

National Biotechnology Development Strategy

2015-2020



Promoting bioscience research, education
and entrepreneurship



सत्यमेव जयते

Department of Biotechnology
Ministry of Science & Technology
Government of India





National Biotechnology Development Strategy

2015-2020



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THE GENESIS

Moving ahead from strategy - I

The Department of Biotechnology (DBT), Government of India, announced the National Biotechnology Development Strategy in September 2007. Through the strategy, biotechnology was recognized as a sunrise sector that needed focussed attention. The cornerstone of the strategy was to focus on building coherence and connectivity between disciplines and bring together variegated skills across sectors to enhance synergy.

Necessary guidelines for transgenic plants, recombinant vaccines and drugs, stem cell therapy have been evolved. A strong base of indigenous capabilities has been created. Many innovations and research applications for socio-economic development have been supported in the areas of medical, agricultural, environmental and industrial biotechnology. PPP models have been successfully implemented and a new section 25 company a Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC), has been established to exclusively work on PPP programs in biotechnology. Most of the new initiatives announced in the 2007 Strategy are in place.

The implementation of Biotech Strategy 2007 has provided an insight into the enormous opportunities. Thus, it was felt opportune to take a critical look at the Indian biotech sector as it will likely unfold over the next 5-6 years. The National Biotechnology Development Strategy-II 2015-2020 (hereinafter referred to as 'NBDS 2015-2020-II') is the direct result of formal and informal consultations over the past two years with over 300 stakeholders including scientists, educators, policy makers, leaders of industry and civil society, voluntary and non-government organizations, regulators and international experts. The consultations offered an opportunity to discuss and evaluate technological, societal and policy aspirations, critical success factors as well as barriers that will impede growth and put them in newer and broader perspective and action plan. The new strategy would seamlessly build on the earlier Strategy to accelerate the pace of growth of biotechnology sector at par with global requirements.

Boundaries between disciplines once considered distant are now beginning to blur and as a consequence of their convergence given birth to newer opportunities and challenges. Hence biotech education policies have to be reshaped to bring in breadth and depth as accelerated growth is propelled by both a highly skilled work force and talented leadership. Our universities need to be redesigned for evolving an ecosystem in which scientists, innovators and future entrepreneurs can be nurtured. University research output must show a quantum jump for us to achieve global competitiveness. Building a skilled workforce would accord top priority in our renewed mission.

Scale up and sustainability are important for novel efforts and approaches to make institutional mechanisms of innovation empowering. Hence significant investment would be made for building the knowledge environment which would encompass niche research areas, 'the centres

of excellence', innovation clusters, centralized R&D infrastructure and research tools - data centers, repositories. Efforts would be taken to provide access to these research resources nationally.

Life sciences research once perceived for understanding the creation and the nature, gradually evolved into technology oriented research aimed at improving the lives and living of millions. Of late, bioscience is being increasingly perceived as one of the potential enterprise activity capable of fulfilling societal needs through manufacturing and providing employment opportunities. Hence efforts would be directed in nurturing entrepreneurship and in accelerating technology for market absorption.

Research in all areas of basic and interdisciplinary sciences using modern biotechnology would be supported. Emphasis would be on *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 is a paradigm shift in the relation-ship between government, academia, industry and civil society. This is critical for the new era of science-driven, society relevant innovation and entrepreneur-ship. DBT is committed to building newer instruments for connectivity. DBT would enter into strategic partnerships globally, nationally with other departments, ministries and private sector and more so with the society for achieving inclusive development.

Since biotechnology is a scientific revo-lution and creating the unseen, it is also our commitment in taking the public into confidence, in gaining public acceptance for biotech products, educating them, reaching out to them and providing a more participatory role for improving their understanding of our work. Regulation, standard setting and support of infrastructure for all this would be attended on priority.

The consultations held have resulted not only in identifying ten guiding principles that will drive Strategy-II but also in detailing the instruments through which these principles will be implemented. These are outlined in the key elements and sector-wise priorities.



SECTION - 1

KEY ELEMENTS

Our renewed mission

Realizing that biotechnology has the potential to be a globally transformative intellectual enterprise of humankind, our renewed mission is to:

- **Provide** impetus to fulfilment of the potential for a new understanding of life processes and utilizing the knowledge and tools to the advantage of humanity;
- **Launch** a major, well-directed effort backed by significant investment for 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.
- **Empower**, scientifically and technologically, India's incomparable human resource;
- **Create** a strong infrastructure for research, development and commercialization for a robust bioeconomy;
- **Establish** India as a world class bio-manufacturing hub for developing and developed markets;

Ten guiding principles that will drive the strategy

Consultations with stakeholders have identified the following 10 guiding principles that shall drive the renewed mission through Strategy-II.

Building a skilled workforce and leadership

Biotechnology as a discipline is highly dynamic and rapidly evolving. Recognizing the importance of capacity and competence building, DBT prioritises the following for facilitating training, education and research aspirations of students, faculty and other biotech professionals.

- Specialized training programs for professionals - to facilitate technology competence and for updating professional skills required in the dynamic system.
- New career options for students - aimed at motivating young minds towards biotechnology for a career and to make higher education, enterprise driven and interdisciplinary
- Faculty improvement Program - for continuous improvement, lateral growth and for recognition of the dedicated services rendered
- Attracting Skills - for imbibing the overseas talent (scientists and post docs) in our development process.

Instruments for implementation

- ✓ *Overseas and national fellowships for working professionals for specialised skill training in interdisciplinary and translational research*
- ✓ *Overseas exchange and clinical training programs*
- ✓ *Overseas associateship for UG and PG teachers*
- ✓ *Promote bioscience and biotech higher education and research programme in engineering system*
- ✓ *Dual degree M.Sc/MBA in agribusiness, pharmanbusiness and bioenterprise management*
- ✓ *Support for integrated and interdisciplinary PG and Ph.D programs*
- ✓ *Graduate research fellowships including summer training*
- ✓ *Polytechnic schools for skill development*
- ✓ *Recognition of promising star colleges and nurturing them*
- ✓ *Establishment of EMBL like centres in the country*
- ✓ *New scheme to be launched to increase mobility of industry professionals into academic institutions and vice versa*
- ✓ *Career development and distinguished awards for teaching faculties*
- ✓ *Prestigious positions such as 'Science chairs' for best brains in India and from overseas*
- ✓ *Establish a National Council for Biosciences and Bioengineering to provide outstanding training to trainers, linked to advanced technology platform in universities and inter institutional centres.*

Revitalizing the knowledge environment at par with the growing bioeconomy

Capacity for innovation and technology development in biotechnology rests largely on access to core facilities and instrumentation. The Department of Biotechnology (DBT) is committed to building world-class facilities and its access across the country. In addition to providing support for core equipment in universities and research institutes, the following would be achieved.

