



सत्यमेव जयते

NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY

[2020-2025]

Knowledge and Innovation Driven Bio-economy

DEPARTMENT OF BIOTECHNOLOGY

MINISTRY OF SCIENCE AND TECHNOLOGY

GOVERNMENT OF INDIA

Summary

Over these last few years, we have seen a very encouraging growth in the Biotechnology Sector. This has been primarily due to a strong foundation, which has been established over few decades from research and education to translation and product development. An effort has been made to engage with all stakeholders and provide not just financial support but bring in key policy changes with strong enablers and drivers for this ecosystem.

The Department of Biotechnology, which was setup in 1986, laid out its first Vision Document in 2000 and the Biotechnology Strategy in 2007 and then the Biotech Strategy-II in 2015. Through these Vision and Strategy document over 20 years the effort has been to create a strong enabling environment to promote the growth of the Sector and to ensure that the technologies and products developed through the intervention of cutting edge frontier Biotechnologies are delivered in the service of human kind.

As we move into this next 5 years from 2021 to 2025, we have set out for ourselves an ambitious target of Biotechnology contributing to a *“knowledge and innovation driven Bioeconomy”*. With the current growth trajectory of the sector we are confident that India will be within the top 5 countries globally and be recognized as a Global Biomanufacturing Hub by 2025, with the Sector growing exponentially to achieve a growth of \$150 Billion. This will be possible through a very well articulated Vision/Mission and Goals, driven through a set of well defined strategies and a clearly laid out implementation Action plan. This strategy document brings out this plan and also lays emphasis on the new initiatives to be taken along with certain policy changes which are required to deliver this target.

The recent COVID example has clearly indicated that our focus has to continue to be on 4 major verticals:

- i. Building capacities both human resource and infrastructure to cater to the current needs and also to the future emerging technologies
- ii. Strengthening and nurturing of a strong basic research innovation driven ecosystem across Research Institutes and Laboratories, both public and private sector, with complete engagement of Startups, Small Industry, Large Industry and also reaching out to tier 2 and tier 3 cities.
- iii. The third major focus is on promoting the translation and product development commercialization ecosystem which necessarily needs to engage public and private sector and

also encourage PPP models of co- development. This will require special focus on moving research leads from Laboratory towards technology development.

- iv. The balance between basic and translational research needs to be maintained to ensure that we have a robust pipelines of new knowledge, which helps us to take the translational work forward.

The strength of the research and translation is further enhanced through strategic partnerships and this has also been clearly listed in this document. In addition to innovation on process, technology and product, there is a need for innovation in models of governance and partnerships which have been highlighted. The vibrancy of ecosystem for delivery of product needs a strong regulatory environment with key policy drivers and enablers. This Strategy Document outlines India's strength and confidence in delivering a knowledge Driven Bioeconomy.

VISION & MISSION

Vision: To harness the potential of biotechnology as a premier precision tool for national development and well-being of society

Mission: To make India globally competitive in biotechnology research, innovation, translation, entrepreneurship and industrial growth and be a USD 150 billion Bioeconomy by 2025.

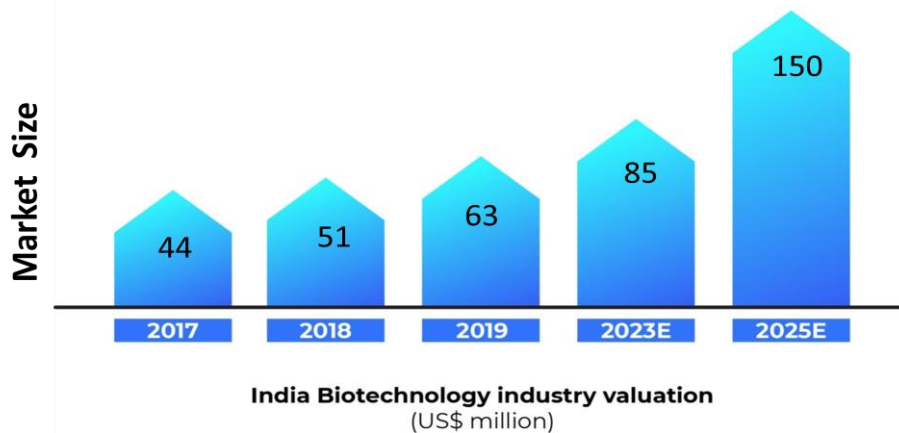
Goals and Objectives:

- To build and strengthen a strong education, research and translation ecosystem across the country
- To make India a global player for the development and deployment of new and emerging technologies
- To build and nurture a vibrant start-up, entrepreneurial and industrial base in the country, connecting the academia and industry
- To position India as a strong bio-manufacturing hub for innovative, affordable and accessible products for the society and also for global markets

INTRODUCTION:

Biotechnology deals with the application of biological knowledge and techniques pertaining to molecular, cellular and genetic processes to develop significantly improved products and services. Biotechnology products and processes have ensured ease of living, improved health care, agriculture output and created livelihood opportunities, etc.

