National Biopharma Mission

The National Biopharma Mission, entitled **"Innovate in India (*i3)* – Empowering biotech entrepreneurs & accelerating inclusive innovation"**was approved by the Cabinet Committee on Economic Affairs in May 2017. This ambitious Mission of the Department of Biotechnology (DBT) is being funded by the Government of India at a total project cost of Rs 1500 Crores for five years on a 50% cost sharing basis via World Bank loan and is being implemented at the Biotechnology Industry Research Assistance Council (BIRAC) - a Public Sector Undertaking of DBT.

The Mission is designed in alignment with the key components of the National Missions such as "Make in India" and "Start-up India" and also aims to take forward the commitments made by DBT in the National Biotechnology Development Strategy. The Mission is focused to transform the health standards of the country through affordable product development and is currently working to bring 5-7 biopharmaceutical products closer to market in the coming 4 years at a total cost of USD 250 Mn (~ INR 1500 Cr.)

Review and Monitoring

- Review and Monitoring of the programme is done annually by a duly constituted Steering Committee, chaired by Secretary DBT.
- Also, the World Bank Conducts a review of the programme on half yearly basis

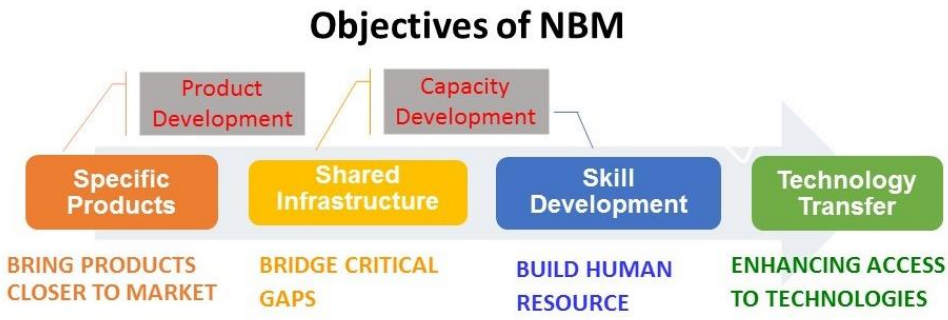
Vision

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

Overall Objectives

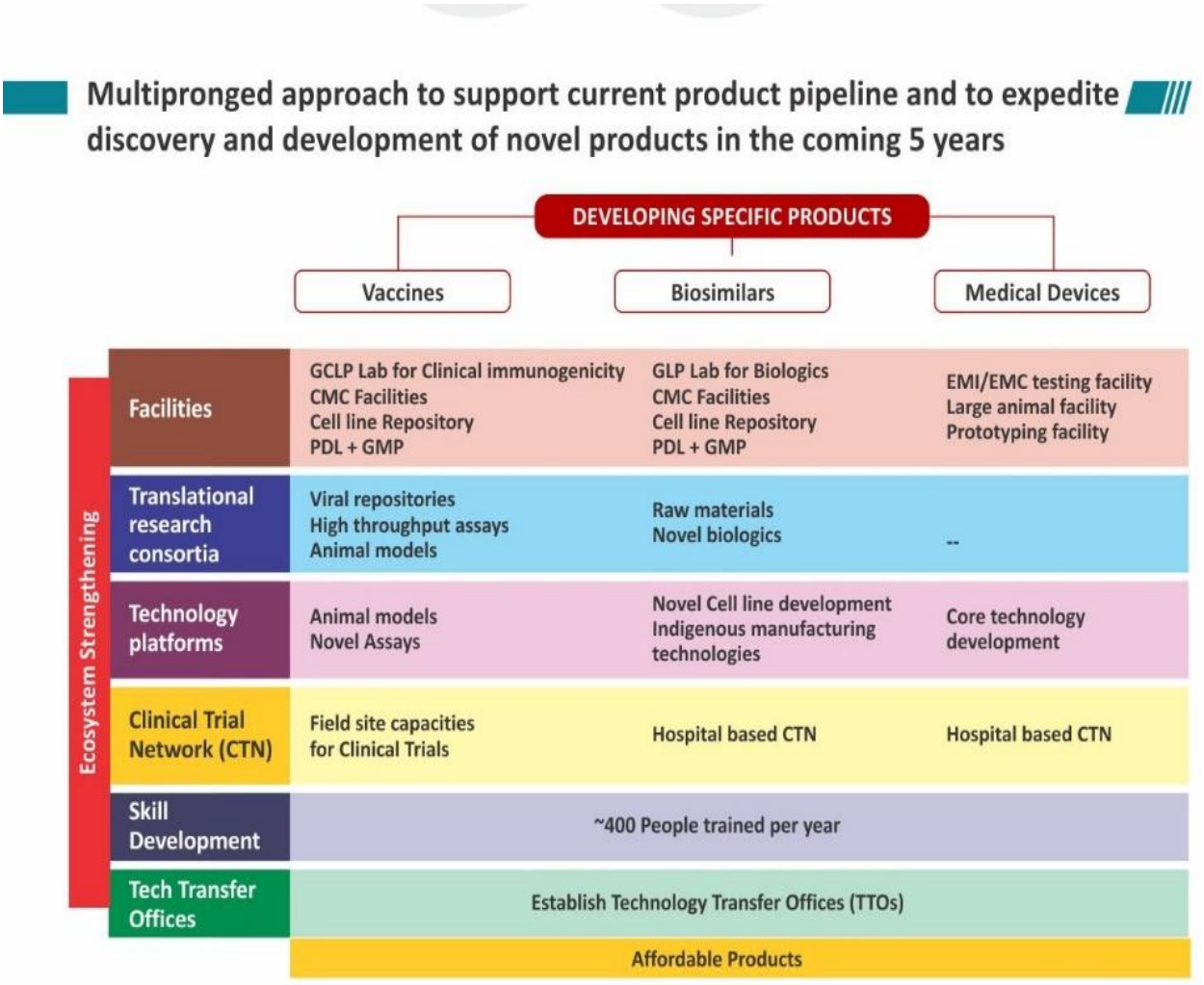
The approved objectives of the Mission include:

- Development of product leads that are at advanced stages of the product development lifecycle and relevant to the public health need in vaccine, biosimilar and medical devices & diagnostics.
- Facilitate and nurture a conducive environment for preparing India's technological and product development capabilities in biopharmaceuticals
- Establishing and strengthening shared infrastructure facilities for product development and validation.
- Developing human capital by providing specific trainings to address the critical skills gap across the product development value chain.
- Creating and enhancing technology transfer and intellectual property management capacities and capabilities.



Current Status and Key achievements

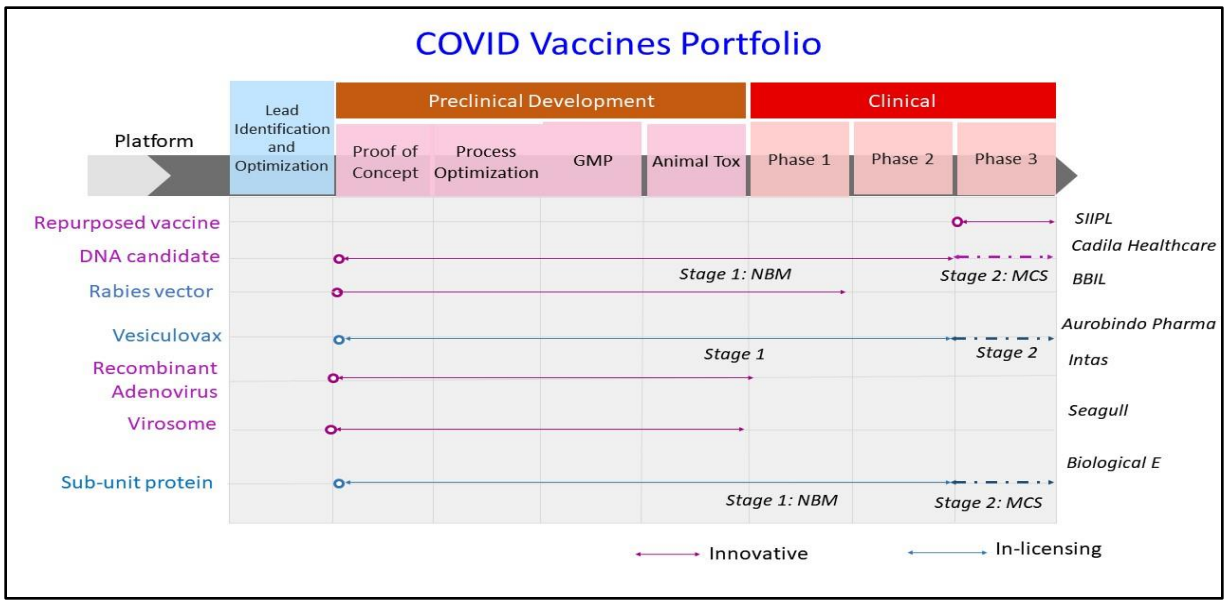
The major activities under this Mission are (i) Specific Product Development (ii) Building Shared Infrastructure and (iii) Building and strengthening domain specific knowledge and management skills.