- Networked resources/skills - Specialised centres in and around existing institutes as 'centres of excellence' or 'bioclusters' for physical amenities as well as the intangible benefits like specialized skill, competence and niche support.
- Strengthening core capacities in institutes- facilities for advanced research programs in existing institutions to empower them in transforming their expertise.
- National institutes for spearheading research and training in emerging areas of biotechnology and which are highly relevant and specific for the Indian context.
- Data centers- DBT would evolve a National data policy for submission of publications arising out of public funded research to the National data center, which will consolidate it and make it publically available. Also nationally generated databases could be deposited in it.
- Repositories-To promote research and development from indigenous efforts and sources, national knowledge repositories would be set up.

Instruments for implementation

- ✓ *Establish Translational Centres for Agri Biotech partnered with State Agriculture Universities to take forward the agriculture crop improvement research including transgenics currently developed by public institutions.*
- ✓ *Establish Centres of Excellence in specialized priority areas such as pre-breeding, transgenic research, bioproducts from marine resource, biofortification, vaccine research, chronic disease, organ based disease biology, regenerative medicine, bioengineering etc.*
- ✓ *Set up new, multiuser, accessible Regional Advanced Technology Platforms with preferred university location, linked to incubators and Inter- Institutional Centres*
- ✓ *Establish new centres on the lines of Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore for all bio clusters.*
- ✓ *Set up a Natural products and technology repository*
- ✓ *Establish a National Centre for Drug Discovery from Natural Products, Marine biotechnology Institute, Institute on Rural Development, National centre for facilitating resources, Interdisciplinary Infection Science Research Centres and bio-design inter-institutional centre.*
- ✓ *Strengthen and create national databases on disease surveillance, epidemiology, disease burden etc.*
- ✓ *The Technology repository to include a broad spectrum of intellectual assets- biomaterials, patents, data, copyrights and business models.*

Enhance Research opportunities in basic, disciplinary and inter-disciplinary sciences

- (i) Providing Sustained support to basic sciences
- (ii) Multi-disciplinarily research in biology to be encouraged; attract non-biologists to address biological questions
- (iii) Individual excellence to be complemented with mission and team-driven approaches to transform basic findings into applications
- (iv) Encourage emerging technologies such as synthetic and systems biology, nano biotechnology, advanced proteomics, imaging, data-intensive discovery, bioinformatics.

Instruments for implementation

- *Grand challenge, network programmes to be supported*
- *Competitive R&D and strategic research funding to be encouraged*
- *Research priorities to include human health- Gene networks for genomic pathways, expression profiling, epidemiological study for assessing disease burden, basic immunology, indigenous vaccine development, pathogenesis of infectious and chronic diseases, affordable diagnostics and therapeutics for diseases of national priority, personalized and preventive medicine, molecular imaging, innovative models of developmental and disease biology (including animal models), cell based models, clinical therapies using stem cells and tissue engineering, biodesign for medical devices, implants, diagnostics etc.*

- *Molecular epidemiological disease surveillance to be encouraged with ICMR*
- *Agriculture- crop science focusing at increasing yield and enhancing nutrition value, transgenics, prebreeding, studies on QTL and MAS for abiotic stress etc.*
- *Animal agriculture- Animal health and productivity including animal reproduction, transgenics, nutrition and animal food safety etc.*
- *Aquaculture- aquatic health, breeding and genetics, food and nutrition etc.*
- *Food and nutrition- biofortification and fortification, functional foods, child malnutrition, food safety etc.*
- *Natural resource management- eco-restoration, metagenomics, climate change, value added biomass from natural resources etc.*
- *Industrial biotech- technologies for clean energy, biosystems and bioprocess engineering, nanotechnology, genome technologies etc.*
- *Bioinformatics, computational and systems biology.*

Encourage use-inspired discovery research

- Innovation for socially relevant biotech products in the areas of food and feed, human health and wellness, animal productivity, energy and ecological security to be encouraged. All relevant extant domestic regulations, as well as international laws to which India is a Party, relating to access to and use of bio-resources would be followed and complied with in the product development process.
- Policies and investments to be strengthened to promote innovation and R&D for development of affordable products for Indian and global market.
- Investment in R&D to be directed towards enhanced turnover of biotech sector, creation of jobs, creation of affordable products and human impact of biotech product.
- New schemes will be created for funding academia and industry through grants for affordable solutions in which price commitment on products will be guaranteed.
- Opportunities for placement of industry workforce in academic environments to be enhanced
- New mechanisms for transnational public-private partnerships to be strengthened
- Global sourcing of technologies to be explored
- Special units 'Intelligent Ideas for Innovation' (III-Units) will be set up.

Instruments for implementation

- ✓ ***Incentivize establishment of Technology Development and Translational Cells in 50 research intensive universities***
- ✓ ***QUICK LINK grants to connect basic and applied sciences within and across institutions and industry.***
 - o *The illustrative programme of this nature will include human microbiome, molecular understanding and signature of premature birth, new drug targets for cancer through chemical biology, engima of foetal growth reduction in South East Asia. Pre-breeding and marker assisted breeding, non-transgenic tools for accelerating plant breeding, next generation bio-fuels, animal genomes and productivity, human immunology and protective immunity agents, important diseases – cancer genomes and epigenomics for customised medicine, biomarker discovery in human, plant and animal systems, data intensive discovery.*

- ✓ *Incentivise R&D aimed at delivering affordable products, demand forecasts, facilitate wide use of safe, effective technologies, support public-private partnerships, pricing mechanism to balance consumer interest and innovation.*
- ✓ *Support to human resource for early translation, pre-clinical and clinical studies*
- ✓ *Support strong technology platforms that are widely accessible*
- ✓ *Establishment and nurturing of open innovation centres*
- ✓ *Create network of clinical sites or testing facilities*

Focus on biotechnology tools for inclusive development

To develop and adopt biotechnologies focussing on improving quality of life and living of the rural and the marginalised sections of the society including human health and employment opportunities, following efforts will be made :

