सत्यमेव जयते
Government of India

Achievements of
Department of Biotechnology
Ministry of Science and Technology
Government of India

From May 2014 to October 2023

Contents

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Government of India from May, 2014 to August, 2023

Biotechnology, recognized as a sunrise sector, is one of the key enablers for driving bio-economy of the country. India's bio-economy has grown from $35.5 billion in 2014 to >$95 billion in 2022. India is ranked 12th in the world in biotech; 3rd in Asia-pacific; 3rd largest Startups ecosystem globally; and the largest vaccine manufacturer.

The Department of Biotechnology (DBT), Government of India is at the forefront of promoting biotechnological innovation missions and entrepreneurship leveraging the strength of strategic partnerships and building capacities across the country. Through strong foresight and vision, efforts have been made by DBT to create and nurture a vibrant biotech research and innovation ecosystem across the country in alignment with national missions of our Government such as *AatmaNirbhar Bharat, Swasth Bharat, Swachh Bharat, Startup India* and *Make-in-India.*

DBT has emphasis on promotion of excellence and innovation driven discovery research in biotechnology and modern biology. The focus is also on promoting public-private partnership, nurturing innovation & entrepreneurship**,** bio-incubators, building capacity in cutting edge areas of research, scaling-up of existing infrastructure, creating right kind of new infrastructure, establishing national and international partnerships.

Achievements of DBT during last 9 years (May 2014-August 2023) have been summarized below:

I. Sectoral Achievements:

A. Healthcare:

i. *Vaccines for 'Swasth Bharat':*

➢ **Quadrivalent Human Papilloma Virus vaccine against cervical cancer:**

- India's 1st indigenously developed quadrivalent Human Papilloma Virus (qHPV) vaccine, CERVAVAC, against cervical cancer, supported by DBT and BIRAC received market authorization in July, 2022.
- DBT and BIRAC supported the development of this vaccine through the pioneering partnership programme ***'Grand Challenges India'***. The qHPV vaccine is effective against HPV serotypes 6, 11, 16, and 18. HPV serotypes 16 and 18 together contribute to approximately 70% of all invasive cervical cancer cases worldwide.
- The scientific completion of the qHPV vaccine was announced by Hon'ble Minister of S&T in September, 2022

➢ **World's 1st and India's indigenously Developed COVID-19 DNA vaccine**

- This was supported by DBT-BIRAC under Mission COVID Suraksha, received Emergency Use Authorization (EUA) for use in 12 years and above. This vaccine also received EUA as a heterologous booster (3mg single dose) in April, 2023.

- **India's 1st Intranasal Vaccine for COVID-19**
  - This has received EUA for use in primary series (18 years & above) and for use as homologous &heterologous booster, in November, 2022.
- **India's 1st Omicron Booster Vaccine**
  - This vaccine based on mRNA Platform, has been developed under Mission COVID Suraksha, and received EUA in June, 2023. Hon'ble Minister of State (IC) for S&T launched this vaccine in June, 2023. This vaccine is stable at 2-8^0 C and is delivered intra-dermally using a needle-free injection device system.
- **Market Authorisation for Pneumococcal Pneumonia Vaccine**
  - **DBT-BIRAC supported 15-valent Pneumococcal Polysaccharide conjugate vaccine** received market authorisation for manufacturing in December, 2022. The vaccine is administered in a 3 dose schedule in the paediatric age group of 6, 10 and 14 weeks.
- **Vaccines for Dengue, Influenza and Chikungunya**
  - **Inactivated vaccine for chikungunya** is undergoing Phase II/III clinical trials.
  - **Live attenuated tetravalent Dengue Vaccine** developed based on in-licensed technology from National Institute of Health, USA, is undergoing Phase I clinical trials.
  - **Recombinant tetravalent protein subunit vaccine for Influenza** is in advanced preclinical development and Phase I Clinical trial is expected soon.
- **Phased Implementation of ROTAVAC® Vaccine in Various States**:

  First indigenously developed rotaviral diarrhoea vaccine, ROTAVAC®, with the support from DBT in a public-private partnership was launched by our Hon'ble PM in March, 2015. This vaccine also received World Health Organization (WHO) Pre-qualification in 2018. Details of introduction of this vaccine are:

  - Phase-I, 2016: 4 States-Haryana, Himachal Pradesh, Andhra Pradesh and Odisha
  - Phase-II, 2017: 5 States-Assam, Madhya Pradesh, Rajasthan, Tamil Nadu and Tripura
  - Phase-III, 2018: 2 States- Jharkhand and Uttar Pradesh
  - Phase-IV, 2019: 25- Rest of the States/UTs

ii. Medical Biotechnology:

- **Data Driven Research to Eradicate TB – *"Dare2eraD TB"***
- DBT launched **Data Driven Research to Eradicate TB - *Dare2eraD TB*** as an umbrella program on TB with the following key initiatives:
  - Setting up the Indian TB Genomic Surveillance Consortium;
  - Hosting the Indian TB Knowledge Hub Webinar Series;

- Development of host directed therapies against TB and developing treatment regimens for extra-pulmonary Tuberculosis.

➢ **Pan India Genome India project:** A total 14,529 study participants have been enrolled so far and their phenotyping, blood biochemistry assessed. Whole genome sequencing of 6,425 individuals have been completed and analysis after sequence variant calling is under process.