India is ranked amongst the top 12 biotech destinations in the world and ranks 3rd in Asia. The Indian biotech industry is likely to experience significant growth due to increasing economic prosperity, health consciousness and a billion-plus population base. Current estimates value the industry at USD 63 billion in FY2019-20, which is expected to grow to USD150 billion by FY25. At present, the biotechnology industry in India comprises >3500 biotech start-ups and is estimated to reach 10,000 by 2024-25. The biotech sector is primarily divided into five major segments: bio-pharma, bio-services, bio-agri, bio-industrial and bio-informatics, which together contribute to the Bioeconomy. Biotechnology industry growth in India is primarily driven by vaccines and recombinant therapeutics at present.



OUR KEY STRENGTHS

Strengths:

- Large reservoir of scientific human resource including scientists and engineers
- Cost-effective manufacturing capabilities
- ~3500 biotech start-ups
- Large number of national research laboratories; centres of academic excellence in biosciences
- Biotechnology parks and incubators established across the country to translate research into products and services by providing necessary infrastructure support
- Several universities, professional colleges, educational and training institutes offering degrees and diplomas in biotechnology, bio-informatics and biological sciences
- Presence of a well-defined and vibrant drug and pharmaceutical industry
- Highest number of USFDA approved manufacturing plants outside the U.S.
- Rich Biodiversity: India's human gene pools offer an exciting opportunity for genomics
- Fast developing clinical capabilities with the country becoming a popular destination for clinical trial and contract research

We however need to focus on:

- Building a strong Research Academic partnership
- Enhancing venture capital for high risk science
- Enhancing R&D expenditure by industry
- Strengthening the link between research and commercialisation
- Ensuring Quality assurance of Indian products as per international standards
- Ensuring Educational curriculum needs to be aligned to prepare students as per industry demands.
- Creating and strengthening State-of-the-art research facilities and translational centres

BIOTECHNOLOGY AS A KEY DRIVER FOR A KNOWLEDGE-BASED ECONOMY:

In the last several decades, life sciences *per se* has changed monumentally than virtually any other field of science or engineering. Until recently, the objective of most basic research was to generate new knowledge and advance understanding of biological and biochemical processes. The steady, incremental advance of the life sciences has now started yielding important benefits of healthcare, particularly through the pharmaceutical industry focusing on new healthcare interventions and delivering innovation and greatly enhanced agricultural production and productivity through improved process innovation and new technology. Discoveries from the basic research undertaken in publicly/private funded research institutions are now being applied more rapidly and broadly for societal impact. Key among the changes in the Indian context was the setting up of BIRAC by DBT in 2012 that provided the impetus and a mechanism for nurturing and support intellectual property rights and work with companies seeking to commercialize the inventions coming from academic universities and institutions.

World over biotech industries have forayed into wide-ranging applications in medicine, agriculture and foods, informatics, nano and forensics, among others. However, moving forward there would be advances that are yet to be imagined. Industries will adopt new technologies and there will be new discoveries made, that would impact every aspect of our lives – from health to food production, climate, and environment so on and so forth. Therefore, to create favorable conditions for sustainable development and deployment of biotechnologies to act as an engine for the knowledge-based bio-economy, it is imperative to have a strategy rooted in the Indian perspective to drive Biotechnology to the next level.

IMPACT OF COVID ON BIOTECHNOLOGY SECTOR:

In the past few months, the COVID-19 pandemic has impacted every sector of our economy. However, despite the many challenges that have emerged due to the pandemic, biotechnology's key growth drivers have remained intact. Notably, the industry continues to generate innovative new products in both the short and the long term.

The pandemic has presented some significant challenges to the scientific community. However, at the same time, this offered opportunities for the pursuit of new scientific activities, particularly in biotechnology. As a society, we have finally begun to reap the benefits of the various scientific and medical advancements made in the past decade. The classic example is the recent surge in novel drugs and treatment modalities that is apparent from the fact that the vaccine for the SARS-CoV-2 coronavirus is the fastest any vaccine had previously been developed, right from viral sampling to approval for use. Advances in genomics and proteomics, as well as in DNA sequencing technologies, have enabled a more informed and targeted approach to designing of drugs. Scientists and researchers are also now better equipped than ever before to identify new mutations that drive diseases; to design new drugs with better efficacy and safety; and to improve diagnosis of patients so that the best treatment options can be found to improve clinical outcomes at a comparable timescale. India is also looking to be self-reliant in developing and producing COVID-19 vaccine as the world races to mitigate this deadly pandemic. Led by the Department of Biotechnology (DBT), Government of India, and implemented by a dedicated Mission Implementation Unit at Biotechnology Industry Research Assistance Council (BIRAC), the existing activities under National Bio-Pharma Mission (NBM) and Ind-CEPI Mission are also providing complementary strengths to ***Mission COVID Suraksha-The Indian COVID-19 Vaccine Development Mission*** that facilitates preclinical development, clinical development and manufacturing and regulatory facilitation for deployment, and consolidate all available resources towards accelerated product development. The highlights of the COVID-19 R&D efforts include support for >100 projects in the thematic areas of vaccines, diagnostics and therapeutics, enabling 7 vaccine candidates by industry and 8 candidates by academia, development of clinical trial sites and centralised laboratories to facilitate vaccine development and leveraging international partnerships, COVID 19 testing at 9 DBT AIs, approved as Hubs for their respective City/Regional clusters, rapid scale-up of manufacturing of indigenous COVID-19 diagnostic kits with a production capacity of about 15 Lakh kits/day, deployment of nation's first infectious disease mobile laboratory in Haryana, 5 COVID19 Biorepositories with more than 40,000 samples available to researchers and industry, development of therapeutics from natural products in partnership with M/o AYUSH and nearly 50 BIRAC supported startups have developed innovative products for COVID-19.