- Support to biotechnology research focusing on improving life and living
- Documenting and developing rural knowledge and skills
- Cooperative outreach

Instruments for implementation

- ✓ *Put in place appropriate policy instruments to create demand*
- ✓ *Support research on Health & Sanitation, Environment & Biodiversity monitoring including climate change, Animal Husbandry, Dairy and Fisheries, Integrated Farming, Multi institutional multi agency driven integrated networking projects on sustainable use of Bioresources, Product / process development and value addition, all envisaging societal upliftment.*
- ✓ *Documenting farmer/ community innovation, enabling farmers in patenting innovations and traditional knowledge, establishment of centers of rural entrepreneurship development and rural bioresource complex/hubs.*
- ✓ *Networking of institutions, individuals, NGO, Krishi Vigyan kendras and others working on similar lines.*
- ✓ *Strengthening of twinning R&D program, biotech hubs, infrastructure and capacity building activities in North eastern states.*

Commercialization of technology - nurturing innovation, translational capacity and entrepreneurship

DBT has a key role to play in transfer of technology, validation, licensing and in creation of infrastructure and training for the above requirements for successful commercialization of technologies emanating from hard-core research. Thrust will be on :

- Translational capacity to be embedded in all major research centres and programmes
- Support for business incubation infrastructure, technology validation and scale-up infrastructure
- Technology management professional development and licensing of technologies for accelerated commercialization

Instruments for implementation

- ✓ **Strengthen and creating technology incubators to provide technology incubation, validation and scale up support to enterprises**
 - ✓ *Technology development centres within existing academic Institutes*
 - ✓ *Establish/strengthen/encourage domain specific 'Innovation Accelerators' and 'Translational Accelerators' accessible to public- institutions and SMEs to successfully incubate discoveries, and take them through the validation stage, and package them for transfer and licensing. The Translational Accelerator would offer support for preclinical work, clinical trials, field trials of modified crops/organisms, compliance with regulatory requirement and production as per Good Manufacturing Practices (GMP) standards.*
 - ✓ *Through BIRAC create and sustain 'Translational accelerators' in key locations. **The** facility to include validation and transfer centre for facilitating technology licensing.*
 - ✓ *Over 150 Technology Transfer Organizations (TTO) to be set up, spread across the country in research institutes and universities.*
 - ✓ *Work through BIRAC for nurturing entrepreneurship, technology acquisition and commercialization*
 - ✓ *Creation of a scheme to popularize technology transfer training*
 - ✓ *Establishment of Validation centres for nutrition claims with a focus to collect valid data on the phytochemical components of different Indian foods*
 - ✓ *Creating and strengthening infrastructure in the areas of preclinical toxicology and clinical trials in diverse demographical settings*
 - ✓ *Creating manufacturing facilities for production of clinical grade material for evaluating promising vaccine candidates through PPP model*
 - ✓ *Establishment of Rural Technological Innovation & Application Center*
 - ✓ *New scheme to be launched 'Encouraging development and commercialization of inventions and innovations' for DBT scientists of autonomous institutes to explore entrepreneurship.*
- Technology repository for depositing technologies developed indigenously and for global acquisitions
 - Nurturing Bio entrepreneurship

Biotechnology and Society – Ensuring a transparent, efficient and globally best regulatory system and communication strategy

It important to build a regulatory system that is science based, transparent, efficient and dedicated to the safety of consumers and environment. **DBT is committed to ensuring safety of the products and processes generated through biotech research so that they are eventually accepted by the end user for whom it is produced. The focus will be on:**

- **Ensuring safety-** To regulate research, transport, import and manufacture of biotechnology products and organisms.
- **Encouraging safety-** A process reform table of current qualitative and quantitative limits, mechanisms and timelines for preclinical and clinical trials

- Validating research-for diffusion of technology; resources would be built for enabling validation and for creating products as per approved manufacturing processes.
- **Communicating biotechnology-** It is important to raise public awareness of the modern tools of biotechnology and how it could improve our well being, offer food and energy securities and helps in preserving our environment.

Instruments for implementation

- *Establish Biotechnology Regulatory Authority of India (BRAI) through appropriate legislation as an independent and statutory agency to **regulate research, transport, import and manufacture of biotechnology products and organisms***
- *Work with concerned agencies to strengthen the functioning of bodies such as RCGM, GEAC and DCGI to make them scientifically stronger, professionally more competent, conflict free and transparent*
- ***Establishment of a toxicological center to generate toxicity, safety data for biological and chemical contaminants and adulterants along with GM foods and traditionally used herbs***
- *Setting up of efficient regulatory departments well versed in GCP, GMP and GLP*
- *Embed training and re-training of regulatory professionals for regular and periodical skill up-gradation within the system*
- *Regular oversight by inter-ministerial committee*
- *Establishment of LMO detection network which is functional and sustainable*
- *Promotion/strengthening of public communication cell*
- *Establishment of a media resource centre to effectively interface with print and electronic media*
- *Strengthen guidelines and their implementation for commercialisation of technologies by concerned Central/State Ministries*

Biotechnology cooperation- Fostering global and national alliances

DBT would continue to encourage research ties nationally and internationally to promote innovation and in finding newer solutions to long battled challenges. The collaboration to be fostered would also include private players for attaining competitive advantage.

- DBT would pursue global partnerships with governmental organisations, non-governmental organisations and philanthropic research foundations for multinational projects.
- Close cooperation with other national agencies and departments. Interministerial cooperation between the agriculture, health, education, rural mission, women development etc would be forged in attaining our goals.
- High-powered, multi-stakeholder consortia to be launched for biotech missions ensuring agricultural and food security of economically weaker sections, enhancement of animal productivity, health and wellness of vulnerable populations and environmental safety.
- Partnership with private sector (talent and investments) in diverse areas of research and development including building resources and centres of excellence, imparting education and training especially bio entrepreneurship and in accelerating technology from lab to market.
- New paradigm of connectivity between government, academia, industry and not-for-profit organizations dedicated to quality innovation would be created.

Instruments for implementation

- ✓ *Build upon existing global partnerships and develop new models of multilateral alliances*
- ✓ *Global public-private partnerships to be forged*
- ✓ *Functional alliances for overseas exchange to be established*
- ✓ *Establish/ promote offices of BIOCONNECT at 20 institutions (preferably university locations) to **promote forward-thinking interaction and exchange between stakeholders in academia, industry, government agencies, trade, professional services and financial organisations.***

Strengthen Institutional Capacity with redesigned governance models

To cater to the requirement of discovery based innovation driven translational research, new institutional capacity is critical. This would entail

- Institutional redesigning in terms of new governance models
- Institutional capacity strengthening at universities, research institutes, private sector and non-governmental organisations.

