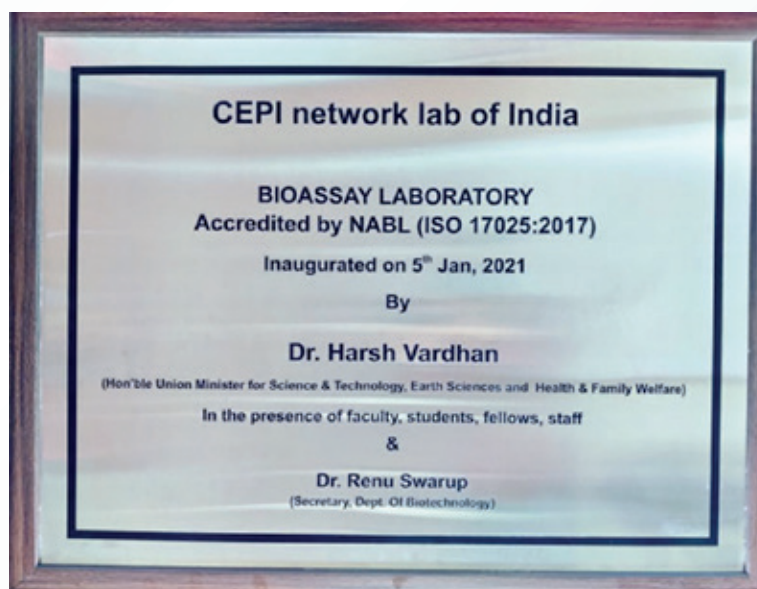
***CEPI Centralized  
Laboratory*** at  
**DBT-Translational Health Science &  
Technology Institute , Faridabad**





The immunoassay laboratory of THSTI, a DBT Autonomous Institute has been recognized globally by Coalition for Epidemic Preparedness Innovations as one of the seven laboratories across the world, for centralized assessment of COVID- 19 Vaccines.

The facility offered immunogenicity assay services to major Indian vaccine manufacturers.

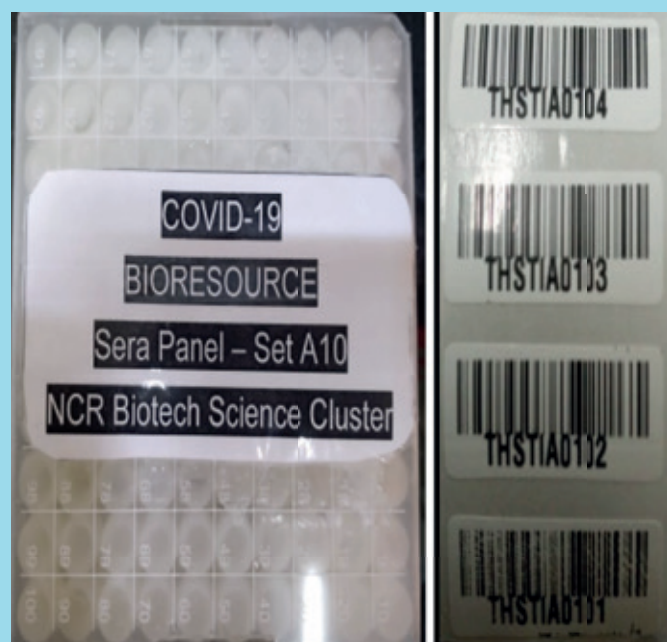
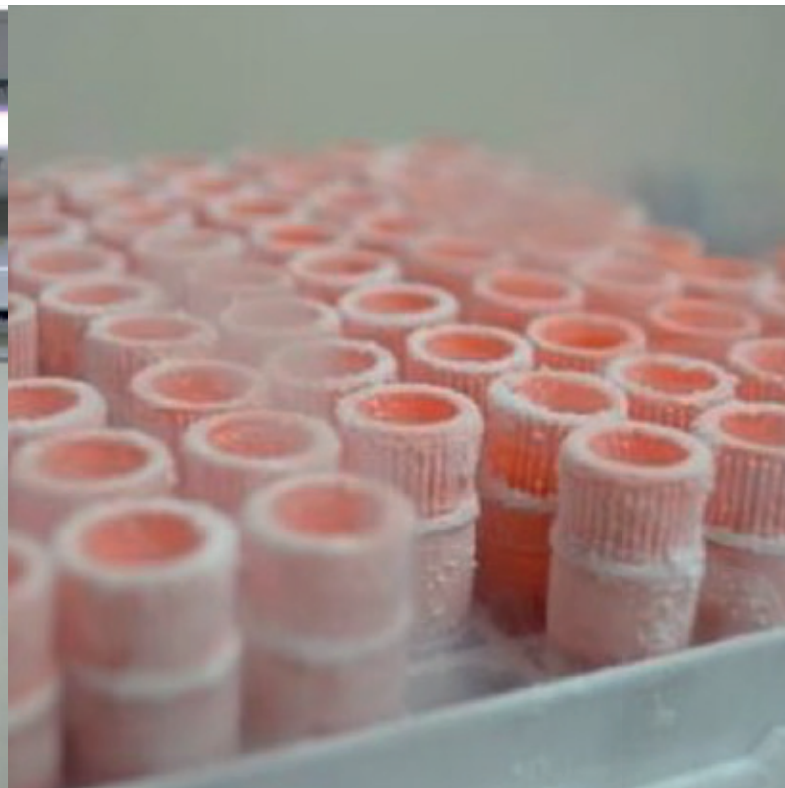