This leads the way forward for achieving success in all other areas even beyond COVID.

THE GENESIS

Quantum jump from the NBDS 2015-20: Department of Biotechnology announced the National Biotechnology Development Strategy-I 2015-2020 at the culmination of highly successful Biotech Strategy 2007. NBDS 2015-2020 resulted from formal and informal consultations with over 300 stakeholders including scientists, educators, policymakers, leaders of industry and civil society, voluntary and non-government organisations, regulators and international experts. Post announcement of the NBDS 2015-20, the focus has been on the generation of biotech products, processes and technologies to enhance efficiency, productivity, safety and cost-effectiveness of agriculture, food and nutritional security; affordable health and wellness; environmental safety; clean energy and biofuel; and bio-manufacturing. There has also been a major thrust on building a skilled workforce to meet the national requirements. Emphasis has also been laid on technology-oriented research aimed at improving lives and living of millions.

The transition from the NBDS 2015-20 to NBDS 2021-25 comes when India is aiming to become a USD 5 trillion economy; making for India and the world, ensuring ease of living for the citizens, skilling its youth to become entrepreneurs and job-creators and ensuring equitable and sustainable development. The new strategy will allow the biotech sector to make a quantum jump in addressing these priority areas.

DBT remains committed to providing a special impetus to new knowledge generation and discovery, launching major strategically driven and directed missions, empowering the country's human resource scientifically and creating a strong ecosystem for research, development, translation and commercialization to create a robust bio-economy. The era of biotechnology-driven, socially relevant innovation and technology development has arrived especially in the wake of COVID-19 outbreak. It will be the key driver of the NBDS 2020-25. DBT would strengthen and widen its strategic partnerships globally, nationally and with the private sector for achieving its ambitious targets.

The consultations held have helped identify the verticals that will drive the NBDS 2021-25 and the instruments for their implementation. These are outlined in the key elements section.

Key Strategies:

- 1) Building Capacities – A skilled workforce and strengthened state of the art infrastructure
- 2) UNATI Biotech Missions – aligned with National and Global priorities
- 3) Building a Self-reliant India (Atmanirbhar Bharat) through Biotech Interventions – Affordable and accessible products and technologies
- 4) Leveraging the Strength of Strategic Partnerships – National and International
- 5) Preparing for the Future – Building the knowledge base

- 6) Taking Science to Society – Empowering the Rural sector
- 7) Effective Outreach and Communication – Building the Public Trust
- 8) Global Benchmarking and Performance Measurement – A Measurement matrix to build quality
- 9) Policy enablers

Implementation plan to drive the strategy:

Developing guiding principles are critical for creating an environment that will take the biotechnology sector on a higher growth trajectory. Consultations with various stakeholders have led to the identification of the following guiding principles that shall drive the National Biotechnology Development Strategy 2020-2025.

(1) Building Capacities – A skilled workforce and strengthened state of the art infrastructure

A skilled human resource and state of the art infrastructure are critical to meet the needs of the growing biotechnology sector. To stay ahead and drive excellence, the sector would require a sustenance plan with a focus on skill up-gradation, skilling for the future, ensuring quality at par with global standards, nurturing future leaders in the field, creating a workforce that is ready to adopt the new and emerging technologies and setting up state of the art infrastructure to facilitate translational research while ensuring principles of equity and social justice.

- a) Build a skilled workforce to cater to the needs of the Biotech Industry and to enhance employability.
- b) Ensure the quality of the human resource across UG to post-doctoral that is at par with the global best.
- c) Expand HRD activities to ensure pan-India coverage and increased footprint in Tier-II and Tier-III cities.
- d) Create a human resource in strategic areas such as data science, synthetic biology, quantum biology, among others and which is future-ready to adopt emerging technologies.
- e) Update the biotechnology curriculum with special emphasis on interdisciplinary areas, IPR and regulatory aspects and periodic assessment of different training programs to keep pace with contemporary developments and to enable seamless movement from one level to the next.
- f) Build future leaders in the field through post-doctoral programmes that include industry exposure and partnerships.