Instruments for implementation

- ✓ *Inter Institutional Centres, DBT Partnership centre and national alliances as key institutional model to be supported with autonomy for governance*
- ✓ *DBT–partnered Centres of Excellence- to promote scientific leadership along with other funding bodies and institutions*
- ✓ *Inter-institution centres- promoting networking for achieving research excellence*
- ✓ *Strategies and support - virtual network centres*
- ✓ *Promote and strengthen establishment of bio-clusters to ensure connectivity.*

Create a matrix of measurement of processes as well as outcome

- This is very important for error detection, error correction, and re-design of initiatives on a continuous basis.
- The guiding principle should be an early exit for things that do not work and interim incorporation of new strategies and practices, as required, for success

Instruments for implementation

- ✓ *Engage professionals to periodically and regularly monitor and evaluate progress*
- ✓ *Define quantifiable “indicators” for both process and outcome in each project*
- ✓ *Mapping of Publication, patent, technology transfer, new product introduction, socially transforming biotech products, Universities with A-grade innovator ecosystem and categorizations of advanced technology platforms.*
- ✓ *Independent review of DBT programs by eminent scientific group for analyzing the programs being implemented and for recommendations on emerging and on-going programs for their continuity and reappraisal.*
- ✓ *Put in place a built-in mechanism of reward and incentives.*



SECTION - II

SECTORAL PRIORITIES

Introduction

National Biotechnology Development Strategy I provided the impetus for and helped in building indigenous capabilities in health, food and environment. It also laid the foundation for offering research support to biotech industries through launching of major PPP programs and spearheaded new frontiers of biotech research by drafting guidelines for transgenic plants, recombinant vaccines and drugs and stem cell therapy. It unfolded enormous opportunities and challenges which have resulted in building a strong foundation and base for India to grow as a major bio economy in the years to come.

The new strategy would seamlessly build on the earlier strategy to accelerate the pace of growth of biotechnology sector at par with global requirements. This strategy, which is a result of various scientific consultations and the experience gained by the DBT, seeks to address a number of identified challenges in terms of tailor-made human capital for scientific research and entrepreneurship; research priorities, resources, and core facilities; creation of investment capital; intellectual property regime; technology transfer, absorption, diffusion and commercialization; regulation standards and accreditation; biotechnology partnerships between public and private sectors both nationally and globally and public understanding of biotechnology.

Skilled Workforce

Biotechnology is a science that emerged from culmination of biological principles and other basic sciences. Hence the domain is highly dynamic and rapidly evolving. Recognizing the importance of capacity and competence building, the DBT is successfully implementing many programs to effectively harness the potentials of this field. In addition to continuous improvement of current programs, the present strategy proposes to address the needs of institutes for facilitating training, education and research aspirations of students, faculty and other biotech professionals.



Specialized training programs for professionals

Specialised training programs to be initiated to facilitate technology competence among professionals. Overseas and National fellowships would be initiated to enable specialised skill training.

- Training programs in Clinical Genetics in close collaboration with Medical Council of India (MCI) & National Board of Examinations (NBE) for physician scientists and Geneticists
- Training in public health for disease prevention and control for health care professionals and researchers in the respective fields

- Postdoctoral fellowships for training in interdisciplinary and translational research including biostatistics, toxicology, molecular immunology, molecular genetics, bioinformatics for in silico drug design, secondary agriculture, molecular pharmacology, phytochemistry, systems and synthetic biology, protein engineering, drug discovery from natural products, chronic and infectious disease biology
- Entrepreneurship education or development programme for scientists, teachers and students
- Long term research fellowships for post docs/young scientists
- To establish effective functional alliances for overseas exchange and clinical training programme in the area of vaccinology
- Support for conducting and participating in specialized scientific workshops for professionals at all stages of their career

New career options for students

Biotechnology offers a new career platform for aspiring science students. The Department would consolidate the ongoing PG teaching programs, assess and review them. Based on the assessment specialized PG courses in gap areas for physicians, veterinary professionals and medical bioinformatics would be planned. To motivate young minds towards biotechnology, DBT proposes to make higher education enterprise driven and interdisciplinary.

- Dual degree M.Sc./MBA in bio-enterprise management, agribusiness management, pharma-business management
- Support to integrated B.Tech, M.Tech and Ph.D. programme
- Choice based credit system for bioinformatics, computational and systems biology course in MSc Biotechnology
- Support for Joint academia-industry Ph.D. programs
- Scholarships for overseas Ph.D.
- One year diploma course for biology students in bioinformatics
- Summer training and short term research fellowships for undergraduate biotechnology students in DBT institutes/DBT programmes
- Centers for practical and services training
- Polytechnic schools for training in equipment repair and maintenance
- Support to specialized online course
- Establish EMBL (European Molecular Biology Laboratories)-like centres in the country

The star college program that is being successfully implemented would be expanded. The most promising colleges from the supported ones would be chosen and nurtured long-term and be recognized as “DBT-STAR College”.

To enhance access to study materials, web based portal in biotechnology would be made. In addition, efforts would be made for introduction of healthcare technologies including bio-design in the curriculum of medical and engineering schools for undergraduate and post graduate programmes. With a vision on building competence, industry participation in all teaching programs would be encouraged.

Faculty improvement program

Skilled workforce is built through culmination of sound knowledge and access to core facilities which enable honing of professional and specialized skills. Domain knowledge is largely imparted

by dedicated teachers and hence lateral opportunities for continuous improvement of their knowledge and recognition of their devotion is foremost in the creation of knowledge environment. It is with these goals DBT would implement the following:

- Separate overseas Associate-ship scheme for UG and PG teachers
- UG and PG teachers training in institutes involved in DBT PG teaching programmes
- Regional institutes for training on the pattern of THSTI
- Distinguished award for superannuated teachers
- Career development awards for teachers
- Provision for training as an integral part of programmes with huge equipment grant

Attracting Skills

To keep abreast with latest developments to meet the needs of trained manpower in rapidly advancing field of biotechnology, it is very crucial that we grow by attracting talent. In this context, opportunities for overseas scientists to work in India would be created. Also skilled post doctorates and scientists would be encouraged to pursue their research activity in India through attractive remuneration. Provisions such as Science Chair would be created to attract the best brains.