➢ **Unique Methods of Management of Inherited Disorders (UMMID) Initiative:**

- During pilot phase, 5 NIDAN Kendras, 7 outreach centres and 6 training centres have been successfully established. So far, screening has been provided to 75064 pregnant women and 41575 new born babies, of which 71% of the pregnant women and 83% of the newborn babies belong to 9 Aspirational Districts.
- This is currently under pan India expansion, and will cover approximately 23 States/UTs through establishment of around 71 UMMID components (33 NIDAN Kendras, 28 Outreach, and 10 Training).

➢ **Indian TB Genomic Consortium:** This is a joint initiative of MoS&T and MoH&FW led by the DBT, aimed at performing Whole Genome Sequencing of 32,500 TB strains and applying AI based methods for prediction of drug resistance, strain lineage, etc. This is aligned with **'TB Mukt Bharat'** initiative of Govt. of India.

➢ **National Biopharma Mission:** Under this Mission, Vaccine candidates (15) for Cholera, Influenza, Dengue, Chikungunya, Pneumococcal disease, COVID-19 (early development) and related technologies (4); Biosimilar products and related technologies (21) for Diabetes, Rheumatological and ophthalmic diseases, Cancer; Medical Devices & Diagnostics (29) have been supported so far.

➢ **Control Programme for Sickle Cell Anemia and Thalassemia:** DBT has implemented this program in 6 districts (Balasore, Bargarh, Cuttack, Jharsuguda, Koraput, Sambalpur) of Odisha, including an Aspirational District –Koraput. Several training workshops were conducted at different levels (State / Regional levels) for doctors/other healthcare workers to train them on different aspects of management and prevention of sickle cell disease and thalassemia in the State. The program is being extended further in other Districts of this State.

➢ DALI, a package containing screening tools for school teachers and assessment tools for psychologists in Indian languages to identify dyslexia was developed by National Brain Research Centre, Manesar.

➢ Indigenous technology has been developed on iron, vitamin B_{12}, folate fortified rice premix from broken rice kernels for addressal of anemia in women and children

➢ Biodesign program, twinning of engineering and medical skills for unmet clinical needs has ignited the nascent med-tech ecosystem in the country through 4 different centers across the country partnering clinical, research and technical institutions. So far, 200 fellows have been trained, 50 med-tech start-ups formed 20 products have been commercially launched, over 5 million screenings completed using these devices and over 30 Cr industry investment received.

- **International Cancer Genome Consortium:** India is one of the 7 founding members of ICGC. Now, 40 countries are participating in this consortium. ICGC-India Project has established a dedicated bio-repository with best international practices at ACTREC, Mumbai and State-of-the-art high throughput Genome sequencing center at NIBMG, Kalyani. Novel genomic signatures and immune profile were identified in tobacco chewing-associated oral cancers prevalent in India and these leads are being used by Indian researchers to improve diagnosis and drug development.

iii. Therapeutic Interventions:

- **First gene therapy clinical trial in India for Hemophilia A**

- The first gene therapy clinical trial for Hemophilia A in India has been approved by the Central Drugs Standard Control Organisation (CDSCO).
- The lenti viral vector for this clinical trial for manufacturing the final drug product with the patient's hematopoietic stem cells (HSCs) at the GMP facility supported by DBT at Centre for Stem Cell Research (CSCR) in CMC, Vellore, a translational unit of inStem, an autonomous institute of DBT in Bangalore.

- **Development of novel blood bag:**
  A study group at inStem, an autonomous institute of DBT at Bangalore developed taurine and acridine containing electrospun-nanofibrous-sheets (Tau-AcrNFS) and showed that Tau-AcrNFS are efficient in scavenging DAMPs from stored human and mice RBCs *ex vivo*. Such prophylactic technology may lead to the development of novel blood bags or medical device, and may therefore impact healthcare by reducing transfusion-related adverse effects.

B. Agriculture Biotechnology, Animal Biotechnology, Aquaculture and Marine Biology:

- Transfer of technologies to companies has been facilitated for mustard and cotton. White rust resistance varieties Varuna, Pusa bold, Pusa Jai Kisan and Rohini were transferred to eight seed companies. Two transgenic events of Cotton (Tg2E-13 and TM2) containing Cry1Ac gene are being transferred through BIRAC;
- **Rice pan-genome genotyping array** (RPGA), a 90K SNP genotyping array based on 3K rice pan-genome had been developed for genomics-assisted breeding and accelerated crop improvement. Contrary to conventional SNP genotyping arrays that relies on single reference genome RPGA assays variants from entire 3K rice pan-genome. This enables RPGA to tag haplotype variation present in entire pan-genome, which include both core (genes shared by all accessions) as well as dispensable (subpopulation/cultivar specific genes) genome. The usefulness of RPGA for large-scale pan-genome based genotyping applications was demonstrated by their high-throughput genotyping in the natural germplasm accessions and RIL mapping population of rice.