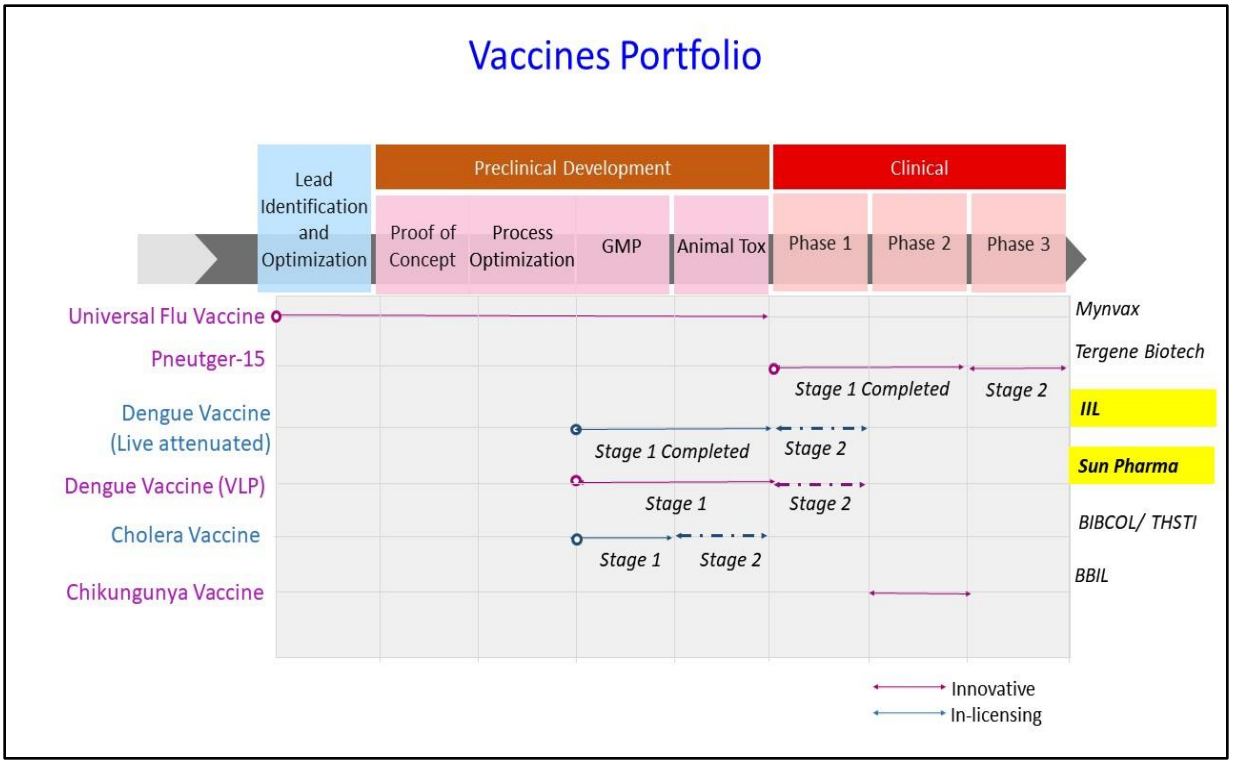


(i) Specific Product Development

The Mission has identified three major verticals for product development namely Vaccines, Biotherapeutics and Medical Devices and Diagnostics.