- g) New Partnership Centers for Research (PaCeR) to be established for augmenting and strengthening institutional research capacity in specific areas of life sciences/biotechnology to boost top-quality research with special emphasis on harnessing benefits from across disciplines of physical sciences, engineering and medical sciences to evolve robust interdisciplinary research programs.
- h) Promote shared infrastructure by creating centres which act as a nucleus to connect universities, institutions and colleges.

Instruments of Implementation

- Programmes on Skill Vigyan for Life Sciences and Biotechnology in partnership with State Science/Biotechnology Councils to be expanded to all States and UT's across the country
- Create UDAAN Centers for Future Technologies to train and nurture young researchers in futuristic technologies as our Next generation Leader
- Model course curriculum to be developed with a focus on learning outcomes to match with regional, societal and national needs.
- DBT BRITE Awards and Fellowships as Young Researcher Fellowship Programmes to offer an independent research grant to young Post-Doctoral Fellows to enable them to emerge as future leaders and take up cutting edge research in areas of Biotechnology and allied areas.
- Expansion of Star College Programme to Tier-II and Tier-III cities.
- Initiate SPARK in collaboration with relevant agencies on the line of BEST (Biotechnology Entrepreneurship Student Teams) programme to foster the entrepreneurial spirit in the UG students from DBT-Star Colleges.
- Initiate a Biotech IMPRINT programme along with the Ministry of Education (MoE) to build research capacities in universities and research institutes.
- Ensure access to the state of art research facilities, research platforms and equipments for researchers across the country through a nearly ten-fold expansion of the DBT SAHAJ programme.
- Set up Partnership Centers for Research (PaCeR) for capacity building and reaching Tier II and Tier III cities . This will be for key interdisciplinary areas of new cutting edge technologies
- Development of innovative service models to offer services out of existing facilities at competitive market rates.
- Set up strategically required Infrastructure for meeting cutting edge research needs for indigenous product developed

(2) UNATI Biotech Missions – aligned with national and global priorities

Biotech Missions have been launched to align with the national and global priorities and give a fillip to the National Development Plans and Sustainable Development Goals. Biotech missions thus ensure that the efforts made in the field of biotechnology converge with other socio-economic efforts being made towards the end goal of achieving sustainable development.

Atal Jai Anusandhan Biotech (UNaTI) Mission

Undertaking Nationally Relevant Technology Innovation

GARBH-INi - A Mission to promote
Maternal and Child Health, and develop
prediction tools for pre-term berth



IndCEPI - A Mission to develop affordable
vaccines for endemic diseases

Development of Biofortified and Protein Rich
wheat - contributing to POSHAN
Abhiyan



Mission on Anti Microbial
Resistance for Affordable Diagnostics and
Therapeutics

Clean Energy Mission - Innovative
Technology interventions for Swachh Bharat



Special Atal Jai Anusandhan Biotech (UNaTI) Missions have been launched on significant national and global challenges of Maternal and Child Health, AMR, Vaccines for infectious disease, Food and Nutrition, Clean Technologies. In future, mechanisms will be put in place to-

a) Identify national priorities which stand to benefit from a focused biotechnology mission such as-

- Mitigation of climate change with a special focus on controlling methane emission from ruminants, solutions for controlling emerging pollutants like microplastics, antibiotics, pesticides in soil and water, recycling of wastewater, rejuvenation of wetlands and restoration of degraded land, unlocking the rich biodiversity of India's 12,000 km long coastline, explorations of cold desert/extremophilic microbial biodiversity.
- Climate-resilient crops towards the second green revolution, nutrient-rich crops with greater bioavailability, developing affordable technologies for cattle semen sexing and sorting, strategies for milk yield improvement.
- Addressing food security, balanced nutrition to tackle various deficiencies, concerted public health nutrition research to develop evidence-based solutions and scale-up of leads in

consonance with the regulatory framework of FSSAI, enhance food availability by decreasing wastage, develop functional foods to tackle the epidemic of lifestyle disorders.

- Novel platform technologies for thermo-stable vaccines, biologicals and biosimilars to increase affordability, formulation/targeted-delivery of monoclonal antibodies/therapeutic proteins/natural products, introduce mechanisms to bridge the gaps in progression of NCEs/ Phytopharma /New Biologicals.
- Establish National Phytochemical Repositories preferably in collaboration with industrial participation to serve as “National reference standards” for Indian Pharmacopoeia and Ayurvedic Pharmacopoeia of India, translational programme on medicinal aromatic plants and aquatic resources.

- b) Expand current missions to achieve SDGs and NDPs by working closely with line ministries/departments/ agencies (such as BMGF, Wellcome Trust etc.) with focus on deliverables.
- c) Introducing new technologies/ products to ensure the success of existing missions.
- d) Special emphasis on integrated Missions addressing national and global priorities in Health, Agriculture, Clean Energy & Environment, HRD and entrepreneurship.
- e) Engage all stakeholders and forge partnerships of young researchers, women scientists, start-ups, entrepreneurs and industries in these Missions.
- f) Directed funding towards new areas of biology (glycobiology, lipid-biology and epigenetics) and blue-sky research linked to SDGs and NDPs.