# *Biorepositories*



05 COVID-19 Biorepositories were supported at THSTI, Faridabad; ILS, Bhubaneswar; inStem, Bengaluru; ILBS, New Delhi and NCCS, Pune.

~60,000 samples have been collected and ~26,000 samples have been shared with industry and academia, which are serving as a valuable resource for validation of diagnostics and therapeutics and understanding predictors of disease pathogenesis.



# Upgradation of *DBT's Laboratories* as *Central Drug Laboratories*

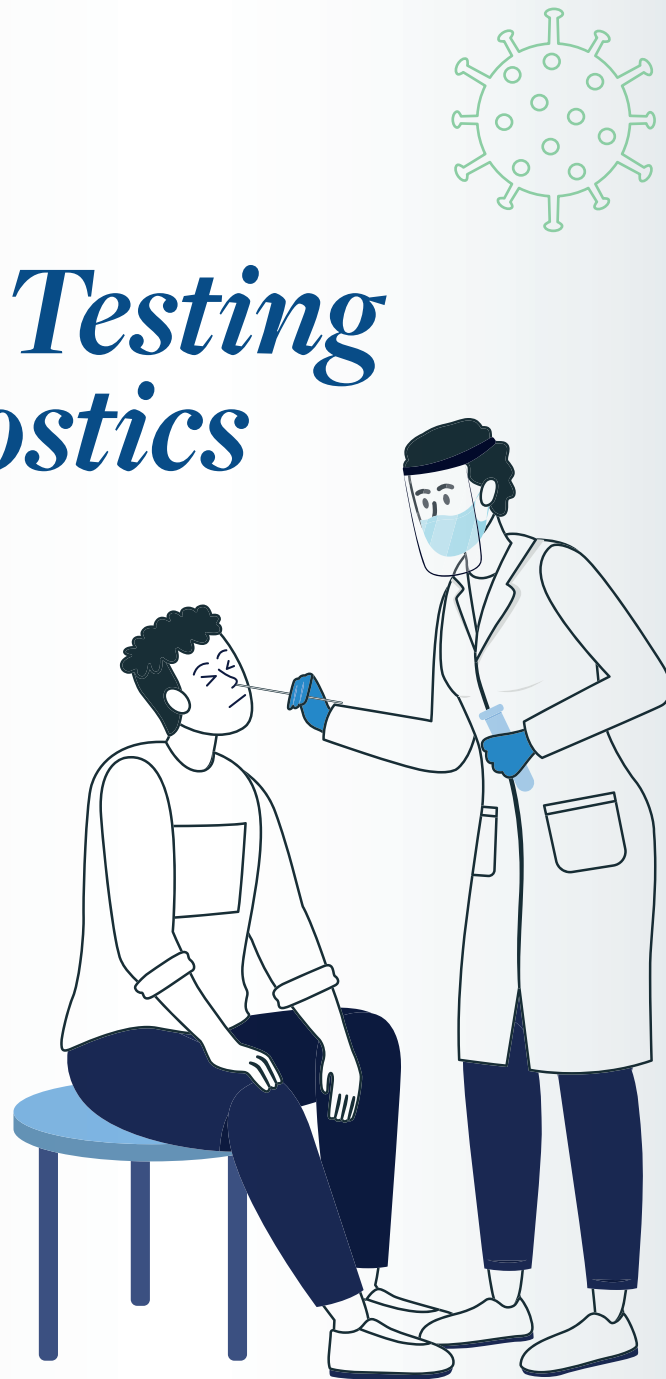




02 DBT Autonomous Institutes-National Institute of Animal Biotechnology (NIAB), Hyderabad and National Centre for Cell Science (NCCS), Pune, have been upgraded as Central Drug Laboratories (CDLs), for vaccine testing. Support for the same was provided under PM-CARES funds. The facilities were notified as CDLs, in 2021 by the Ministry of Health and Family Welfare.