- Improved varieties of food crops and ornamental plants released include:

Crop	Varieties (Prior to 2014)		Varieties (2014-2023)	
Maize	-	-	7	Pusa Vivek QPM9 Improved, Pusa HM4 Improved, Pusa HM8 Improved, Pusa HM9 Improved, Pusa Vivek Hybrid-27, Improved, Pusa HQPM-5 Improved, Pusa HQPM-7 Improved
Rice	5	Paustic 9 (HPR 741), CARI Dhan 6, CARI Dhan 7, Swarna- sub 1, Samba-Mahsuri- sub 1	32	Pusa Basmati 1728, Pusa Basmati 1718, PR128, PR129, IR64– sub 1, Ranjit-Sub1, Bahadur-Sub1, CR_Dhan 802, CG Tejaswi Dhan, CO 43 Sub1, ADT 55, CR Dhan 803 (Pooja-Sub1), CR_Dhan 804, MushkBudji –improved, DRR Dhan 45, CGZR-1, CGZR-2, DRR Dhan -50, Pusa Basmati 1979, Pusa Basmati 1985, CG Barani Dhan-2, Improved White Ponni" namely IWP-Saltol, PUSA Basmati 1789, ADT 46-Sub-1, MTU-1293, MTU 1232, HUR 105-Sub-1, KR16024, TTB Dhan 40 (Dholi), KKL(R2), TTB Dhan 42 (Patkai), KKL (R3)
Wheat	1	HI 8737 - Pusa Anmol	3	Unnat PBW343, PBW771, HI 8759 - Pusa Tejas
Soybean	-	-	1	NRC127
Tomato	2	Arka Vikas & Pusa Ruby	-	-
Chickpea	-	-	3	IPCL4 -14, BG 4005, IPCMB 19-3
Rose	-	-	1	Pusa Mahak
Okra	-	-	1	Punjab Padmini
Bittergourd	-	-	1	Punjab-14 cultivar
Mungbean	-	-	1	HUM 27
Eucalyptus	-	-	1	IFGTB-EH01 and IFGTB-EH-02)
Pea	-	-	1	HUM Palam Matar-2
Groundnut	-	-	2	DBG 3 (improved JL 24) and DBG 4 (Super TMV 2)

- DBT-NGGF **"National Genotyping and Genomics Facility" (NGGF)** a "single-window service system" for advanced genomics technology services was established and has become operational under PPP mode. This facility will offer affordable and competitive genotyping and genomics services to Public and Private Institutions. Major clientele would be Researchers and Scientists from ICAR Institutions (52), SAUs and CAUs (54), Central Universities (39), DBT and CSIR Institutions (10) involved in plant genotyping and/or genomics research. Crop breeding companies and seed companies (205) involved in regular breeding process and activities will be a source of revenue for this facility.
- **Genomic selection and Speed Breeding Facility** was supported under a Network project at IRRI, Varanasi. This is first of its kind facility in India to facilitate faster genetic gains through speed breeding for generation advancement. Speed breeding facility is targeted to undertake haplotype-based backcross breeding to transfer the superior haplotypes from landraces into elite backgrounds, and training and capacity development of 40 young plant breeders from India on breeding innovations.
- An energy efficient, innovative and cheap device has been developed which can address the problem of postharvest losses in India. A Start-up Fruvetech Pvt. Ltd has been registered (CIN: U72900DL2021PTC376517) for commercialization of this technology.
- Under the program, Genome assembly in sesame, linseed, safflower two accessions of wheat and re-sequencing of 58 landraces accomplished. In sesame (2500 accessions), linseed (1200 accessions), safflower (3500 accessions), rice (4224 accessions), wheat (4000 accessions), chickpea (2400 accessions) and pulses (3091 accessions) have been genotyped. Phenotyping of sesame (6500 accessions), linseed (2612 accessions), niger (3524 accessions), safflower (6983 accessions), rice (12116 accessions), wheat (7020 accessions), chickpea (5000 accessions) and pulses (8870 accessions) have led to identification of accessions with superior agro-morphological traits as well as resistance to biotic and abiotic stress.
- **Biotech-KISAN Hubs:** DBT connected the science with the farmers and established Biotech-KISAN Hubs at pilot-scale level in all 15 agro-climatic zones. The programme has now been scaled up and expanded its activities covering 112 Aspirational Districts in the country. In addition, 15 Biotech KISAN Hubs have been setup in the NER to cover 40 backward blocks and villages of the region. The programme leads to link the farmers with the latest scientific innovations with a view to enhance agricultural production and increasing farmers' income. The programme has introduced 55 interventions for the benefit of farming community and more than 300000 farmers have been benefitted during the year through 500+ Farmers' training programmes organized by these hubs. Nearly 200 agri-enterpenurships have been developed in rural areas under the programme
- A novel delta S19 Brucella vaccine has been developed and the technology was transferred to M/s Hester Biosciences Pvt. Ltd.
- A point-of-care aptamer based lateral flow detection system was developed for detection of oxytetracycline in milk. Field trials for detection of oxytetracycline in milk of cow are ongoing.

- Towards developing improved diagnostic assays for brucellosis, an indirect ELISA using the purified BM5 protein of Brucella was developed for detection of brucellosis with DIVA capability. This kit will have the ability to differentiate between the immunity generated by vaccine and the one generated by natural infection. This kit is in the process of field validation.

- A nanoparticle based field applicable kit for detection of subclinical mastitis in farm animals was developed. It is based on the aggregation of nanoparticles in the milk infected with pathogen responsible for mastitis. It will help in screening of animals for mastitis to start timely treatment of animals.

- Live feeds in fish and shellfish culture: Based on the nutritional segregation of the selected microalgal species in terms of carbohydrates, protein and lipids, amino acids, fatty acids and minerals and the feeding trials with the copepod Oithona rigida, new isolates of marine microalgal species such as Nannochloropsis oceanica MACC 24 and MACC 26, Nannochloropsis sp. MACC 22 and Nannochloropsis sp. MACC 27 were identified as potential candidates as live feeds in aquaculture.