Instruments of Implementation

- New Mission Programmes on improved crop varieties through Marker-Assisted Selection for Climate resilience, Disease resistance and Nutritional enhancement.
- Mission Programme on Improved Crop Varieties through Gene Editing.
- Cattle Genomics initiative.
- One Health Mission on AMR for livestock and zoonotic Diseases
- Mission on Management & Treatment of Rare & Genetic Disorders; Establishment of NIDAN Kendras under UMMID program covering all Aspirational districts.
- Mission on Precision Healthcare.
- National Nutrition Mission under the National Technical Board on Nutrition.
- Phytopharma Mission for development of phytopharmaceutical drugs as innovative future affordable drugs.
- Mission on the scaling of indigenous cellulolytic enzymes for 2G Ethanol and development of technologies for next-generation clean fuels including Bio-Butanol, Bio-Hydrogen and

Bio-Jetfuel.

- Mission on Waste to Value Technologies: Operationalise technology platforms designed to convert different solid, liquid and gaseous wastes into renewable fuels, energy and useful products like food, feed and polymers & chemicals.

(3) Building a Self-reliant India (Atmanirbhar Bharat) through Biotech Interventions – Affordable and accessible products and technologies

The development and deployment of indigenous technologies/solutions in the field of biotechnology will go a long way in achieving Atmanirbharata. The indigenous technologies/solutions should be cost-effective and meet global standards of quality. In keeping with the Hon'ble Prime Minister's vision of marching towards 'Atmanirbhar Bharat', in a short span of two months 100% indigenisation was achieved with respect to the production of COVID-19 diagnostic kits through efforts in the field of biotechnology during the recent COVID-19 pandemic. National Biomedical Resource Indigenisation Consortium (NBRIC), a PPP (Public-Private Partnership) initiative of DBT in partnership with Association of Biotechnology Led Enterprises (ABLE) and Confederation of Indian Industry (CII) was also set up to foster indigenous innovation and bio-manufacturing with a focus on developing reagents, diagnostics and therapeutics for COVID-19. Indian start-up ecosystem offers the unique ability to develop frugal innovative products and platform technologies that are globally competitive to address unmet needs. Knowledge translation through the integration of universities, research institutions and industry along with critical enabling support is the need of the hour. India can emerge as a major bio-manufacturing hub and a key player in the global supply chain by promoting indigenous production of socially relevant interventions. During the inaugural address of 'Indian Science Congress 2020', the Hon'ble Prime Minister announced India to become a world-class USD100 billion bio-manufacturing hub. Currently, the Indian market in Biotechnology is less than 5% of the global market. In the next 5 years, we hope to achieve USD150 billion bio-economy against world estimate of USD725 billion by 2025, which will be about 21 % of the global market share. To further the goal of Atmanirbhar Bharat through biotechnology interventions, the following will be the key focus areas:

A. Moving Technology from Lab to Market

- a) Enabling support to Start-ups to propel their technology from proof of concept to manufacturing, prioritisation and indigenisation of technologies, self-reliance in consumables, equipments, reagents, instruments etc. for R&D.
- b) Two-pronged approach of import substitution of key reagents/ products/ instruments while increasing the export of Made in India biotechnology goods and services

- c) Clustering approach with flexible governance models with enhanced private sector investment and promoting co-location and co-development of market-driven interventions within academic laboratories through industry-academia partnerships.
- d) Setting-up of Translational centers and Technology Transfer offices (TTOs) to strengthen India's IPR landscape.
- e) Strengthen biotech-driven microenterprises in Tier-II and Tier-III cities.

Instruments of Implementation

- Setting-up of Translational Center in Academia/Industry under Joint Partnership
- Setting-up of Bio-manufacturing hubs and National Biotech resource Indigenous Consortium (NBRIC) to provide thrust to indigenous manufacturing.
- Cataloguing indigenous manufacturing capacities along with analytical specifications and regulatory approvals for adding credibility to Made In India biotech products.
- Expansion of innovators and entrepreneurs query resolution forums like FIRST HUB in multiple regions.
- Partnership with state universities for establishing microenterprises in Tier-II & Tier-III cities.
- Technology Transfer Offices (TTO) to be set up in research institutes and universities.
- Rs. 250 crore biotech AcE fund and a manufacturing fund of Rs. 1,000 crore to be launched.
- 50 technology management centres, 25 Bioconnect offices and 10 regional centres of BIRAC to be set up.
- Private sector participation and involvement of state government departments for new biotech parks.