To meet the current and future requirements of trained manpower in the field of biotechnology, the DBT would work on the feasibility of establishing “Life science and Biotechnology Education Council” to coordinate, network and implement education, training and skill development activities from school to post-doctoral level. The council shall also be involved for assessment of human resource requirements across disciplines and skill sets, formulating innovative training programmes, fellowships, curriculum development, teachers training, education tool development, accreditation, education policy research and facilitating the monitoring of on-going schemes of DBT.

Building Knowledge Environment

Core facilities and Instrumentation

Capacity for innovation and technology development in biotechnology rests largely on access to core facilities and instrumentation. The DBT is committed to building world-class facilities and its access across the country.

Ironic to the expensive heavy physical equipment the term 'infrastructure' in today's biotech research largely denotes networked resources/skills, centres of excellence (COE) and science clusters which not only provide the physical amenities but also the intangible benefits like specialized skill, competence and niche support. Globally it is felt that networking for sharing skills and resources are prime for successful research. Hence core and niche facilities around established organizations are created to tap and build on the initiatives already happening and to address unresolved scientific challenges. In addition to providing support for core equipment in universities and research institutes, DBT would focus on building facilities for advanced research programs. The existing institutions would be empowered in transforming their expertise for societal benefit.

Specialized centres in and around existing institutes

Food and energy centres

- Establish translational centres for Agri-Biotech partnered with State Agricultural Universities (SAU's) to take forward the transgenics currently developed by public institutions

- Establishment of COEs for pre-breeding
- Establishment of centres for transgenic work
- COEs in marine biotechnology in institutes focusing on bioproduct development from marine environment
- Establishment of at least four centres of excellence in the area of nutrition sciences in agricultural and medical schools with a focus on fortification, biofortification, clinical nutrition, nutritional immunology and nutrigenomics etc.
- Setting up of 5 Joint centre on the similar pattern as existing DBT-ICT, DBT-IOCL and DBT-ICGEB centre for bioenergy
- Centres for natural products

Health centers

- Setting up of clinical bioinformatics units in strategic locations across the country
- Dedicated centres to conduct association studies and correlative biology research to prioritize diseases of national concern where genomics could play a spearheading role in devising appropriate intervention and treatment
- COEs for public-health relevant chronic diseases i.e. cancer, diabetes/vascular biology, neurosciences and Lung-Liver-Kidney
- Organ based disease biology centers with strong association between basic biologists and clinicians
- To establish overseas “COE for vaccine research” to attract overseas talent to facilitate research on vaccines difficult to develop
- To set up centres for regenerative medicine/cell based therapy/bioengineering in existing or new medical schools, engineering schools and institutions
- To establish bio-design inter-institutional Centre at Translational Health Science and Technology Institute (THSTI), Faridabad for ensuring long-term sustainability to biodesign programmes.

Social and Entrepreneur centers

- Establishing COE for social innovation and invention
- Create rural infrastructure for promoting biotech interventions by the prospective farmers and the entrepreneurs like setting up of incubator facilities, technology resource centres, village knowledge centres etc.
- Establish incubator facilities for entrepreneurs to prosper rural industrialization in biotechnology
- Establishment of Rural Technological Innovation & Application Center on a sustainable basis

In addition, technology incubation centers and platforms would be created for nurturing entrepreneurship. For detailed discussion on this pl. refer to section 5.4.

Strengthening core capacities in institutes

- To identify few agricultural universities for research as advanced agricultural biotechnology resource centres
- Strengthening of Biotechnology Information System Network (BTISnet) - a monitoring system for evaluation and upgrading performers. More advanced state-of-art facilities to be provided to the centres in the universities and colleges

- Developing world class computing facilities- supercomputing facilities to be increased, introduction of Cloud / Parallel computing in the country
- Service centres in existing institutions engaged in high-throughput experimental research
- Strengthening existing infrastructure in institutes providing training and degrees in Pharmacognosy to have end to end facility for new drug discovery and development
- Providing basic research infrastructure facilities to Medical colleges and hospitals in Infectious Diseases area.
- Special units 'Intelligent Ideas for Innovation' (III-Units) will be established.

Proposed National institutes

Few national institutes are proposed to be built which would spearhead research and training in highly technical emerging areas of biotechnology and which are highly relevant and specific for the Indian context.

- Setting up of a National Centre for Drug Discovery for discovery and development of natural product based drug candidates
- Interdisciplinary Infection Science Research Centres : A twining institute between North-East Region and Faridabad for collaborative research with focus on high priority public health problems and leveraging expertise across multiple organizations
- Setting up a national Institute on Marine biotechnology
- Establishment of Biotechnology Institute on Rural Development
- National Centre for facilitating resources for low end virtual supplier for smaller organization as well as for high-end critical resources like microarray, knockout mice etc. to be managed by independent public-funded set ups



Validating research for gaining public trust

Technology revolution is always accompanied by uncertainty and fear. Therefore for diffusion of technology in public good, there is a need to gain acceptance on the processes and products. It is therefore important to build resources for enabling validation and for creating products as per approved manufacturing processes. With these goals in mind DBT would constructively support:

- Establishment of a toxicological centre to generate toxicity, safety data for biological and chemical contaminants and adulterants along with GM foods and traditionally used herbs
- Create and strengthen infrastructure in the areas of preclinical toxicology
- Establishment of Validation centres for nutrition claims with a focus to collect valid data on the phytochemical components of different Indian foods
- To improve manufacturing facilities for production of clinical grade material for evaluating promising vaccine candidates through PPP model
- To support setting up of efficient regulatory departments well versed in GCP, GMP and GLP
- To strengthen clinical trial infrastructure in diverse demographical settings

- Nanobiotechnology Translational Research Center- to facilitate and encourage scientists to move the knowledge outcomes with translational values for further validation and prototype development.

The DBT would build appropriate bilateral partnerships in developing R&D infrastructure including but not limited to customized experimental animal resources, Centralized R&D infrastructure for priority public health diseases like cancer, diabetes, vascular biology on PPP models.

Data centres

Patents and publications provide state-of-art on the subject domain and helps researchers identify gap areas for further development. DBT would evolve a National data policy for submission of publications arising out of public funded research to the National data center, which will consolidate it and make it publically available. Also nationally generated databases could be deposited in it.