C. Energy and Environment:

- Miniaturized gas sensors developed was by Indian Institute of Space Science and Technology to monitor the emissions (CO, CH4, NH3, and N2O) from the soil for precision agriculture.

- 3 generations of improved catla were produced by selective breeding from the base population created by bringing catla from different geographical regions. The improved catla showed 30% higher growth rate in comparison to the normal catla.

- Successful trial was undertaken for 2G Ethanol Technology using rice straw and cotton stalk at 5 T/day scale at the Demonstration plant at Kashipur in Nov 2019. On the other hand, indigenous highly active, cost-effective cellulolytic enzyme was developed and produced at 5000 L Fermenter and successfully tested for producing 2G ethanol

- **DBT-BIRAC Clean Tech Demo Park at Barapullah drain site**, near Sundial Park, Sarai Kale Khan, was inaugurated by Hon'ble Minister for Science & Technology, Health & Family Welfare, and Earth Sciences on 08 Oct 2020. The DBT-BIRAC Clean Tech Demo Park will be used to demonstrate innovative Waste-to-Value technologies with support from DBT and BIRAC. Successfully demonstrated 5 Waste to Value technologies have been identified to set up at Clean Tech Demo Park. This park will be managed by the Clean Energy International Incubation Centre (CEIIC), a public-private-partnership incubator set up jointly by DBT, BIRAC and Tata Power.

- **UNATI Mission Clean Technologies for Swachh Bharat:** DBT has developed various technology platforms designed to convert different solid, liquid and gaseous wastes into renewable fuels, energy and useful products such as food, feed, polymers and chemicals. Under the UNATI Mission, 10 promising clean technologies have been identified for demonstration with DBT support at different

sites across India, in collaboration with local stakeholders such as municipalities and other urban local bodies. The identified technologies include bio-methanation, constructed wetland, bio-toilets, chemical & membrane free water purification etc. The first five projects under this initiative were formally launched on 01st Oct 2020, on the eve of Gandhi Jayanti, with an aim to achieve “Swachh Bharat”.

- 2G ethanol technology demonstrated with development of cost effective biomass treatment technology, cellulytic enzyme, lignin to bitumin process.
- An integrated carbon capture and utilization technology demonstrated at pilot scale conversion of waste carbon from acetate into omega 3 fatty acid using oleaginous yeast.
- Cyanobacteria, microalgae and fungi engineered to develop heterologous pathways for production of low carbon products to replace various petro-chemical products.
- Sunlight distribution-based photo-bioreactors were demonstrated at 100,000 Liter in Mumbai coast to grow marine algae using sea water and CO_2. Algal biomass is generated to develop fuels as well as high value biocommodities.

II. Human Resources Development:

- **Skill Vigyan Programme**: DBT has initiated Skill Vigyan Programme for providing quality hands on training in tools and techniques in multidisciplinary areas of Biotechnology for entry level students (10+2 and Graduates in Biotechnology and Life Sciences). DBT is providing support for skill development under two categories (A) DBT-Skill Vigyan State/UT S&T Council Partnership Program in Life Sciences and Biotechnology (ii) Certificate /Diploma Program for Skill Development in area of Biotechnology- so far 15 certificate/Diploma courses have supported by Department. Department has adopted hub and spoke model for implementation of Skill Vigyan State partnership programme. State Councils have been identified the partnering institutes in their respective States for imparting skill training.
- **Biotechnology Career Advancement and Re-orientation Programme (BioCARe)**: A total of 308 Women Scientists have been supported since 2014. Around 45 BioCARe Women Scientists got Permanent employment.
- **Increasing human capital and quality leadership:** Ramalingaswami Re-entry Fellowship: 279 scholars were awarded Ramalingaswami Re-entry Fellowship during this period.

III. Infrastructure:

- DBT-SAHAJ portal was launched in 2018-19. It has led to the consolidation of all facilities supported and established by the department. Through the SAHAJ portal, 3.45 lakh users/individuals have access to these facilities. A revenue of 41.30 crores have been generated through the facilities/ services listed under SAHAJ portal. Since 2020, 12 projects have been supported under SAHAJ.

IV. North Eastern Region (NER) Programme:

- Special focus was given to the North Eastern Region in terms of capacity building through implementation of 670+ twinning projects, 126 Biotech Hubs and setting up of 7 advanced research facilities. Four CoE have been established focussing on conducting R&D on local resources. These programmes have trained 3000+JRF/SRF/RAs; 500+ publications; 9 granted patents, 5 commercialised technologies. With the capacity now built in NER, the Department has launched programmes addressing NER specific challenges e.g. MDR-Tuberculosis; NE Scented Rice, Banana, Citrus, Tea; NE-food fishes; Animal Disease Diagnostic & Surveillance (ADMaC) programme etc.