B. Scaling the Innovation Ecosystem

In 2012, the DBT had established a public sector undertaking Biotechnology Industry Research Assistance Council (BIRAC) to catalyse innovative research, development, and Entrepreneurship in the biotechnology sector. In a short span of eight years, BIRAC has nurtured over 1,102 entrepreneurs, start-ups and SMEs, 10,000 manpower for high-end skills, created 150 industry partnerships, invested Rs. 3529.87 Crores in R&D (BIRAC contribution of Rs. 2149.45 Crores plus industry contribution of Rs. 1380.42 Crores) and created 5,68,719 sqft of incubation space through support to 52 bio-incubators and 4 Regional Entrepreneurship Development Centres. These activities resulted in the filing of 268 patent applications and development of more than 150 products/ technologies.

Connecting Start-up India with Make In India: Access to facilities for designing, fabrication and validation of proof of concept, and further scaling is the missing link between Start-up India and Make in India.

Technology clusters harbouring Technology Propellers (**T-Propellers**) and Manufacturing Zones (**M-Zones**) need to be set up to facilitate single product start-up to move to integrated enterprises. Such initiatives would benefit the growing number of biotech start-ups (10,000+ by 2024) especially engaged in projects aimed towards import substitution, cutting edge, mass impact, market deployment, export-oriented and disruptive technologies to integrate and add value to the national priorities of Make In India.

- **T-Propellers** to serve several incubators and pool of start-ups to take their research leads from proof of concept stage to pilot facility. This will address the large gap in the ecosystem by providing design improvisation, material selection, process standardisation, validation for manufacturing, regulatory compliances, licenses etc. to facilitate market deployment.
- **M-Zones** for the successful scaling of technology-based start-ups to “Manufacturing Stage” by providing affordable access to new and existing manufacturing facilities which include raw material clustering, hardware & software vendors, distribution network, marketing and design labs, advertisement industry, industry associations, professional societies, investors, centre, state agencies, investments pooling from VCs advanced modelling & simulation tools for design and process improvement.
- Develop a central mechanism for the intake of exciting new lead candidates from research institutes and facilitate the development of products in mission mode as part of a national effort and not just as a PI/institution-driven activity.

	Current Status	2020	2022	2024
Bio Economy (US\$)	51 billion	60 billion	100 billion	150 billion
Startups	2000	2500	5000	10000
Bio Incubators	45	50	100	200
URJIT Biotech Translational Clusters	4	5	7	10
Technology Propellers	-	1	4	5
Bio Manufacturing Zones	-	1	3	5

World-class, US\$100 billion Bio-manufacturing hub by 2024

Instruments of Implementation

- Establish 'Innovation Accelerators' and 'Translational Accelerators' accessible to public-institutions and SMEs to successfully incubate discoveries.

- Work through BIRAC for nurturing entrepreneurship, technology acquisition and commercialisation.
- 10 Strategically located Technology Clusters to be established
- 5 Bio-manufacturing Zones to be established in the vicinity of SEZs.
- 10 Biotech URJIT Clusters to be set up for connecting universities, research institutes, industries and start-ups and to undertake industry-inspired projects.
- Biodesign Centers in NITs/IITs/IIITs etc. to be explored for developing products for identified clinical needs/ agri-field requirements.
- Biotech Angel Network for catalysing early-stage Investments in 150 start-ups in next three years through Angels, Family offices, HNIs, early-stage VCs.
- Setting up of 250 e-YUVA centre networks in the country for undergraduates to create a culture of Biotech entrepreneurship.

(4) Leveraging the Strength of Strategic Partnerships – National and International

Joining hands and pursuing complementary targeted research with the best talent available nationally and internationally will leapfrog the Indian research community to the next level of innovation. Strength of leveraging partnerships also lies in the fact that multidisciplinary networks of biologists, chemists, physicists, computational biologists and others can address most pressing scientific challenges in a comprehensive manner and in a much shorter time. This is also when India is transitioning from technology receivers to co-developers of technology. In light of these recent developments, it becomes imperative that partnerships are strategically driven where India has a greater say in deciding areas of co-operation and creating market access for indigenous products/technologies has to be kept central in future discussions. India's contribution to LMICS, Africa, PACT clinical trial framework for neighbouring countries should also form the backdrop for deciding future partnerships. Areas such as agriculture biotechnology, which have traditionally been our strength but have not been adequately represented in international partnerships, should find greater representation in the future.

- a) Collaborations with multilateral forums like SAARC, BRICS, G-20, G-6 and professional organizations e.g. National Center for Biotechnology Information (NCBI), European Molecular Biology Laboratory (EMBL), DNA Data Bank of Japan (DDBJ) to highlight strengths of the Indian biotech sector on global platforms.
- b) Build upon existing global partnerships with Government/Non-Govt/Philanthropic organisations and develop new models of multilateral alliances.
- c) Global public-private partnerships to be forged by connecting Indian start-ups to the global ecosystem and setting-up of test bed facilities for start-ups.

- d) Strategic partnerships for building quality human resource and a strong technology and knowledge base – IndCEPi, VAP, Mission Innovation, HFSPO, EMBO, EMBL, ICDA, ICGC, Global AMR, HCA.
- e) Expand the scope of R&D and entrepreneurship development with the collaborating partners and initiate mission mode projects in bioinformatics, functional genomics/ Encyclopedia of DNA Elements (ENCODE), AI and Big Data, Bio-resources to put India on the world map.
- f) Strengthening partnership with States for strengthening the biotech sector in India.
- g) Collaboration with other government ministries & departments.

