Department of Biotechnology
Ministry of Science and Technology
Government of India

NATIONAL BIOPHARMA MISSION
innovate in India for Inclusiveness (i3)

birac
Ignite Innovate Incubate

THE WORLD BANK
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Cabinet approved Program of the Department of Biotechnology

NATIONAL BIOPHARMA MISSION

Industry-Academia Collaborative Mission for Accelerating Discovery
Research to Early Development For Biopharmaceuticals

"Innovate in India *(i3)* Empowering biotech entrepreneurs & accelerating inclusive innovation"

Implemented by Biotechnology Industry Research Assistance Council

Funded by GoI (50% cost sharing through World Bank loan)




April 2018: Loan agreement between Department of Economic Affairs and World Bank

Mission Implementation

Department of Biotechnology

NBM Team

Conceptualization of National Biopharma Mission – Unique Model for Long-term Sustainable Growth of India's Biopharmaceutical Industry

Mission

"The National Biopharma Mission (NBM) is a government-industry-academia collaboration dedicated to 'Accelerating Discovery Research to Early-stage Development for Biopharmaceuticals"

Vision

"To enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals to a level that will be globally competitive over the next decade and transform the health standards of India's population"

Objectives

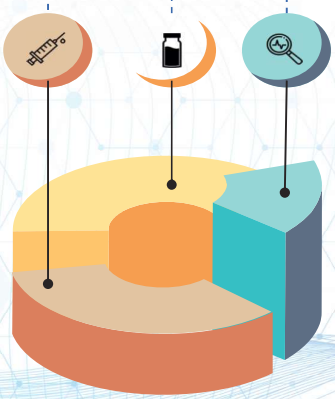
1. Development of advanced stage products **relevant to public health needs**
2. **Establishing and strengthening shared infrastructure facilities** for product development & validation
3. **Creating and enhancing technology transfer** and IP management capacities and capabilities
4. **Development human capital** by providing specific trainings to address critical skills across product development value chain

Components of National Biopharma Mission

A two-pronged approach to enable Accelerated Product Development

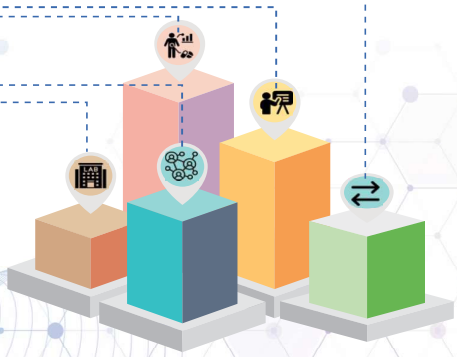
Products Development

- Vaccines
- Biotherapeutics
- Devices & Diagnostics



Ecosystem Strengthening

- Shared Facilities
- Scientific Research Consortia
- Clinical Trial Networks
- Skill Development
- Technology Transfer Offices



NBM ACHIEVEMENTS SNAPSHOT

70	21	07	46	18	33	42	7K
Project Successfully Completed	Shared Service Facilities	Technology Transfer Offices	GCP Compliant clinical trial sites	Products in Market	Patents Filed/ granted	Novel Product including Technologies Developed	People trained

Success Stories

ZyCOV-D Covid Vaccine

World's First and India's indigenously developed DNA Vaccine (Early Emergency Use authorization (EUA) received in age groups 12years and above

CorbevaxTM COVID Vaccine

Emergency Use authorization (EUA) received in age groups 05 years and above - India's first heterologous booster vaccine for Covid

- Biological E's Corbevax, was launched in market at a price of Rs 800 (excluding GST) a dose for the private market, and at Rs 145 per dose.
- NBM supported early phase trial of this vaccine

Pneutger 15 Pneumococcal Conjugate Vaccine (PCV) - India's first 15-valent Pneumococcal Vaccine – By Tergene and Aurobindo Pharma