# *COVID-19 Testing and Diagnostics*



# *Contribution to COVID-19 Testing and Diagnostics*

Ramped up COVID-19 testing efforts in the nation:

- DBT Autonomous Institutes proactively conducted COVID-19 testing activities.
- Mobile diagnostic labs were deployed for COVID-19 testing in remote and inaccessible areas.





# COVID-19 *Testing Laboratories*

DBT has identified 30 City /Regional clusters to scale up COVID testing as a part of the Hub and Spoke model.

10 DBT Autonomous Institutes, namely, THSTI, NII, ICGEB, ILS, CDFD, inStem, RGCB, IBSD, NIBMG and NCCS have been approved as Hubs for COVID-19 testing. Over 82 lakh samples have been tested as on date.

# *Mobile Diagnostic Laboratory: Facilitating COVID-19 Testing in remote areas*

Mobile diagnostic labs (i-LAB) were deployed to cater to testing in remote and inaccessible areas. i-LAB was also deployed for the North Eastern Region.





# DBT- AMTZ COMManD (*COVID Medtech Manufacturing Development*) Consortia

Asia's first medical equipment ecosystem- Andhra Pradesh Med-tech Zone (AMTZ) at Vishakapatnam. DBT- AMTZ COMManD Consortium addressing the shortage of technology in the field of health care during the pandemic.

The country's first-ever i-Lab was built in a record time of 8 days at the AMTZ.