V. Regulatory Reforms:

- **Launch of Biological Research Regulatory Approval Portal (BioRRAP):**
  - Keeping with the spirit of ***"One Nation, One Portal"***, the **BioRRAP** has been developed by DBT **as a whole of Government approach**. This portal is the 1st step in enabling **ease of doing** *scientific research* in India.
  - The BioRRAP caters to all those seeking regulatory approval required for biological research and development activity in the country. This portal will strengthen interdepartmental synergies and bring accountability, transparency and efficacy in functioning of agencies regulating various aspect of biological research and issuing permission.
  - Through the unique "BioRRAP ID", the portal is serving as a gateway and will help researcher to see stage of approval of the applications for regulatory clearances and also preliminary information on all the research work being undertaken by the particular researcher and/or organization.
- **SoPs for regulatory review of Genome Edited Plants:**
  - DBT notified the Standard Operating Procedures (SOPs) for regulatory review of Genome Edited Plants under Site Directed Nuclease-1 (SDN-1) and SDN-2 categories for enabling regulatory streamlining of genome edited plants and resilient crops for future.
  - Plant genome editing is amongst one of the most promising technologies in terms of applied biological research and innovation with a huge economic potential in a wide range of sectors.
  - *'Guidelines for the safety assessment of Genome Edited Plants'* were notified in May, 2022. The guidelines determine regulatory requirement for appropriate category of experiments and provide the regulatory framework and scientific guidance on data requirement in context of research and development of Genome Edited Plants.
  - Towards enabling biosafety regulation by Institutional Biosafety Committees (IBSCs) the SOPs and Checklist were drafted to bring clarity to all the stakeholders. SOPs were notified in October, 2022.

- Regulatory Reforms prior to 2014, and the reforms undertaken after 2014:

S. No.	Status Prior to 2014	Reforms Undertaken After 2014	Future Action Plan
1	The Review Committee of Genetic Manipulation (RCGM) which functions in the Department of Biotechnology was conducting its meeting in every 45th day with submission of 23 copies of applications to Secretariat.	• An online portal i.e. Indian Biosafety Knowledge Portal for submission and review of applications and issuing of authorization was made functional in year 2019. • The meetings of RCGM are being conducted every fortnightly. • Institutional Biosafety Committees have been empowered to take certain decisions. Time for taking decision on an application was reduced significantly from 90-180 days to 7-30 days depending on the type of application. • Online Interactive sessions for creating awareness for IBSCs are being organized. • Rapid Regulatory Response Framework issued for CIVD 19 research and development. Guidelines for handling to handle COVID 19 specimen for R & D purpose was issued in 2020. • 10 Guidelines on biosafety related issues were developed/revised. • Process of Biopharma product development and its approval has been streamed lined and two times approval time points from RCGM has been reduced to one-time submission. The number of consistency batch requirement for IND molecule was reduced to 3 from 5.	To bring guidelines on newer biotechnology and updating of existing guidelines.
2	Task Force based system which comprised of more than 20 Committees was functioning based on the requirement.	**Competitive Grant System Online:** The Department has introduced a new online Competitive Grant System w.e.f. October, 2018. The standard operating procedures (SOPs) have been prepared for competitive grant functioning with time lines to ensure a cycle time of not more than six-months. The process of competitive Grant system was further streamlined in 2021 by reducing the numbers of document required to submitted.	

3	There was no concept of linking National Facilities	**Launch of SAHAJ "National Service Facility/ Research Resource / Platform:** The primarily aim was to create "National Service Facility/ Research Resource/ Platform" and facilitate access to resources to cater the needs of a larger community. 465 equipment are available and users are more than 1.8 Lakhs.	
4	There was less encouragement on commercialization of research leads	Reforms for encouraging Development and commercialization of Inventions and Innovation notified.	
5	There was no Venture Fund for Biotechnology sector	**Launch of BIRAC AcE (Accelerating Entrepreneurs) Fund:** Fund of Funds is the First Venture Fund being promoted by DBT under the aegis of Make in India initiative through BIRAC as the implementing agency.	
6	All programs were implemented with physical files only.	**Reforms in E-Governance Systems:** The Department initiated major reforms in the eGovernance systems and all applications have been made online. Development of different portals like eProMIS -PI Module; eProMIS- Creation of new area to invite proposals; eProMIS Award Application	

VI. National Resources/Facilities:

- **National Centre for Microbial Resource (NCMR):** NCMR has been established at DBT-NCCS, Pune with a mandate of conserving the vast microbial diversity of India, so as to explore their biotechnological potential for industrial and health purposes.
- **Established Repository for Antimicrobial Resistant (AMR) Organisms;** AMR repository will perform the risk assessment studies to estimate transmission routes in the environment, and also in animals & human setups.
- **Biotech-PRIDE (Promotion of Research and Innovation through Data Exchange) Guidelines**: The Biotech-PRIDE Guidelines have been developed through extensive expert consultation and inter-ministerial consultation to facilitate and enable sharing and exchange of high-throughput, high-volume biological data, knowledge and information generated within the country for promotion of research and innovation.
- **International Depository Authority (IDA):** NCMR has been recognized as an IDA, and currently holds >280 patent deposits across the globe with an assurance of keeping these deposits under high confidentially and secrecy for 30 years from the date of deposit.

- **Artificial Intelligence (AI) initiative:** Under this, AI tools for affordable and accessible Healthcare-Big Data and Genomics in areas of cancer, tuberculosis and pulmonary diseases, diabetic & cardiovascular diseases, ophthalmological diseases, neurological disorders and methods/ drug development were supported. An Imaging BioBank for Cancer was also established to develop AI tools and database for advance research in cancer and will also be aimed at cancer diagnosis/ prognosis and cancer care.