- PCV providing protection against 15 pneumococcal serotypes compared to currently available **10, 13 and 14 valent vaccines**
- Will be priced at ~40% lower than that of other Pneumococcal vaccines
- Have potential to prevent millions of severe illnesses and save lives among children **under 5 years age** in India

Manufacturing license received from CDSCO

Chikungunya (CHIK) virus vaccine, BBV87

Bharat Biotech International Limited

- Vero cell derived
- purified inactivated CHIKV antigen
- Inactivated with beta-propiolactone (BPL)
- Formulated with aluminium hydroxide
- NBM has supported funding and program management support for Phase II clinical trial of BBV87 in India.
- Phase II completed in India. Vaccine has been found to be safe and immunogenic in individuals aged 12-65 years in India, Latin America, and Thailand.

Freeze-dried Live-attenuated Tetravalent Dengue vaccine Indian Immunological Pvt. Ltd.

The Phase I trial report is being compiled and is expected to be submitted to the Indian regulatory agency by Q3 2024, after which, upon receiving necessary approvals from DCGI, Indian Immunological intends to proceed to Phase II clinical trial.

Liraglutide Biosimilar

- Levim Biotech LLP has developed the biosimilar of Liraglutide injection after completing Phase-1 PK and Phase-3 efficacy & safety studies
- **Successful grant of US and European patent for process innovation**
- Co-development of indigenous pen device **translated into a highly cost-effective - marketed at a price of INR 1855 per PEN, Rs 100 for a standard daily dose of 1.2 mg compared to INR 5374 per PEN of Innovator Victoza.**

Story featured in ET Health World 'Lirafit's impact could alleviate the diabetes burden in India in terms of cost' https://health.economictimes.indiatimes.com/news/industry/lirafits-impact-could-alleviate-the-diabetes-burden-in-india-in-terms-of-cost-quality-of-life/109878159

OmniBRx BIOTECHNOLOGIES

Single-use bioreactor technology : : "CellBRx®" is the first-of-its-kind bioreactor device with complete automation which makes it a most reliable platform for vaccine manufacturing. CellBRx® SUBs are developed upon the concept of Dynamic bed reactor technology, - **Nutritional & gaseous homogeneity across the cell carrier bed resulting into ultra high-density cell culture.**

The 50L bioreactor was validated at Serum and Biological E site with CHO and Vero cell lines.

https://youtu.be/QBLtRp8ygOM

https://www.omnibrx.com/

Under NBM grant, domestic and PCT have been filed. 70+ total staff have been employed. Sold > 20 units and generating revenue

currently there is no Indigenous culture media for CHO cells, commercial production costs 2000-3000 INR/ Liter. A single 1 kL batch needs 30 Lacs INR media

Himedia Laboratories Pvt. Ltd. Launched indigenous chemically defined Serum free medium with feed supplements

LAB ICONICS

Lab Iconics Laboratory Information Management Systems LIMS and Electronic Laboratory Notebooks ELN help streamline data management, enhance workflow efficiency, and improve collaboration for startups and MSMEs in the pharmaceutical, biotechnology, and academic sectors.