Instruments of Implementation

- Partnerships with EMBL, Max-Planck and similar professional organisations.
- Launch major international projects in bioinformatics/Genomics/AI etc. wherein India can become a leader through strategically identified Bilateral and Multilateral cooperation
- Set up international incubators in areas such as Agriculture, AMR, Clean Energy.
- Establish cooperation with Low and Middle-Income Countries (LMICs) and emerging economies of Asia, Africa and Latin America.
- New biotech parks with the active participation of the state governments.
- Attract and retain the highly qualified scientists in the country through ongoing Ramalingaswami Re-entry Fellowship and other such specialized schemes.
- Working and engaging with the Global Indian Diaspora to take their full potential

(5) Preparing for the Future – Building the knowledge base

To stay ahead of the curve, it is crucial to build HR capacity, set up necessary infrastructure and put in the adequate investment to prepare for future technologies. These new and emerging technologies have an immense potential for transformative change in Healthcare, Agriculture and Environment. Also, since most of these technologies are nascent, it provides a unique opportunity to position India as a global leader in these technologies.

- a) Greater and focused funding towards new and emerging areas of biology and cutting edge blue-sky basic research in the prioritized areas - Precision Medicine, CAR-T technology, Gene editing and therapy, CRISPR- CAS biology, Synthetic Biology, Lipid biology, Glycobiology, Epigenetics, Secondary plant metabolites, Marine biology, Natural products and medicinal chemistry etc.
- b) Artificial Intelligence and machine learning in Precision Health.
- c) Snake envenomation & novel monoclonal antibodies which are cost effective & globally accessible.
- d) Integrating stem cell technology and embryo manipulation technologies with genome editing to develop xeno transplantation models and chimeric animals for tissue/organ transplant models.]

- e) Application of nanotechnology for regenerative medicine and enhancement of new generation of technologies like photonic/thermal/cryo interventions in medical practice.
- f) To initiate a major network programme on CRISPR/Cas mutagenesis with identified traits in some of the selected crops.
- g) To promote research on aerobic cultivation of rice, low till cultivation of wheat, rice and resistance to terminal heat stress in wheat as well as disease resistance in rice and wheat.
- h) Development of technologies for cattle semen sexing and sorting.
- i) Development of integrated technologies for 'Bioeconomy' through the bio-refinery concept.
- j) Sequestration of effluent gases into various platform chemicals.

Instruments of Implementation

- Establishment of Centres of Excellence centred on New Emerging technologies (CONEs) like Gene Editing, Gene Therapy, Regenerative Medicine, CAR-T Cell Therapy, Big-data Analysis, Data Analysis, Adjuvants, Data Science and Artificial Intelligence (AI), Speed breeding platforms & Precision Agriculture etc.
- Network proposals with well-defined goals in priority areas.

6. Taking Science to Society – Empowering the Rural Sector

Under the overarching umbrella of Scientific Social Responsibility, scientific solutions need to percolate down to the grass-root level to have a wider societal impact and ensure Ease of Living of the citizens. This will bring biotechnology closer to fulfilling societal needs and in the same vein society will also be brought closer to fruits of biotechnology which in the long run will contribute to building the public confidence in scientific solutions. Creating employment opportunities through biotech led micro-enterprises, wealth creation, and ensuring local resources' sustainability are some of the myriad ways biotechnology can interface with society.

- a) Establish biotech innovation hubs for societal development, including in the Aspirational Districts.
- b) Promote rural bio-entrepreneurship and upscaling of grass-root innovations through the demonstration of viable and ecologically compatible technologies to the target group for adoption in a holistic and sustainable manner.
- c) Promote scientist-farmer partnership for agriculture innovation through participatory research to connect science laboratories with the farmers to find innovative solutions and technologies to be developed and applied at the farm level.
- d) Promote frugal innovation and awareness of natural resources.

Instruments of Implementation

- Establish Biotech-Krishi Innovation Science Application Network (Biotech-KISAN) Hubs in all aspirational districts and 15 agro-climatic regions across India.
- Setting up Rural Bioresource Complexes/Rural Technology Clusters in Aspirational districts for social enterprises.
- DNA Clubs (DBT's Natural Resource Awareness clubs) at school level for 6th-10th standard in all Aspirational districts.
- Wider outreach of hands-on training in frugal science programmes for teacher and student training.