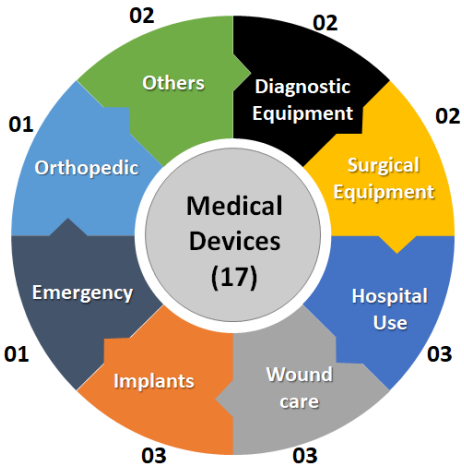
Vaccines: The vaccine component of the mission is focused on accelerating vaccine development for complex, emerging and high-priority infections in India.Recombinant BCG, repurposed COVID vaccine candidate of Serum Institute of India is undergoing Phase III clinical trial. Additionally, Cadila Healthcare (DNA vaccine candidate) and Biological E (Protein subunit platform) has completed Phase II CT supported by NBM and has currently progressed to Phase III clinical trials. Other vaccines supported are for Dengue, Chikungunya, flu and cholera.

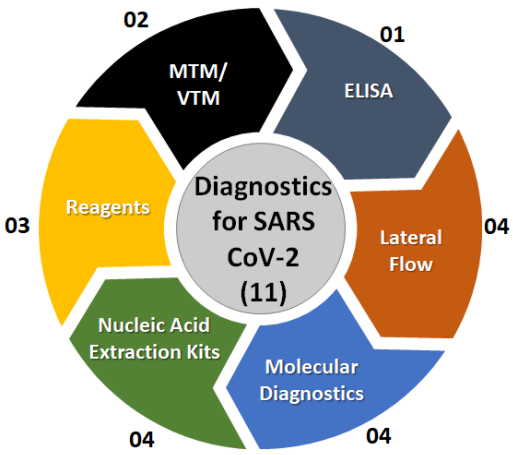




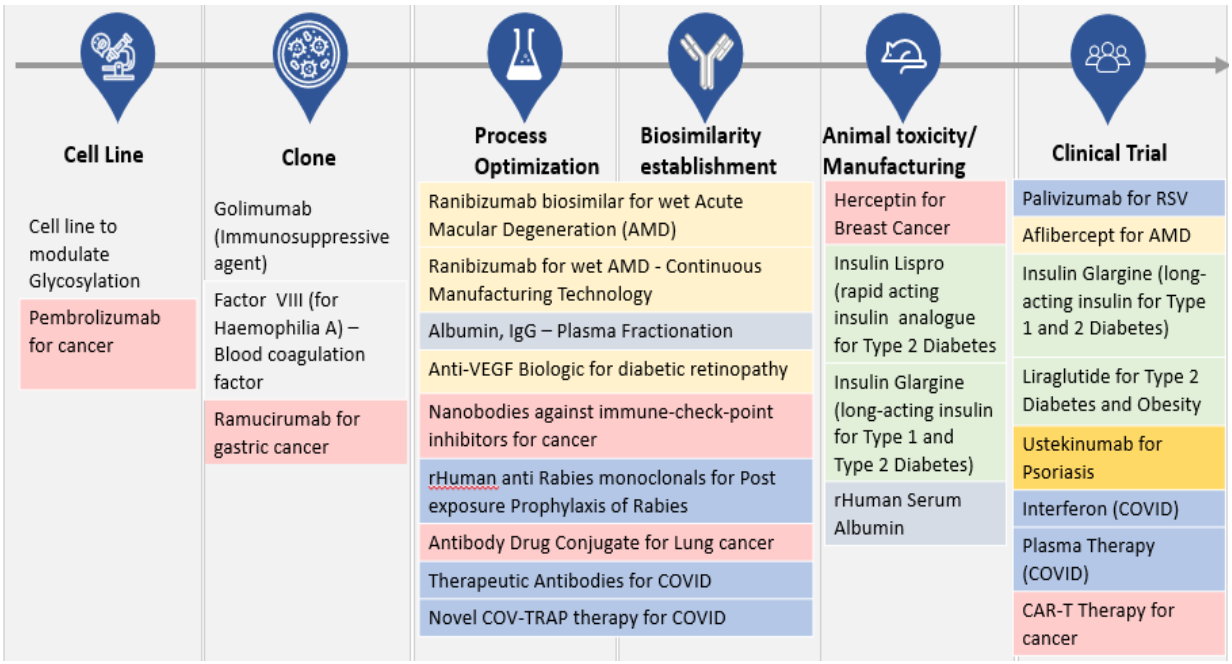
Medical devices & diagnostics: With a view to reduce import dependency, improve affordability and increase the innovation quotient, the Mission is supporting development of products in the areas as depicted below. Considering that 75% of medical device market is dominated by imported products, the Mission is focused on developing core technologies

offering cost effective indigenous alternatives to existing foreign makes. Development of materials for bio-absorbable implants (bone implants), slip ring CT scanners, next generation endoscopes, next generation MRI scanners and few more as depicted below. Different diagnostic platforms for COVID-19 testing are supported, some of which are already in market.