- **GARBH-ini (interdisciplinary Group for Advanced Research in Birth outcomes- DBT India Initiative):** This is a unique pregnancy cohort comprising >8700 women to study Pre Term Birth (PTB). The biorepository houses 6,00,000 serial ultrasound fetal images across pregnancy, 10,00,000 different types of bio specimens in biorepository, 400 videos.

- **Human Microbiome:** Implemented *"Human microbiome initiative on select endogamous populations of India"* with the target of sampling >3400 individuals across the country from 11 endogamous and 6 tribal communities. Comprehensive data on diet and demography, especially of the tribal population, which is not exposed to modern drugs, will provide an insight into the microbiome associated with vast number of ethnic groups of Indian population and serve as tool for risk assessment of diseases regulated by the microbiome.

- **Indian Biological Data Centre (IBDC):**

  - The IBDC is the 1st National repository for life science data in India established at Regional Centre of Biotechnology (RCB), an autonomous institute of DBT at Faridabad. IBDC is committed to the spirit of data sharing as per FAIR (Findable, Accessible, Interoperable, and Reusable) principles.

  - Data submitted to INDA is actively synced with the INSDC (International Nucleotide Sequence Database Collaboration) repositories like GenBank, ENA, and DDBJ, and is simultaneously assigned accession IDs from both IBDC and INSDC repositories.

  - IBDC also hosts an online 'Dashboard' for the genomic surveillance data generated by the INSACOG labs. The dashboard provides customized data submission, access, data analysis services, and real-time SARS-CoV-2 variant monitoring across India.

- **Revamping of BTIS Network:** New set of centres of BTISNet are being funded in the areas of Structural Bioinformatics/ Drug discovery/ Drug development/ Cheminformatics, Machine Learning, Genome Informatics/ Metagenomics/ Systems Bio/Microbial, Agriculture/ Plants/ Animal, Human diseases/ Disease informatics, Biodiversity, Proteomics and Metabolomics. These centers (Spokes) will be linked to IBDC (Hub). Under the revamped BTIC Network, 63 databases/software have been developed.

- "MANAV: Human Atlas Initiative": Manav 1.0 annotation platform has been developed to perform proof-of-concepts (PoCs) on annotation guidelines, data capture, data validation and platform validation by engaging ~100 students.

- DBT established Kalam Institute of Health Technology (KIHT) in the Andhra Pradesh Medtech Zone (AMTZ) at Vishakhapatnam to function as a think-tank for medical devices sector. KIHT was established with overall aim to facilitate research on critical components in medical devices through transfer of technical

knowledge, policy implementation, market analysis and strategic interventions on industrial promotion in medical device segment.

- **Vaccine Testing Facilities established with PM-CARES Support:**
  - Two 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).
  - At present, Central Drug Laboratory at Kasauli is the only dedicated National Control Laboratory for testing of immunologicals meant for human use.
  - The PM-CARES Funds Trust supported upgradation activities. MoH&FW has notified these VTFs CDLs for testing and lot release of COVID-19 vaccines.
- **DBT-DNA Fingerprinting services by Centre for DNA Fingerprinting and Diagnostics (CDFD*):***

  DBT-CDFD offers DNA Fingerprinting services (~100/year) for law enforcing agencies, medico-legal applications and quality testing. CDFD expertise helped in establishing identity (within 24 hrs.) of Army and Air Force Officials during helicopter crashes. In addition, CDFD also offers diagnostic services for various genetic disorders including rare genetic disorders which help in reducing the disease burden in the country. Approx. 75 samples/year of Basmati rice are being checked for their purity which is economically very useful for Indian farmers.

VII. Policy Reforms:

- DBT has subsumed its 14 Autonomous Institutions to create one Apex autonomous body, ***Biotechnology Research and Innovation Council (BRIC).*** This has been done with a larger goal to enhance the scientific character and science outcomes at the institutes by building research synergies, new education programs in line with National Education Policy (NEP), improving human resource structures across cadres and effective management and monetization of assets emanating from research.
- BRIC will build on the foundations developed at the DBT institutions to foster synergies while maintaining their distinct research mandates. With an emphasis on interdisciplinary interactions that cut across institutional boundaries, BRIC institutes will undertake cutting edge research addressing national priorities.
- Compliance with governmental processes and administrative issues will be centrally managed in a coordinated effort thereby achieving ***"Minimum Government, Maximum Governance".***

VIII. Recognition by International Bodies:

- ***DBT renewed (through Cabinet approval) the cooperation with the Bill & Melinda Gates Foundation (BMGF)*** to support and initiate R&D cooperation for development of innovative and novel approaches, therapies and interventions needed to solve challenges concerning health food and nutritional equities.
- India-centric Coalition of Epidemic Preparedness Innovations (Ind-CEPI): Under the initiative on "*Epidemic preparedness through rapid vaccine development:*

Support of Indian vaccine development which is aligned with the global initiative of the CEPI", **bioassay lab at THSTI**, Faridabad has been **recognized as one of the 7 labs, globally**, for centralized assessment of COVID-19 Vaccines.