Comprehensive and critical review summary like disease burden, epidemiological studies, check list of common contaminants/pathogens in bioproducts and biodiversity data helps focus attention on priority areas and validate claims. DBT would encourage :

- Maintenance of electronic medical records in hospitals, including relevant genomic information.
- epidemiological data followed-up by deep phenotyping and correlating with cellular, molecular and cytogenetic data
- Surveillance for infectious diseases of national concern in collaboration with ICMR/DHR/M/o HFW
- To establish surveillance systems or network studies to better assess disease burden in specific target populations
- Support to national database on occurrence of bio- and phytocontaminants to address safety concerns of animal products and promote their export under the WTO regime
- Development of data repositories for promoting translational bioinformatics
- To build a database of scientists in all fields of life sciences for use in mission mode projects.
- Nanobiotechnology Knowledge Centre – for maintaining a dynamic system to update the researchers in specific areas such as drug delivery, diagnostics, sensor, bioseparation, tissue engineering, regenerative medicine, bio-imaging and diagnostics through network of activities engaging specific domain experts.



Repositories

To promote research and development from indigenous efforts and sources, following national repositories would be set up.

Natural products repository

- Repository of extracts, phytochemicals and botanical reference standards for quality assurance of plant-based drugs
- Repository to act as national resource, to be established in collaboration with Ministry of AYUSH
- Accessible to researchers across academic institutions and industries subject to signing a Material Transfer Agreement (MTA)
- Maintaining comprehensive information system for all research leads generated from natural resources

Technology repository

A technology repository to be structured for acquisition, maintenance and transfer of technologies for commercialisation.

- For broad spectrum of intellectual assets- biomaterials, patents, data, copyrights and business methods
- Maintain transgenics, germplasm, markers, expression systems/platforms, clones etc. that were indigenously developed
- Separate repositories for maintaining stem cells and cell lines
- To also contain information on traditional fermented food micro organisms, validated QTL, donor lines and deregulated events
- Global acquisition of technologies including transgenes, markers, germplasm etc. for every major crop grown in the country
- Access transaction to be structured by trained professionals
- Access for affordable solutions, subject to translational validation and subsequent transfer to enterprises for commercialization

Research Opportunities

Human well-being

DBT supports research activities for promoting human health broadly in the areas of human genome research, vaccines, infectious, chronic disease biology, stem cells & regenerative medicine and the biodesign programmes focused on implants, devices and diagnostics.

Human Genome Research

With a vision to convert hospitals currently engaged in treatment to prediction and prevention of diseases using genomic tools, the department would support the following research and developmental activities on priority.

- Understanding of mechanisms of predisposition, initiation and progression of diseases that have multiple low-penetrant genes
- Systems biology approach to generate gene networks for studying genomic pathways
- Expression profiling studies to define biomarkers and therapeutic targets
- Small molecule screening and synthetic biology for better understanding of genetic disorders
 - ✓ impact of these molecules based on genomic information
 - ✓ design and test synthetic peptides and RNA blockers for vaccination and treatment
- Correlation of adverse drug effects with genomic-backgrounds of the patients
- Genetic epidemiological studies especially with reference to cancers most predominant in India (Cervical, Oral, Lung and Breast)

Vaccine research

To alleviate all suffering from vaccine preventable disease, the DBT would continue supporting basic research in immunology and indigenous vaccine development efforts:

- Science of neonatal and maternal immunity, host immunity, immunization and the development of immunological models for evaluating immunity
- Studies on development and validation of new biomarkers of immune function
- Technologies such as gene-based vaccines, virus-like particles, plant-derived vaccines, novel adjuvants and delivery systems aimed at enhancing potency, safety and affordability
- Assessment of disease burden in populations for future vaccine development
- Rapid and cost-efficient production, optimization of formulations, stability profiles
- Technologies aimed at minimizing cold chain and improving delivery systems
- Support quality testing procedures including development of novel cell substrates, multi-use technologies such as platforms
- Improved methods for assessing vaccine efficacy and safety including development of better animal models

The DBT would encourage preclinical and clinical development of vaccines against Rotavirus, Cholera, Typhoid, Rabies human (DNA based), Malaria, Dengue, Tuberculosis, Japanese Encephalitis. New approaches for development of affordable vaccines against Cancer (HPV), Polio, Pneumococcus and HIV would be supported.

An Interministerial Committee has been formulated involving ICMR/DHR, DBT, MOH&FW. MoU has been jointly signed to establish a Centre for Policy Research on vaccine preventable disease. DBT would actively pursue this initiative for achieving disease prevention in Indian population.

Infectious diseases

The DBT recognizes the importance of understanding of disease biology and development of diagnostics and interventions to safeguard public health in the face of threat from emerging pathogens.

Support would be aimed at understanding basic biology of infection and for translational research.

Basic research focus to include:

Basic research initiatives are important for the understanding and treatment of infectious diseases. Understanding pathogenesis, virulence factors, patterns of transmission, host susceptibility and development of new technologies and counter-measures for disease detection, diagnosis and treatment would be important.

- Environmental factors that facilitate emergence, maintenance and transmission of infections: Studies on impact of environmental changes and climatic variability on the emergence of microbes
- Evolution of pathogenic infectious agents that result in changes in their infectivity, virulence, transmissibility and adaptations at molecular level
- Host and pathogen factors that facilitate emergence and spread of infections including the use of antimicrobial and immune-suppression drugs

Translational focus to include:

- Host-targeted interventions as therapeutics specific for infectious diseases: To stimulate innovation in the discovery and development of therapeutics that target host-encoded functions required for infection, replication, spread and/or pathogenesis
- Host and pathogen biomarkers for rapid diagnosis
- Development of assays for high-throughput screening for use in probe and pre-therapeutic discovery. This would also ensure indigenous production of quality laboratory reagents
- Development of new diagnostic tools that can support rapid and accurate diagnosis including field conditions especially for disease of national concern- HIV, tuberculosis, influenza, chikungunya, dengue, enteric diseases, respiratory tract infections, CMV and other opportunistic infections in immunocompromised subjects.

**Human Developmental and Disease Biology- Maternal & Child Health**

This program focuses to accelerate research in the area of Human Developmental and Disease Biology: to understand the mechanistic paradigms underlying foetal growth & development, premature or abnormal birth, complications during pregnancy, and developmental basis of adult onset of diseases. Also it aims to develop preventive & therapeutic intervention for the above conditions.