https://labiconics.com/

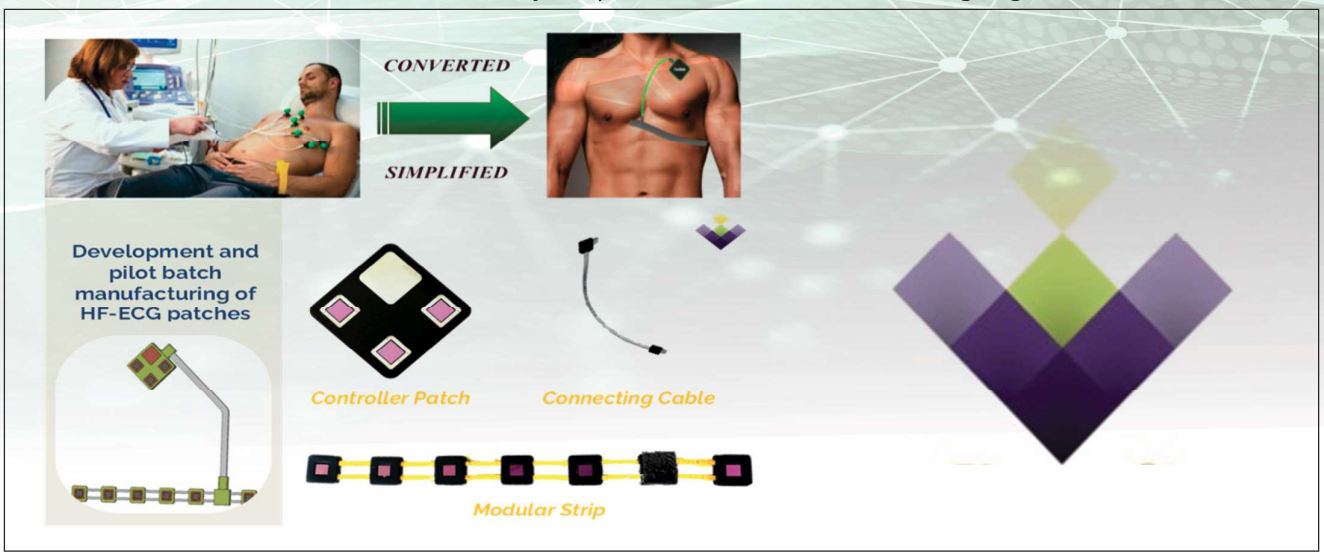
Sold 30 units; >30 staff employed and generating revenue

Voxelgrids Innovations Pvt. Ltd.

- **India's first affordable MRI scanner in stationary and mobile configurations.**
- Enhanced imaging capabilities - 1.5 Tesla superconducting magnet as well as well as a gradient amplifier, both built in India.
- Priced 40% lower cost in comparison to other MRI scanners.

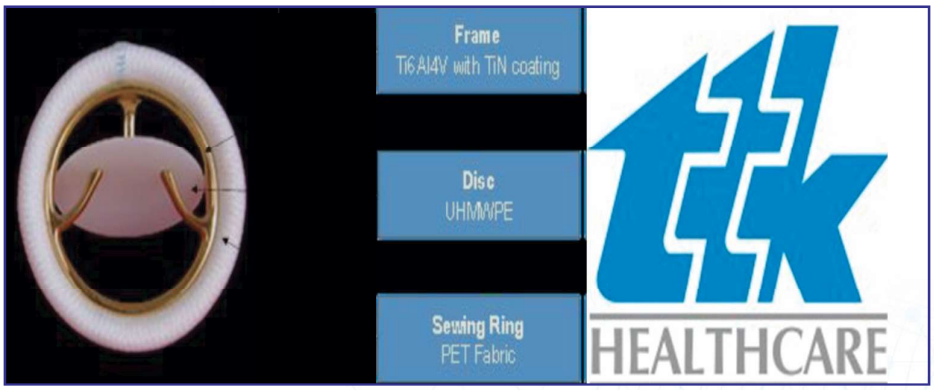
High Frequency ECG device Developed by Carditek Medical Device Pvt Ltd.

- Carditek's Indigenized Real Time multifunctional ECG device, ranges even into ultra high frequency ECG
- Pilot scale clinical trials have been successfully completed and clinical validation is ongoing



TTK Healthcare has introduced the TC2 artificial valves represents a significant advancement in cardiac health technology. It has improved thrombo-resistance and **reduced** bare metal exposure to the bloodstream by Titanium nitride (TiN) coating on frame surface.

- CDSCO Test Manufacturing License received
- The technology now entering in multi-centric clinical trial.



Covid Diagnostics in Market


MTM and NAE kits – Huwel Lifesciences Pvt. Ltd.


RT-PCR Kits Huwel Lifesciences Pvt. Ltd.