IX. Biotechnology Industry Research Assistance Council (BIRAC):

Promotion of Biotech Startups ecosystem through Public-Private Partnership:

- DBT established BIRAC as its industry-academia interface to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.
- The mandate is to nurture innovation for the entire product development chain that is from idea to *proof-of-concept*, to early and late stage translational research, validation, scale up to commercialization.
- Over the 9 years, BIRAC has taken up a multitude of activities from providing funds for high-risk translational research, supporting nascent ideas, capacity building through creating specialized bio-incubation centers as shared infrastructure, handholding through mentoring and training, policy advocacy for empowering the biotech ecosystem in India.
- BIRAC's programs, schemes and policy initiatives are supplemented through strategic collaborations, public private partnerships with National & International bodies, Government departments, States, Industry, Angels/VCs, Mentors, Experts, Philanthropic organizations, NGOs etc.
- BIRAC as a central enabler, has nurtured the Biotech Innovation Ecosystem in the country for development of globally competitive affordable products to address the unmet needs of society.
- BIRAC has inculcated a culture of biotech entrepreneurship creating a pipeline of >11,000 aspiring entrepreneurs & 6300+ biotech Startups.
- Biotech innovation ecosystem is largely driven by startups. BIRAC has supported 4000+ Startups, entrepreneurs and other beneficiaries.
- BIRAC has established a vibrant biotech innovation network. This includes:
  - 75 bio-incubators across 21 states/UTs supporting 1800+ incubatees.
  - 4 Regional centres for mentoring and handholding, especially covering Tier 2, Tier 3 regions.
  - 7 Technology Transfer Offices
  - 12 Daughter Funds under Fund of Funds
- About 800 Regulatory queries from Startups/Entrepreneurs/Innovators supported through BIRAC Regulatory Information Facilitation Centre platform. BIRAC's efforts have enabled filing of >1300 IP; So far, >800 biotech products/ technologies have reached to the market; >30,000 high skilled jobs created.
- **Biotechnology Innovation Fund**-Accelerating Entrepreneurs (AcE) Fund, '*a Fund of Funds'* was launched to invest equity in startups to provide the risk capital to undertake innovation, research, and product development. AcE mobilized >930 crore with BIRAC/DBT committing 114.5 crore in biotech startups, SMEs

- **Funding Support to Startups**: Out of 11000+ new innovative ideas, BIRAC supported:
  - 950+ Startups were supported under 'Biotech Ignition Grant'
  - 159 Startups provided equity investment through SEED and LEAP Fund
  - 77 Companies provided investment through *Fund of Funds*-AcE Fund

- **Global Bio-India 2021:** DBT along with BIRAC organized Global Bio-India 2021 on a digital platform. This has showcased Indian biotech's potential both within the country and to the international community. The theme was '*Transforming Lives*' with the tag line *'Biosciences to Bio-economy*'. The event witnessed participation from >8400 delegates; 40+ countries; >50 international speakers; >1000 Entrepreneurs/Startups; facilitated 23 Awards; >140 Investor-Startup meetings; >150 exhibitors; >350 Bio-partnering meetings.

- **Biotech Startup Expo 2022:** Organised First Biotech Startup Expo-2022 from June 9-10, 2022. This Expo was inaugurated by Hon'ble Prime Minister. The event was attended by more than 6,000 participants representing all the stakeholder segments of the biotech ecosystem. A large no. of exhibitors including Startups, Incubation Centres, Research Institutions exhibited their products/technologies and research leads in the event. In addition, stakeholders of biotech sector including entrepreneurs, Startups, experts, SMEs, Industry, academia, researchers and investors attended the event. 75 Universities from across the country also joined online during the Inaugural ceremony and also conducted satellite events across the country.

- **BIRAC's Impact from 2014 to 2022:**

Outcome	2014	Multiplier	2022
Biotech Startups	<700	90x	6300+
Incubators	6	12x	75
Number of Products	10	80x	800
Fund Raised (INR)	10 Cr	400x	4200 Cr+
Jobs Created	<500	60x	30000
IP filed	125+	12x	1300+
Bio-Economy ($ USD)	35.5 Bn (2014)	2.5 x	95+ Bn

X. Achievements During the COVID-19 Pandemic

DBT along with BIRAC rapidly responded to the emergent pandemic and had drawn out a research plan aligned with the R&D blueprint of WHO, with a focus on '*testing, prevention and treatment*'. As early as in February 2020, DBT-BIRAC COVID-19 Research Consortium was launched to facilitate development of effective biomedical solutions and interventions. Mission COVID Suraksha was also implemented under Atmanirbhar Bharat, to accelerate Indian COVID-19 vaccine development efforts.

➢ **COVID-19 Vaccine Development**

The following 5 COVID-19 vaccines developed under "*Mission COVID Suraksha-The Indian COVID-19 Vaccine Development Mission*", have received Emergency Use Authorization (EUA):

- World's 1st and India's indigenously developed DNA Vaccine, ZyCoV-D;
- Protein subunit vaccine, CORBEVAX™, for use in 5 years and above mRNA vaccine GEMCOVAC-19™; World's 1st Intranasal COVID-19 Vaccine (iNCOVACC);
- India's 1st mRNA based Omicron booster vaccine (GEMCOVAC-OM);
- ZyCoVD, CORBEVAX™ and iNCOVACC have been approved as boosters.