- Inter-Ministerial Collaboration: DBT-ICMR/DHR - DBT would address health issues of mother and children in comprehensive manner through connecting basic and clinical, operational/ implementation research with participation of the private sector.
- Preterm Birth Program - to achieve appropriate risk stratification of women in early pregnancy for Preterm Birth.
- Child & adolescent obesity and related chronic diseases like cardiovascular disease and metabolic syndrome - to perform studies for evaluation of interventions across pregnancy to early childhood and predict their outcome.

Chronic disease biology

Chronic diseases are generally less responsive to treatment and the treatment response varies

highly among individuals as these diseases do not arise due to a single pathogenic event but due to multiple cellular and molecular changes in the cell.

Hence the vision is to develop personalized medicine and to convert therapeutic approaches to preventive medicine.

Cardiovascular & Cerebro-Vascular

- Understanding vascular biology & Revascularization
- Management of heart failure including cardiac- transplantation
- Affordable and non-invasive diagnostics / imaging for early diagnosis and optimal management of hypertension (including community based)
- Point-of-care interventions to prevent/minimize hypoxic tissue damage
- Devices & Non-Pharmacological interventions
- Rational drug development & Polypills

Obesity & Diabetes

- Monitoring of Glycaemic state (point-of-care & affordable)
- Affordable, stable insulin and alternate routes of insulin (oral/nasal etc)
- Disease modifying therapy
- Beta-Cell regeneration & transplantation

Cancer

New approaches for effective primary & secondary prevention

- Identify high risk population based on Exposure / Genetic profile
- Biomarkers & Non-invasive diagnostics suitable for field / homes
- Cancer Vaccines; monoclonal antibodies, small molecule inhibitors
- Targeted Therapies
- Affordable diagnostics
- focus on Biosimilars

Mental Illness & Neurological Disorder

- understanding pathogenesis
- Development of animal models
- Development of new pharmacological & non-pharmacological therapies, including cognitive retraining paradigms
- Affordable and non-invasive diagnostic approaches including structural, functional and molecular imaging

Stem Cells and Regenerative Medicine

Conventional therapies were based on drug substances to arrest a pathogen or an unlikely cellular event. However the latest in line for clinical therapy is regenerative medicine wherein cells are used as therapeutics. Understanding of developmental biology and disease biology is important for advancing the science of stem cell biology and regenerative medicine. Hence DBT would provide focused support for-

- Innovative models for studying developmental biology in models such as Drosophila – lower animals/higher animals, cell based models (ESC/iPS);
- Innovative disease models in higher animals (farm animals/non-human primates);
- Disease specific cell based models for cancers/hereditary genetic diseases (ESC/iPS);
- Creation of animal models for safety and efficacy study;
- Pilot studies and randomised controlled clinical trials;
- To improve biomedical approaches of clinical therapies involving stem cells based cell therapy and tissue engineering research would be encouraged including generation of patient specific cell lines, basic biology of stem cells, use of cells for screening drugs and studying toxicology.

Biodesign Programme focused on implants, devices and diagnostics

Biodesign programme is a model for inclusive med-tech innovation in the country to provide need-based novel technological solutions for patients. With a vision to create biomedical technology innovators and entrepreneurs to identify unmet clinical needs through clinical immersion and then develop solutions by converting the ideas into indigenous affordable products for clinical applications, the strategy will be as follows:

- To promote “Global Affordable Need Based Development in Healthcare Innovation” (GANDHI);
- To connect medical institutions and its resources with engineering and basic science institutions for development of affordable, indigenous devices, implants and diagnostics through multi-disciplinary approach and international partnership;
- Make in India initiative would includes: a) identify in India, b) invent with India, and c) implement globally;
- Capacity building for pre-clinical and large scale clinical validation; testing; technology transfer and commercialization of the indigenous affordable products;
- Facilitate sharing of ideas, resources, infrastructure and facilities in the country through National Biodesign Alliance

Bioengineering

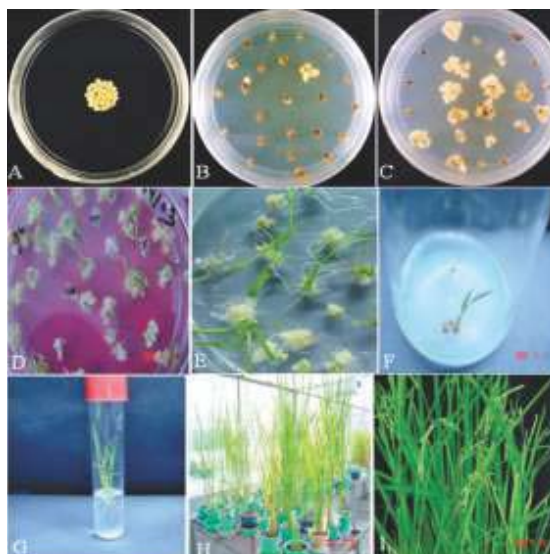
To apply the knowledge of allied quantitative sciences such as physics, mathematics, chemistry, computer sciences and engineering in the domain of biological sciences for effectively addressing the biomedical challenges, the DBT has been supporting innovative projects on bio instruments, devices, implants, bio-imaging, sensors etc.

The programs would be pursued and additionally focused efforts would be aimed at exploring new avenues for technologies:

- a. Technologies for lifestyle related conditions such as obesity and diabetes leading to more cost effective and accurate chronic disease management
- b. Smart Materials –Integration of smart materials and radio frequency identification technology into products to create smart implants and the convergence of medical technologies with traditional devices and minimally invasive techniques for surgical procedures
- c. Outpatient care technologies and telemedicine
- d. To develop simple, rapid, indigenous, low cost medical devices and implants by applying 4 components i.e. affordability, accessibility, availability and appropriateness.

Sustainable Agriculture for food requirements

Agriculture, with its allied sectors, is the largest livelihood activity in India. Sustainable agriculture, in terms of food security, rural employment, and environmentally sustainable technologies is DBT's priority. The DBT strives to adopt modern tools in improving the productivity of the food sector through innovative research.



Crop science

The DBT aims to achieve higher productivity and better quality food while reducing resource inputs through research support to biotechnology programs.