RT-PCR Kit – Yaathum Biotech Pvt Ltd.


Antigen detection LFA – Ubio Systems Pvt. Ltd


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

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

Facilities Creating Impact

ANALYTICAL TESTING AND MANUFACTURING FACILITIES – BIOTHERAPEUTICS

CAPS Syngene, Bangalore GLP

CBA, Venture Centre, Pune

CSIR IICT, Hyderabad

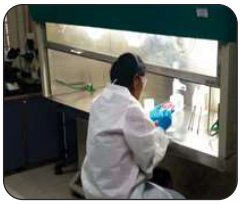
cGMP Manufacturing Shilpa Biologicals Pvt Ltd, Karnataka

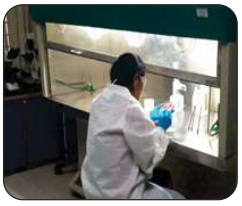
cGMP CAR-T Manufacturing Centre and Tata Medical Centre, Kolkata

GCLP Laboratories for Immunogenicity testing

1. Viral Clinical Immunogenicity Lab

- National Immunogenicity and Biologics Evaluation Centre (NIBEC) IRSHA, Pune
- Assay validation - as per ICH Guidelines
- International Quality standards
- 10 BSL2 and 01 BSL3 facility

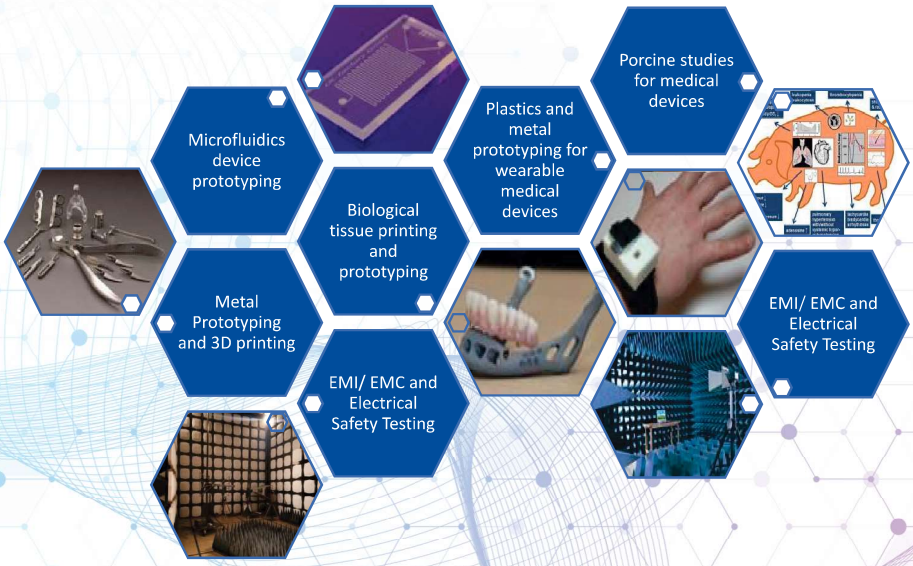




2. Bacterial Clinical Immunogenicity Lab

- Central Research Laboratory attached to Kempegowda Institute of Medical Sciences (KIMS), Bangalore
- Support immunogenicity assessment Pneumococcal vaccines by other manufacturers particularly for WHO-PQ
- Technology transfer of MOPA and ELISA assays from WHO collaborating centers

MedTech Facilities – Testing and Prototyping



Medical Device Manufacturing Facilities

DBT-AMTZ National CoMManD Consortium

- Common Manufacturing Facility
- 15,000 Ventilators
- 0.2 million RT-PCR tests and 2 million Serology tests
- Mobile Diagnostic Laboratory - iLab