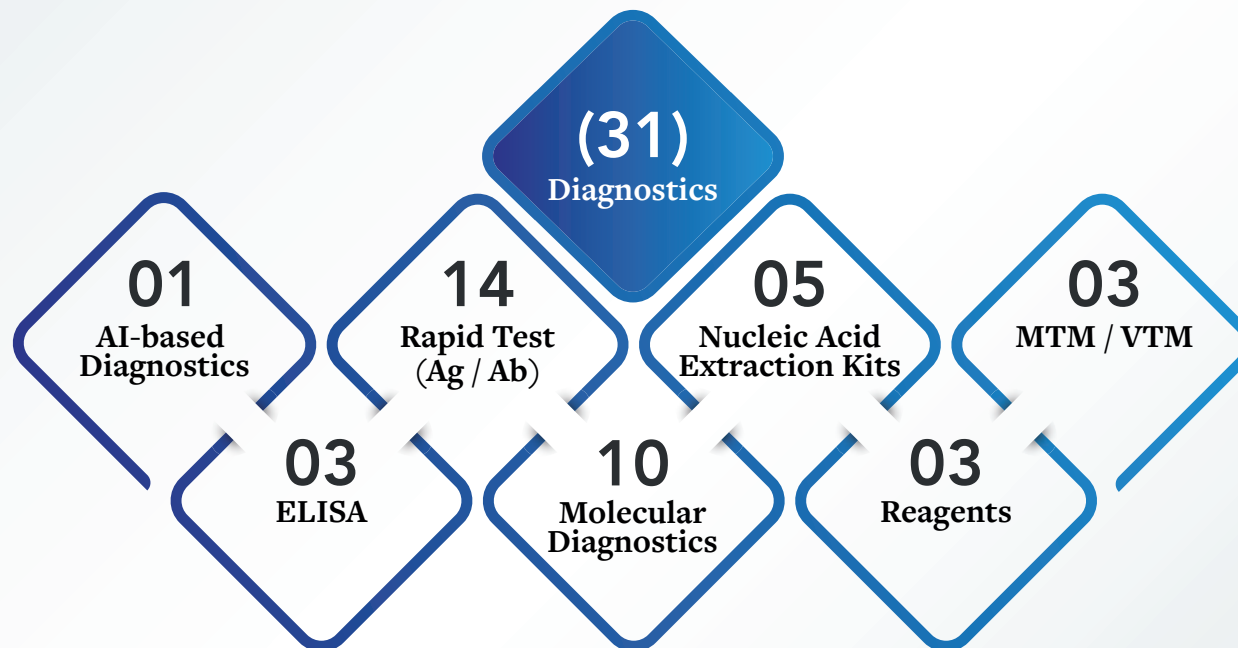
Ventilators



Kit Manufacturing Facility



# Development of *COVID-19* *Diagnostics*



Through sustained support adequate production of diagnostic kits was achieved.COVID-19 diagnostic kits based on different platforms – RT-PCR tests, Rapid Antigen and Antibody detection tests – are in market. DBT supported 'AMTZ COMManD (COVID-19 Medtech Manufacturing Development) Consortium', an indigenous plug-and-play manufacturing facility enabled rapid ramp-up of COVID-19 diagnostic kit production.

## Products in market -Startups

RT-PCR Kits Huwel Lifesciences Pvt. Ltd.

Ag & Ab -detection Lateral Flow Assay - Dhiti Life sciences



MTM and NAE kits - Huwel Lifesciences Pvt. Ltd.



Patho Detect RT-PCR Kit MyLab Discovery Solutions Pvt. Ltd.



Antigen detection LFA - Ubio Systems Pvt. Ltd

IgG/IgM detection LFA - Ubio Systems Pvt. Ltd.

# *COVID-19 Therapeutics*



Virafin (pegylated interferon alpha-2b) by Zydus Cadila - approved for Emergency Use for moderate COVID-19 infection. Available in 200+ hospitals across the country. 13,000+ units sold so far

Phase-II/III clinical trials of Anti-dengue botanical drug (AQCH) for COVID-19, in progress across 16 trial sites in India

Panels of human neutralizing monoclonal antibodies against SARS-CoV-2 developed by ICGEB; Functional and structural characterization underway

# DBT-Ministry of *AYUSH initiative* for *COVID-19*



DBT initiated a major network programme with National Medicinal Plants Board, Ministry of AYUSH, for testing and screening of selected medicinal plants and traditional Ayurvedic formulations for anti SARS-CoV-2 activity. AYUSH 64 was found to exhibit potential antiviral activity in vitro.



**AYUSH – 64**  
An Ayurvedic Anti- Malarial Drug

# *Genomic Surveillance*



# Indian SARS-CoV-2 Genomics Consortium (INSACOG) for Genomic Surveillance



PAN-India network of 59 laboratories

Coordinated by DBT, with other stakeholders



Monitoring of genomic variations in the SARS-CoV-2 by sentinel sequencing

Whole genome sequencing data helps understanding virus spread and evolution



Data generated by INSACOG aids public health response

# INSACOG

INDIAN SARS-COV-2 GENOMICS CONSORTIUM



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



वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्  
COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH  
(विज्ञान एवं प्रौद्योगिकी मंत्रालय, भारत सरकार)  
MINISTRY OF SCIENCE & TECHNOLOGY, GOV. OF INDIA



icmr भारतीय आयुर्विज्ञान  
अनुसंधान परिषद्  
INDIAN COUNCIL OF  
MEDICAL RESEARCH  
Serving the nation since 1911