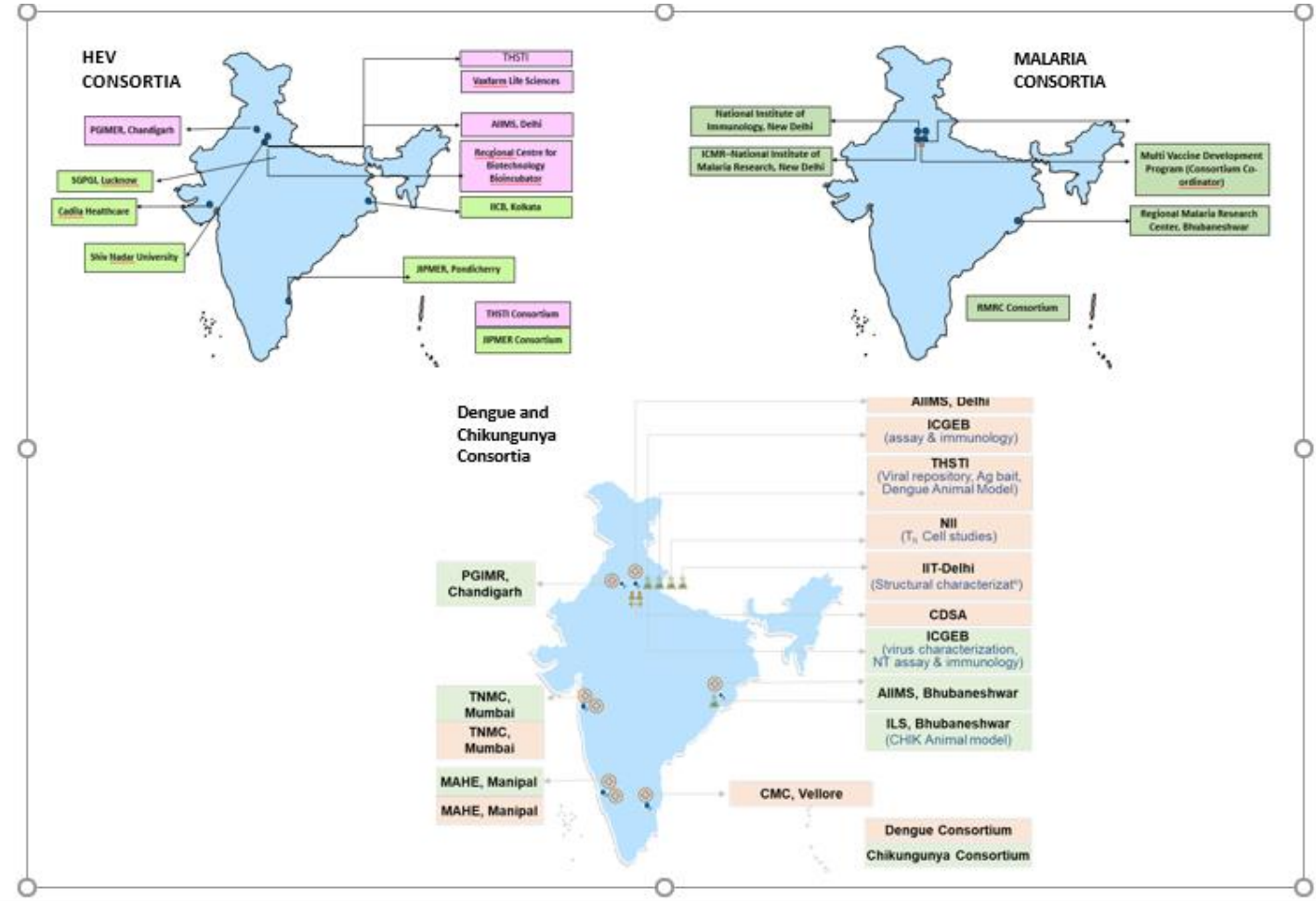
Biotherapeutics Portfolio: The Mission is working to bring biosimilar products (*therapeutic proteins and monoclonal antibodies*) closer to market. The product category of biotherapeutics supports development of novel cell line, biosimilar clones, and biosimilars at different developmental stages and for different indications like cancer, diabetes, Rheumatoid arthritis, wet AMD, infectious diseases, including Covid-19.