Huwel Lifesciences

- Fluorescent Probes for MDx kits
- Products – VTM and NAE kits

Facility

Ventilators

Kits Manufacturing

iLab

Probe Synthesis

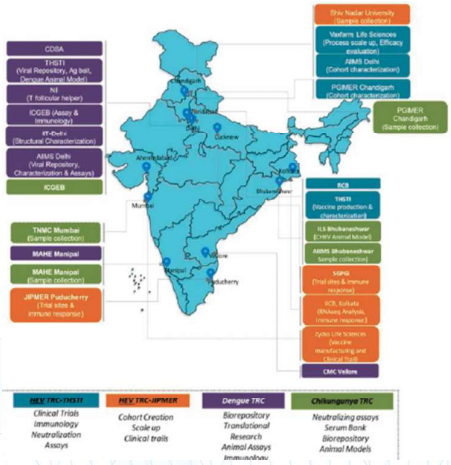
NAE kits

Shared Facilities IMPACT

- **>300 users of Facilities**
- **Differential service cost for academia, start-ups, SMEs**
- Decrease in out licensing of tests and faster turn-around times
- First cGMP facility of CAR-T in Indian hospital
- 4 more ISO 13485 certified medical device facilities in various regions of the country
- 05 GLP and GCLP facilities
- **150** personnel employed
- Employment generation in rural, semi-urban areas, like Dharwad, Aurangabad, Mangalore

Translational Research Consortium Supporting vaccine Development

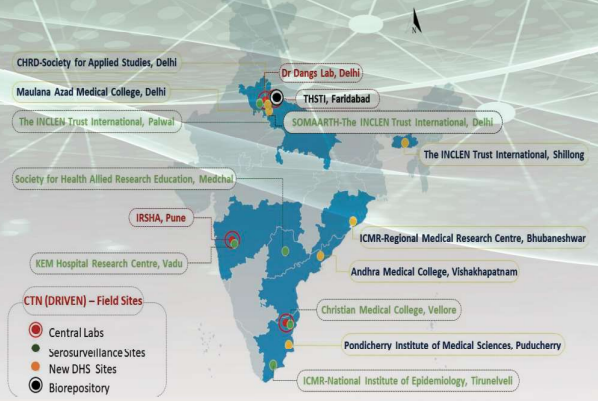
Ensure the translational ecosystem to stimulate, standardize and provide support for advancing development and evaluation of vaccines and monoclonal antibodies



Outcomes from Dengue and Chikungunya Consortiums

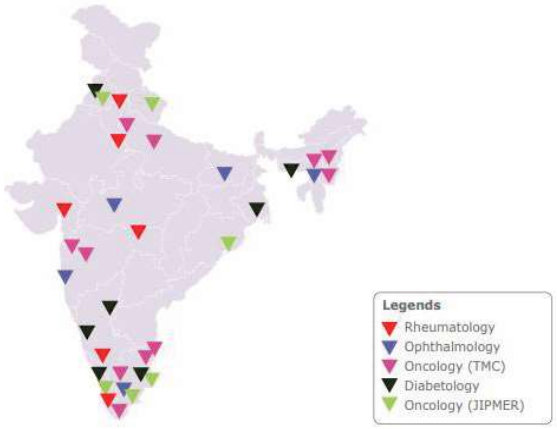
Biorepository of characterized serum samples with patient history	Future scientific research and better understanding immune responses
Virus repository of circulating clinical viral/ parasite isolates with sequence information	Leverage for understanding virus evolution and further virologic research
Animal Models established for vaccine or Drug trials/ viral characterization	Animal development capabilities leveraged for other flaviviruses
	Fee-for services for animal testing available to researchers
High-throughput assays and reagents with standardized SOPs	Transfer of assays to GCLP labs for clinical assessment of Dengue and Chikungunya Vaccines

DBT's Resource of Indian Vaccine Epidemiology Network (DRIVEN)



- 11 GCP compliant sites
- Population data including health parameters, household characteristics and other environmental factors mapped
- Urban, Semi urban, Rural and Tribal population
- Access to more than 900,000 healthy population
- E-Data Management: Paperless data collection methodology-SOMAARTH
- Quality Management Systems
- COVID, Dengue & Chikungunya seroepidemiology
- Acute Febrile Illness study across 10 sites in India including North East ongoing