Ministry Of Health  
And Family Welfare  
Government Of India



Continued  
Surveillance



Hospital  
Network



Sewage  
Surveillance



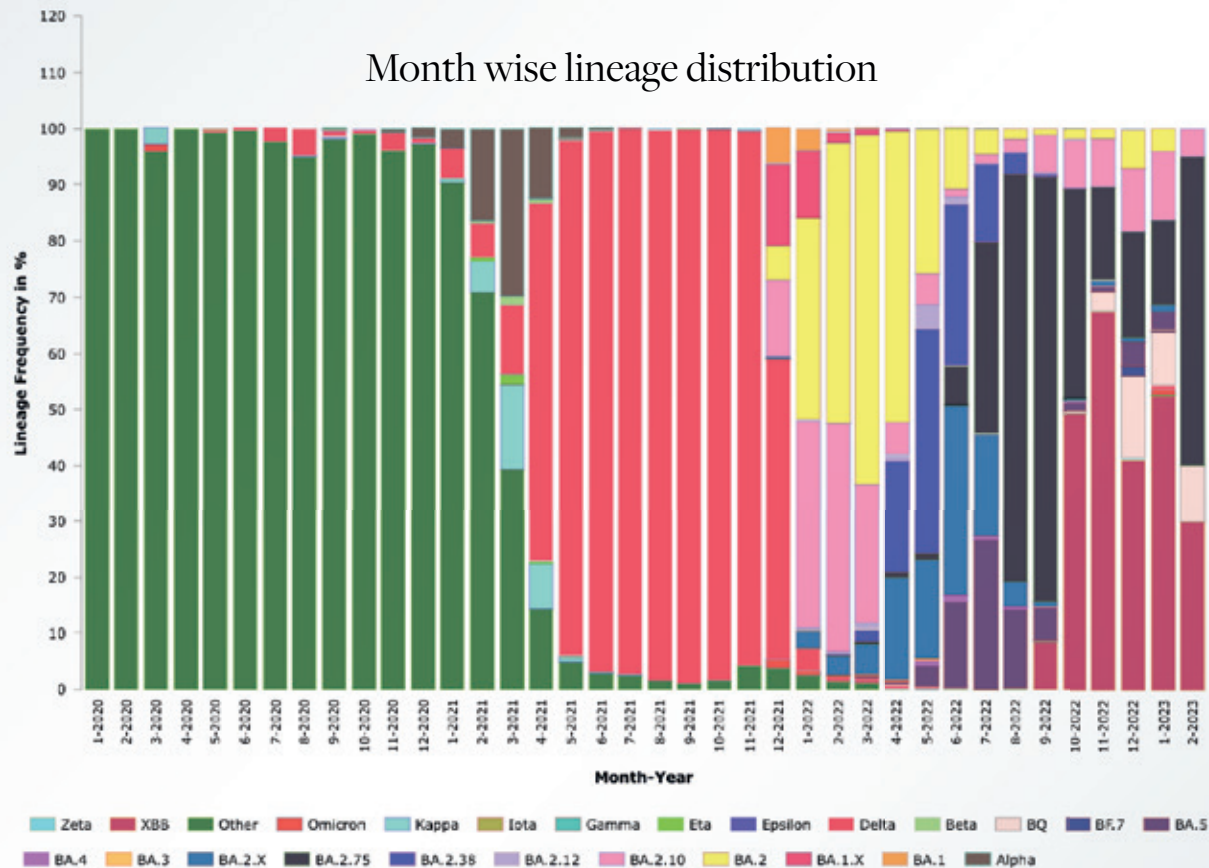
Trend based  
dynamic scale up  
of sequencing

- 3lakh+ SARS-CoV-2 genomes sequenced and analyzed by INSACOG network.
- Weekly release of INSACOG Bulletin and Meetings of Scientific and Clinical Advisory Group.
- Publications in Nature and Science.

# INSACOG:

## Country-wide Analysis

As on: 17-02-2023 13.30.00



# *Wastewater Surveillance of SARS-CoV-2*

Wastewater surveillance is a cost-effective way to identify outbreaks in pockets of cities. SARS-CoV-2 positive samples are subjected to whole genome sequencing.



Collection of sewage samples



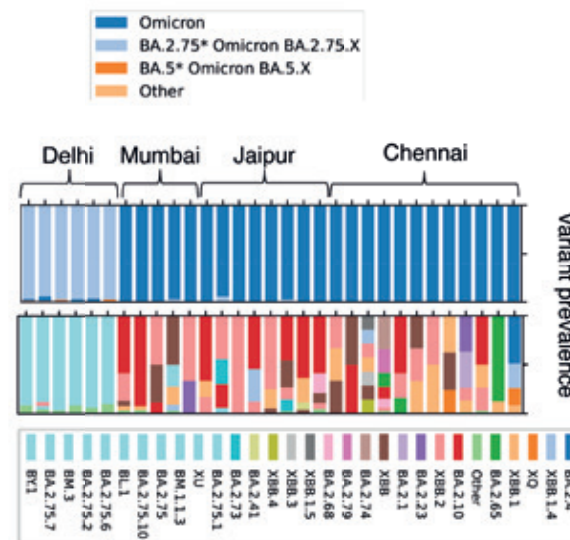
Real-time PCR of RNA samples



Sequencing using Novaseq-6000



- Number of STPs covered: 10
- Number of sampling sites including drains: 52
- Total number of samples tested: 267
- Total positive samples found: 11



# Our Ecosystem

## Mohali (Punjab)

- National Agri-Food Biotechnology Institution (NABI)
- Center of Innovative and Applied Bioprocessing (CIAB)