➢ **DBT-BIRAC's Efforts for Creating Ecosystem for Vaccine Development**

- GCLP compliant clinical trial sites to facilitate clinical trials for COVID-19 vaccines such as ZyCoV-D, Covovax, GEMCOVAC™-19, CORBEVAX™, Covaxin Booster, rBCG (Serum Institute) and J&J's COVID vaccine.
- 5 COVID-19 Biorepositories have archived with clinical samples and viral isolates for sharing with industry & academia.
- Animal challenge facilities and immunoassay labs offered crucial services to several industry-based vaccine developers. DBT-THSTI, Faridabad, offered hamster models and neutralization assays for ZyCoV-D and CORBEVAX™. DBT-NII, New Delhi, provided immunogenicity assay services for iNCOVACC Phase III clinical trials.
- Augmentation of manufacturing facilities for enhanced COVAXIN production, at Bharat Biotech International Limited (BBIL), Malur facility, and Indian Immunologicals Limited (IIL), Hyderabad enabled production of ~70 million doses equivalent of Covaxin Drug Substance.

➢ **COVID-19 Testing in a Hub and Spoke Model:** DBT established 21 City/Regional Clusters in Hub and Spoke Model, to scale up COVID-19 testing, to meet the requirement of testing in the country.

➢ **Mobile diagnostic labs (I-Labs):** They have been deployed including in North East Region, for COVID testing in remote and inaccessible areas of the country.

➢ **Development of COVID-19 Diagnostic kits:** Through sustained support by DBT and BIRAC for COVID-19 diagnostic kits reached the market and our country achieved self-sufficiency in diagnosis of COVID-19, within a few months of the pandemic. In addition, DBT and BIRAC supported Biotech Start-ups have commercialized PPE kits, ventilators, masks, sanitizers, remote consultation devices, and monitoring devices.

➢ **Regulatory Facilitation:** DBT has proactively taken several steps to support researchers and industries involved in research on COVID-19 and issued Biosafety Regulations for COVID 19, in close coordination with CDSCO, for facilitating expedited approvals/clearances. The following Biosafety Regulations for COVID 19 have been provided by the Review Committee on Genetic Manipulation (RCGM):

- Rapid Response Regulatory Framework to provide expedited regulatory approvals for all diagnostics drugs and vaccines. This includes: a) Regulations and Guidelines for Recombinant DNA Research & Biocontainment-Interim; b) Guidelines of laboratory biosafety to handle COVID 19 specimens for R&D

purpose; and c) Guidelines for sharing of Bio-specimen & Data for Research on COVID-19, in consultation with NITI Aayog.

- Regulatory support to start-ups was provided by BIRAC through the weekly sessions of the FIRST (Facilitation of Innovation and Regulation for Start-ups and innovators) Hub initiative.
- During pandemic, DBT established the following key international partnerships:
  - Engagement with ACT Accelerator wherein DBT was the focal point for R&D and manufacturing;
  - Quad Alliance to strengthen vaccine manufacturing for global equitable access;
  - Partnership with CEPI to facilitate preparedness for pandemics through rapid vaccine development; DBT-THSTI's Bioassay lab supported under the Ind-CEPI Mission has been selected as one of the 07 global laboratories for centralized assessment of COVID- 19 Vaccines.
  - Under the Partnerships for Accelerating Clinical Trials (PACT) programme, ~2400 participants from 14 neighbouring and friendly countries (Afghanistan, Bahrain, Bhutan, Bangladesh, Gambia, Kenya, Myanmar, Maldives, Mauritius, Oman, Nepal, Somalia, Sri Lanka, Vietnam) were trained for strengthening of clinical trial capacities.

➢ **Indian SARS-CoV-2 Genomic Consortium (INSACOG):**

- Indian SARS-CoV-2 Genomic Consortium (INSACOG) an inter-ministerial network of nearly 67 genome sequencing laboratories was established by DBT (as Coordinator) with other national agencies, for surveillance of SARS-CoV-2 variants in India. Overall aim of INSACOG is to sequence SARS-CoV-2 from COVID-19 infections in India to monitor the emergence and community circulation of viral variants and Variants of Interest/Variants of Concern.

XI. Inter-Ministerial MoUs Signed:

	Agreements Signed	Date of Signing
1.	National Medicinal Plant Board, Ministry of AYUSH and DBT for validation of traditional knowledge.	31st December, 2018
2.	Tripartite MoU among CSIR, ICMR and DBT for Inter-Ministerial co-operation for "promotion and facilitation of innovative research on Phyto-pharmaceuticals"	31st December, 2018
3.	Department of Atomic Energy and DBT for Collaborations in the area of Cancer Research	22nd May, 2019
4.	ICAR and DBT for collaborative R&D activities	14th January, 2019
5.	MoES and DBT for setting up of DBT MoES Polar research centre.	14th July, 2021
6.	Ministry of AYUSH and DBT on Inter-Ministerial Cooperation for evidence based biotechnological interventions in Ayush sector	25th May, 2022
7.	Department of Atomic Energy and DBT on Inter-Ministerial Cooperation in the area of Nutrition and Metabolism	3rd June, 2022

XII. New Initiatives and Futuristic Technologies:

- "***Fostering High Performance Bio-manufacturing***" under the following 6 thematic areas: (i) Bio-based Chemicals and Enzymes, (ii) Functional Foods and Smart Proteins, (iii) Precision Bio-therapeutics, (iv) Climate-Resilient Agriculture, (v) Carbon Capture and Utilization, (vi) Futuristic Marine and Space Research.
- One health consortium for future pandemics

The goal of Department of Biotechnology is to nurture technological and scientific advancements as well as interventions to drive a biotech-based circular economy.