(ii) **Scientific Research:** Promoting Indigenous manufacturing and novel Biologics: NBM has also funded several proposals promoting indigenous development of technologies for affordable biotherapeutics and novel therapies. The activities funded under this area include novel cell line development, resin preparation, disposable bioreactors, and IT platform

The Mission is also supporting the creation of Translational Research Consortia (TRC) for Dengue, Chikungunya, Hepatitis E virus and Malaria, consisting of a Consortium of premier Indian institutions that would enable the development of multidisciplinary translation ecosystem partnership platform. The TRCs are aimed at generating resources, reagents, infrastructure and knowledge that would fast-track national efforts to tackle these infectious diseases, which are growing public health problem. The Mission is supporting five consortia. The goal of Translational Research Consortia (TRC) is to assemble, coordinate and develop translational research activity for building sustainable capacity in India towards Dengue, Chikungunya,

Malaria and Hepatitis E virus (HEV). These are consortia comprising multidisciplinary units from various premier organizations of the country as depicted in map below.

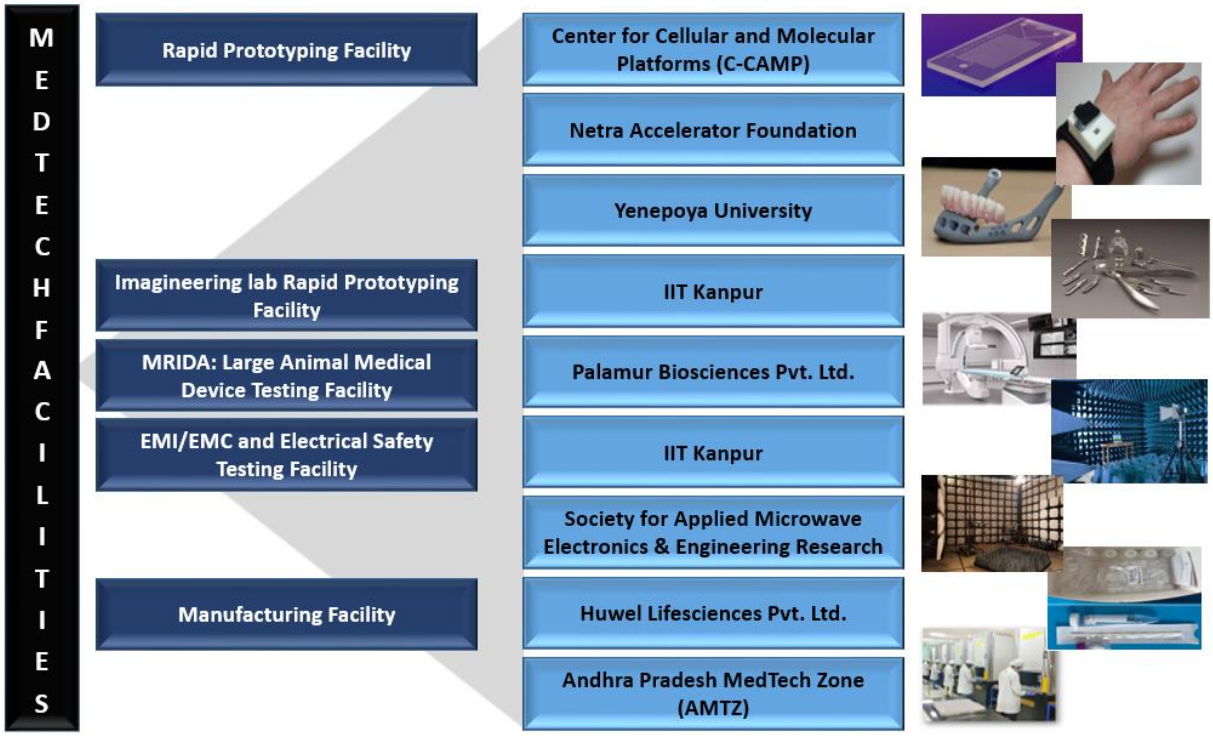


NBM Supported TRC Ecosystem

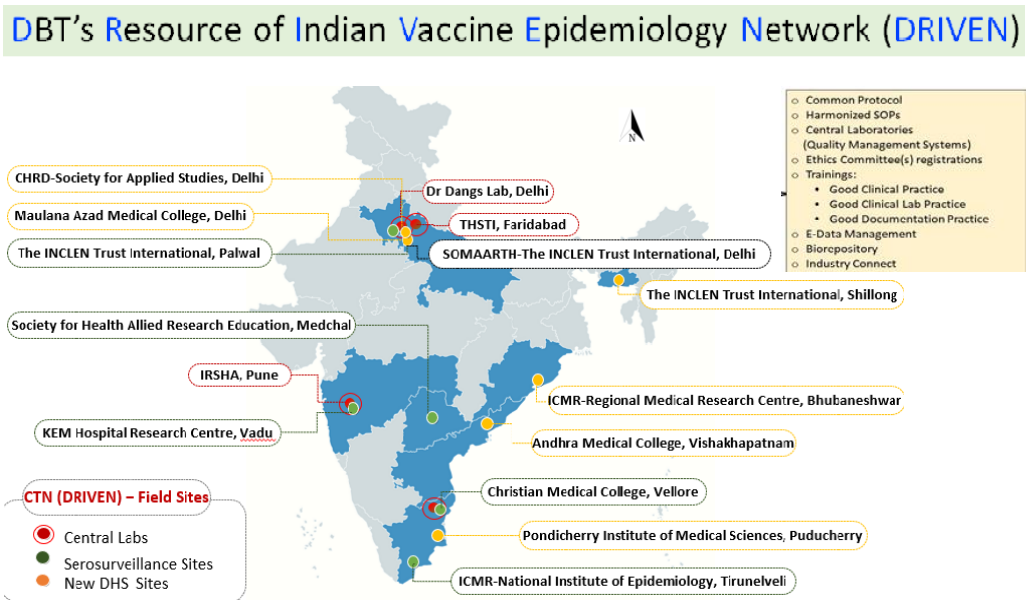
(iii) Building Shared Infrastructure

The program is dedicatedly working to create an enabling ecosystem for affordable product development in the country. The facilities being supported by Mission include (i) GLP compliant facility for analytical characterization of biotherapeutics, (ii) GCLP facilities for clinical immunogenicity, (iii) GMP manufacturing facilities for biotherapeutics (Microbial and Mammalian) iv) Lentivirus manufacturing facilities for cell therapy (v) Medical Device and diagnostics rapid prototyping facilities, (vi) EMI and EMC facilities for electrical safety testing of electronic medical devices and (vii) a large animal facility for evaluation of implantable medical devices.

Some MedTech facilities supported by NBM for capacity enhancement are as under the various thematic areas such as medical devices, testing facilities and apparatus, manufacturing and scale-up:

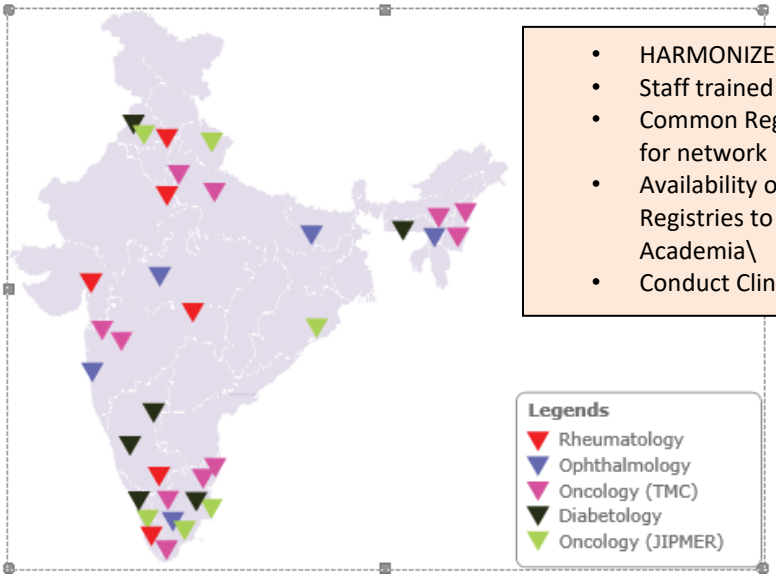


The Mission is further focused on strengthening clinical trial capacities, for testing biologicals as well as vaccines, and establishing a data management system for enhanced data analysis and reporting.