7. Effective Outreach and Communication– Building the Public Trust

With data becoming central to the decision-making process, there is a need to move towards data-driven communication to build public confidence in biotechnology solutions. Communication needs to be effective and should reach end users/beneficiaries of biotechnology interventions/solutions at the grass-root level. This can significantly increase acceptance and also create channels to assess ground level requirements. Effective communication strategies are also crucial from the standpoint of projecting the growth and success of the Indian biotechnology sector to a global audience. This, in turn, could attract investment in the Indian biotechnology sector from various quarters. Moving ahead the following need to be prioritised:

- a) Emphasis on data-driven communication and advocacy.
- b) Deeper engagement with stakeholders through multiple channels.
- c) Focus on a bottom-up approach to feel the pulse of society.
- d) Combining data and evidence from various quarters for decision making.

Instruments of Implementation

- Setting up a Communication unit at the interface of DBT and stakeholders.
- Promotion of public communication through print, digital and social media.
- Global Bio-India events for projecting strength of Indian biotechnology sector to a global audience.
- India International Science Festival for the scientific community and other stakeholders.
- Organisation of outreach programmes such as Nobel Prize Series.
- Centres for analysing and enabling the interaction of Biotechnology with social and economic thought and developmental studies.

- Establish Science Policy Coordination, Collaboration, and Reporting section.

8. Global Benchmarking and Performance Measurement – A Measurement matrix to build quality

An exercise to measure biotechnology and benchmark activities through an internationally acceptable statistical framework needs to be initiated. This is important from the perspective of measuring the impact of activities of DBT and its autonomous institutions and how it fares in comparison to global efforts.

- Global Benchmarking to be done in the context of the size of the sector, available resources, societal impact and other discernible indicators.
- Develop a portal to provide information on scientific achievements and authentic knowledge about biotechnology in technology licensing, IPR and regulatory issues. This should also be a source of information for policymakers.
- Setting up a Data Monitoring unit.
- Develop strong impact assessment capabilities, including data-based and objective assessment of social and economic impact, for both basic and applied research.

Instruments of Implementation

- Internationally acceptable statistical framework to be set up for measuring the bioeconomy.
- Engaging with professionals/third parties for periodic assessment of performance metrics.
- Periodic socio-economic impact assessment of schemes/ programs of DBT.

9. Policy Enablers

With the motto of minimum government maximum governance, policies and regulations need to be streamlined in response to stakeholder requirements and evolving policy environment. Significant efforts have gone into creating a facilitative regulatory environment, establishing a vibrant research and entrepreneurship ecosystem and professionalization of research funding mechanisms. During the current COVID-19 pandemic, Rapid Response Regulatory Framework for expedited regulatory approvals for all diagnostics drugs and vaccines was put into place. Guidelines for sharing bio-specimens and data for research related to COVID-19 were also developed to ensure that there were no impediments to scientific research. Future efforts in this direction will be as follows-

- a) Develop an 'Ease of Doing Science Index' to ensure effective use of both disbursed funds (including flexibility of fund utilisation) and the researchers' time.
- b) Develop regulatory guidelines for plants, microbes, insects, poultry, livestock, gene editing and other cutting edge technologies.
- c) Define policy on sharing biological data specifically pertaining to modern high-throughput, high-volume data, such as data generated by nucleic acid sequencing and microarrays, bio-molecular structures and flow cytometry and set up the first indigenous biological data centre.
- d) Developing a "Network of infrastructure under Biosecurity and Biosafety" across the country to strengthen the nation on biosecurity and biosafety front and for preparing the country for future epidemic/pandemic.
- e) To have a molecular surveillance system with advanced diagnostic facilities and customary network facilities to tackle pathogens affecting humans, livestock, animals.
- f) Continuously improve the Indian biotechnology industry's ability to compete globally, by interventions at the level of policy and support.
- g) Develop policies and frameworks for the utilisation of Biotechnology-based products that have a social but not necessarily market-based value in key areas.
- h) To establish a dedicated unit for framing policies on health genomics that addresses issues related to Ethical, Legal, and Social Implications (ELSI).
- i) To streamline the policy and regulatory framework for genome edited products, particularly those generated through SDN1 and SDN2, which are considered to be almost equivalent to those generated through conventional breeding.
- j) Guidelines for addressing ethics and regulations for AI in healthcare
- k) Technology Transfer and Innovation Policy to serve as a central resource on matters involving technology transfer and innovation.
- l) Policy to promote and strengthen Biomanufacturing ecosystem.
- m) Policy on the ethics and usage of Synthetic Biology and Emerging Technologies.
- n) Frugal Innovation policy through engagement with state governments & state science & technology councils.

Instruments of Implementation

- Formulation of Biological Data Storage, Access and Sharing Policy of India and setting up the Indian Biological Data Centre- PRIDE policy.
- Formulation of Regulatory Guidelines for Gene Editing.
- Indian Bio-safety Knowledge Portal (IBKP): For ease of doing business.
- Harmonisation of Regulatory guidelines such as Updation of Risk Group, Formulation of stacked event guidelines, Environmental Risk Assessment (ERA) of Genetically Engineered Microorganism, Updation of recombinant DNA guidelines.

- DNA Technology (Use and Application) Regulation Bill.
- Setting up a Policy Unit /Think Tank , an forecasting and developing policy white paper on new and emerging areas and strategic priority areas.