## New Delhi

- National Institute of Immunology (NII)
- National Institute of Plant Genome Research (NIPGR)
- International Centre For Genetic Engineering And Biotechnology (ICGEB)
- **Biotechnology Industry Research Assistance Council (BIRAC)**

## Gurgaon (Haryana)

- National Brain Research Centre (NBRC)

## Faridabad (Haryana)

- Translational Health Science and Technology Institute (THSTI)
- Regional Centre for Biotechnology (RCB)

## Bulandshahr (UP)

- **Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL)**

## Imphal (Manipur)

- Institute of Bioresources and Sustainable Development (IBSD)

## Kalyani (West Bengal)

- National Institute of Biomedical Genomics (NIBMG)

## Bhubaneswar (Odisha)

- Institute of Life Sciences (ILS)

## Hyderabad (Telangana)

- Centre for DNA Fingerprinting and Diagnostics (CDFD)
- National Institute of Animal Biotechnology (NIAB)

## Pune (Maharashtra)

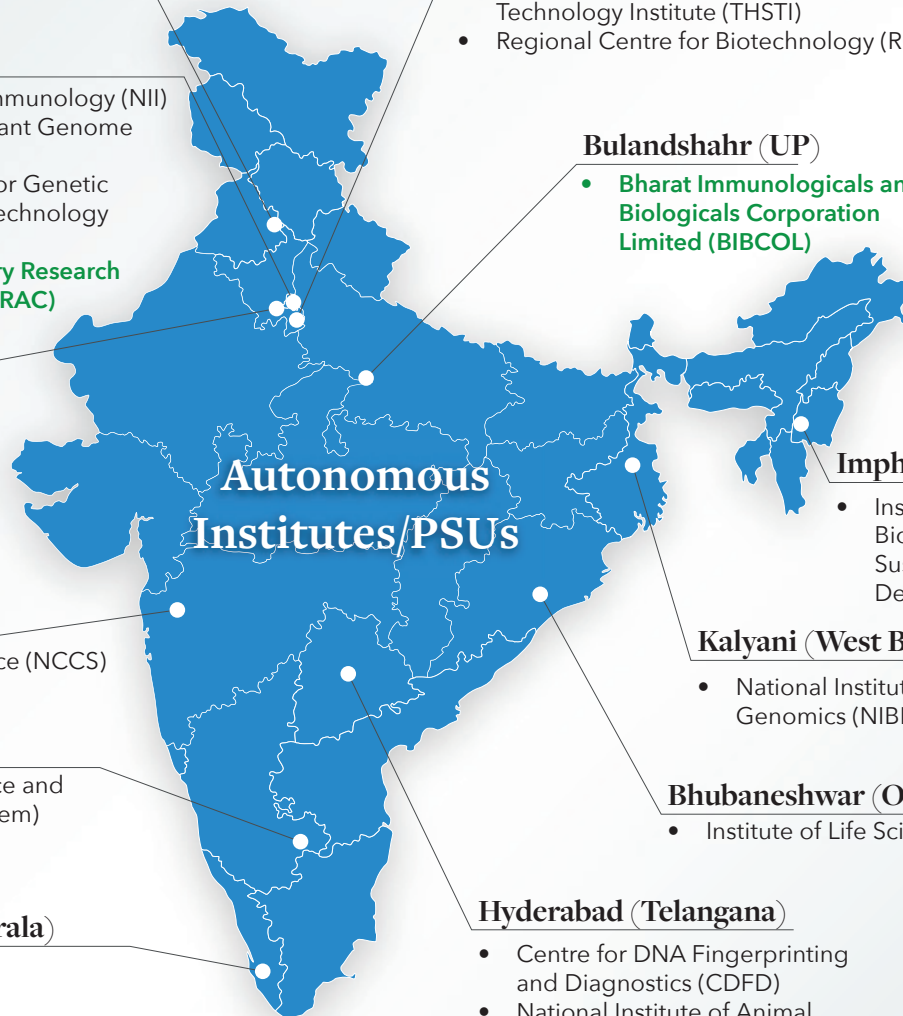
- National Centre for Cell Science (NCCS)

## Bengaluru (Karnataka)

- Institute for Stem Cell Science and Regenerative Medicine (inStem)

## Thiruvananthapuram (Kerala)

- Rajiv Gandhi Centre for Biotechnology (RGCB)



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*Mission COVID Suraksha*



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