- Clinical trial networks for hospital-based trials in patients for testing biologicals in different specialties of oncology, diabetology, rheumatology and ophthalmology. Are being created. Currently, 05 consortia including 35 hospitals are being supported.

Hospital Sites

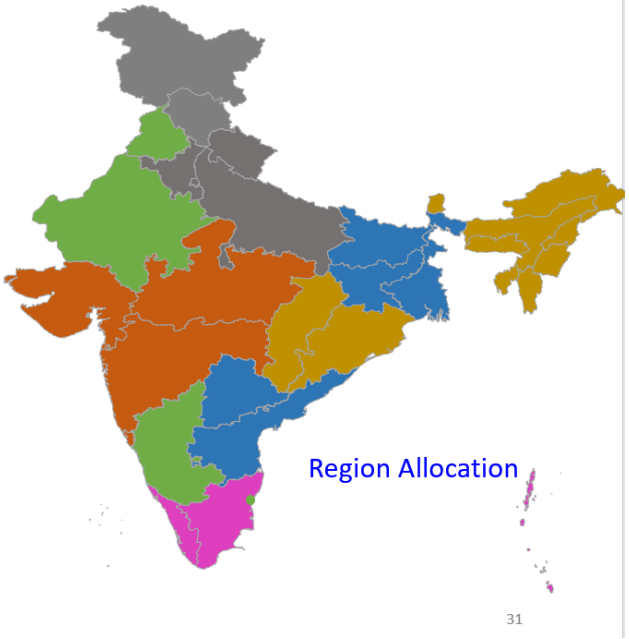


- HARMONIZED SOPs
- Staff trained in GCP
- Common Registry Platform for network
- Availability of Disease Registries to industry, Academia\
- Conduct Clinical Trials

Deliverable : Provide a ready reference for identification of pool of eligible subjects for any proposed clinical trial Form protocols for Standard of care in low resource settings and/or Low Middle Income regions and conduct GCP compliant trial

Strengthening the technology transfer capacity of the country is another major focus area of the Mission as part of which, seven (07) incubators have been identified to establish Technology Transfer Offices.The Mission is simultaneously working towards generating skilled taskforce in the area; via trainings and workshops. Furthermore, a consultancy engagement to train the personnel at the TTO's is on board.

iTTO (Innovation Technology Transfer Office): FITT, New Delhi.
TechEx.In Venture Center, Pune.
KIIT TBI-TTO (KIIT Technology Business Incubator-Technology Transfer Office) KIIT-TBI, Bhubaneshwar.
OTT (Office of Technology Transfer) Center for Cellular and Molecular Platforms (C-CAMP), Bengaluru.
IKP-PRIME (Platform for Regional IP Management Ecosystem) IKP, Hyderabad.
* Shree Chitra Thirunal Institute for Medical Science and Technology (SCTIMST), Thiruvananthapuram.
* Biotech Consortium India Limited (BCIL), New Delhi



Locations and Functions of TTOs

(iv) Building and strengthening domain specific knowledge and management skills

The Mission supports trainings and workshops as per its mandate. As on date,1406 candidates have been trained under Mission supported trainings with about 37.12% female participation up till now and about 644 candidates trained with 46.89% female representation in 2020-21. The workshops were conducted in the areas of clinical research, regulatory compliances, technology transfer, biopharmaceuticals and medical devices. Several more workshops are enqueued as a regular activity under the Mission.

Way forward

It is expected that this programme would enable strengthening of translational capability of academic researchers and empower bio-entrepreneurs and small and medium scale enterprises. The global experience of World Bank would be instrumental in building sustained global linkages, technical assistance and knowledge flow between public private partners for business promotion in biotech sector. It is envisaged that this programme will help deliver new products for the country, create several dedicated facilities for next-generation skills, and create employment opportunities.