National Biopharma Mission supported Network of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology



- Public and private hospital sites covering different regions of the country
- 21 Patient Registries across networks to enable development of protocols for clinical trials
- Teams trained in GCP & Bioethics

Ready sites with pan India patient registry for conducting clinical trials of biologics, drugs and devices

IMPACT OF CLINICAL TRIAL NETWORKS

- Disease Epidemiology Data (Dengue, COVID, Chikungunya)
- 21 Multicentric Disease Registries >90,000 patient data
- 14 new Clinical Trial Units established
- GCP, GCLP, GDP Trained Manpower
- Access to >800 k healthy population for vaccine studies
- E-Data Management Platforms
- GIS Mapped DHS Sites across the country
- Access to Urban, Semi-urban, Rural and Tribal Populations
- 10 publications from the networks

First National level largest effort of converging Technology Transfer Institutions

The National Biopharma Mission (NBM) established 7 Regional Technology Transfer Offices (RTTOs) to facilitate research translation and public-private partnerships

- Creation of 7 TTOs across the country
- Creation of IP awareness
- Strengthen the Bio-cluster ecosystem
- Facilitate technology transfer activities

These RTTOs territories encompassing over 1310 academic, research institutions, and incubators. Tailored to each territory's unique ecosystem, they address specific needs based on economic development stages and regional advantages.

Nationwide TTO

RTTOs Impact

- ~20 Spin-outs created from Academia
- ~60+ Technologies licensed /Term sheets negotiated
- ~29 professionals recognized as RTTPs
- ~150+ IP & Tech Transfer sensitization program
- ~190+ Linkages with Academic Institutes/ universities established

Figure MoU between TIMed and HuT Labs Amrit Vishwa Vidyapeetam

Breakthrough Treatment in Sepsis, the cause of 1 in 5 deaths in ICUs Globally, Licensed to Dutch Spinoff SurvivX by C-CAMP & ILS

Sepsis treatment developed by researchers in Bengaluru and Bhubaneswar licensed to Dutch firm

TTO FITT Innovation-Technonolgy Transfer Officer (i-TTO) FITT facilitated transfer of three frugal and socially impactful technologies successfully on September 14,2023 to M/s Rudray Industries, a Nashik based start-up

License Agreement transactions facilitated by KIT-TBITTO Technology Synthesis of toluidine blue o & a kit for mucosal application (Quick-Blue) Application, early detection of oral potentially malignant & malignant disorder

BCIL: Technology, A novel process for the production of the anti diabetic sugar,D-allulose by using a D-allulose 3-epimerase of Bacillus sp-Origin-technology was transferred to M/s Kothari Sugar and chemical Ltd (KSCL) on April 04, 2024

Skill Development

Training Areas

- GXP (GCP, GCLP): 22
- Regulatory Compliance for Accelerating Innovations: 06
- Technology Transfer and Commercialization Trainings: 03
- Trainings under Product Development 09
- Trainings under Product Development 09
- Bioethics webinars: 04
- Environment and safety webinars: 06
- Sero-surveillance trainings: 01
- Establishment of Demographic, Development and Environment Surveillance Site 01
- Acute Febrile Illness Study protocol 01

Key Highlights

- **Total trainings conducted 43**
- Trainings on 'Good Clinical Practice' **(GCP)**, 'Good Clinical Lab Practice' **(GCLP)** and '**Bioethics**' were held in collaboration with CDSA
- As on date, about **~7000 participants** have been trained under different trainings and workshops under the National Biopharma Mission including **3039 female participants.**
- A series of webinars conducted for **promoting Clinical Research Ethics capacity in India**
- A series of **webinars** on 'Environment, Health and Safety' to sensitize and create awareness about environment management and sustainability