- Basic Research aimed at
 - (a) Improved photosynthetic, nitrogen fixation and nutrient utilization potential
 - (b) Improved reproductive efficiency with regard to yield convertibility
 - (c) Protection of yield loss due to stress/climate change
 - (d) Mitigation of post-harvest loss
 - (e) Enhancement of nutritional value
- Pre-breeding research utilizing genomics information and interfaces with wide hybridization, molecular mapping
- Transgenic crops for resistance against biotic & abiotic stresses
- Heterosis Breeding
- Introgression and pyramiding of useful genetic loci in diverse germplasm
- Studies addressing gaps between QTL and MAS for drought/abiotic stress
- drought (water relations, cellular tolerance, floral biology, stay green) and radiation use efficiency (photosynthesis efficiency, source to sink)

Also as noted earlier (section 3.1.1.1), the DBT would establish Translational Centres for Agri Biotechnology partnered with SAU to take forward the transgenics developed by public institutions and the toxicology of the same could be validated in the proposed toxicological centre.

Animal agriculture

To enhance animal health and productivity through a multi-pronged approach, the research in the areas of breeding, reproduction technologies, nutrition and health care is being and would continue to be supported.

Genomics and Genetic Characterization : Livestock and Poultry- Application of genome-wide marker-assisted selection (GWMAS) for enhancement of production, FCR and disease resistance in indigenous stocks viz. cattle, chicken, buffalo, sheep pigs

Animal Reproduction and Transgenics

- Sperm sexing technique for enhancing productivity
- Biopharming for therapeutic proteins specifically in purification of recombinant proteins
 - Production of biologicals for embryo transfer technology
 - Generation of transgenic animal model for disease /disease resistance
- Development of new tools for detection of silent heat and pregnancy in cattle
- Major multicentric programme on generating transgenic animals in livestock would be launched.

Nutrition

- Metagenomics of gastrointestinal tract of livestock and poultry and identification of metabolic pathways for re-engineering in culturable microbes
- Feed and fodder enrichment by lignin degrading enzymes and plant breeding strategies
- Methane mitigation strategies
- Nutrigenomics for optimization of feed formulation

Animal Food safety

- Affordable animal products including designer egg /meat with adequate food safety and longer shelf life
- Predictive microbiology approaches aimed at ensuring safety of animal products
- Simple and rapid assays for detection and quantitative estimation of incriminating factors such as pesticide, heavy metals, veterinary drugs and other toxic residues in animal feed and products

Aquaculture

India has a coastline of over 8000 Km, an exclusive economic zone (EEZ) of over 2 million sq. Km and hence aquaculture plays a vital role. India currently is ranked second in global fish production, inland capture and aquaculture, and seventh in marine capture production. Fisheries are an important sector in India and are a predominant employment provider to millions of people. However sustainable productivity and management had been a concern.

DBT would leverage biotechnology research to address the concerns and enhance aquaculture productivity thereby contributing to food security. The research program would focus on improving feed and nutrition, aquatic health and breeding techniques for obtaining desired and disease resistance traits.

Larval feed and nutrition

Live feed plays an important role in early developmental stages of the finfish and shellfish larvae and is an essential part of mariculture operations.

- Development of Microdiets for larviculture
- Live feed enrichment with HUFA
- Enrichment of aquafeed with microbial enzymes
- Improve digestive tract and FCR efficiency
- Economically viable alternate source of feed material

Health

Health of the aquatic animal largely depends on the health of the aquaculture environment. Development of healthy brood stock of all cultivable fin and shell fishes is very important.

- Prevention and control of WSSV and vibriosis
- Diagnosis and control of OIE listed diseases in finfishes
- Etiology and diagnosis of diseases like monodon slow growth syndrome
- High health brood stock development

Breeding and genetics

DNA marker technology is being used in various species for trait characterization related to growth, disease resistance and salinity tolerance and could be exploited for enhancing productivity

- QTL identification through genome wide scanning
- Breeding strategies for productivity enhancement
- Molecular coordinated regulation of reproduction
- Application of nutri genomics for nutrient utilization

Products and Processes from Medicinal and Aromatic Plants

Contrary to the popular belief, even today 80% of the world population relies on medicinal plant for their primary health care needs. Medicinal and aromatic plants are increasingly gaining attention among the urban population as chemical drugs are posing severe challenges in terms of development, safety, resistance and cost.

India possesses an unmatched heritage represented by its ancient systems of medicine which are a treasure house of knowledge for both preventive and curative healthcare. The positive features of the herbal medicine, namely, their diversity and flexibility; accessibility; affordability; a broad acceptance by a section of the general public; comparatively low cost; a low level of technological input and growing economic value have great potentials to make them providers of health care that the larger sections of our people need.

Biotechnological capabilities offer unique opportunities to advance our knowledge on medicinal and aromatic plants. DBT has been supporting the salient aspect of the Indian medicine system through research opportunities aimed at understanding the mechanism of action of medicinal plant based drugs, understanding the biosynthesis pathways for commercial application, botanical pesticides & insecticides and studies on genetic diversity. The DBT would now prioritise on the translational aspects of this domain.

- Translational research on leads already available for taking them forward to development of natural products and processes following multi-disciplinary approach.
- A focused programme on translational research on natural products including drugs, formulations, essential oils, cosmeceuticals, resins, gums, mucilages, natural foaming agents etc. to be supported
- Generating genomic resources on medicinal and aromatic plants to enhance the content of the therapeutically important product
- A network programme on aroma engineering on selected crops relevant to the country
- Developing medicinal and aromatic plants based products for animal healthcare
- Support to network programme on anti-viral agents from plant sources

Food and Nutrition

With a vision to address micronutrient deficiency and metabolic syndrome by enhancing nutritional value of food through biotechnology, the following research programs would be strengthened.

Food fortification and biofortification of food crops

- R&D in food fortification and biofortification
- Addressal of micronutrient deficiencies with a special focus on iron deficiency anemia
- Development of newer technologies to improve nutrient bioavailability, protection of vitamins from oxidation and newer fortificants which could provide an alternative source of iron of higher bioavailability

Child malnutrition with a focus on severe acute malnutrition (SAM): To indigenously develop micro and macronutrient formulations for addressal of the incidence of moderate and severe acute malnutrition in children and also protocols to understand digestibility of food protein under chronic under nutrition conditions

Treatment and prevention of diet related chronic diseases: To investigate the genetic factors of obesity, diabetes mellitus and metabolic syndrome relevant to Indian populations and their interaction with different diets and novel targets and approaches for control of appetite.

Functional foods and nutraceuticals for health promotion

- Development of nutraceuticals and functional foods for the prevention of diabetes, obesity, cardiovascular disease etc
- Beneficial role of probiotics and prebiotics in human health. Identification of probiotics and validation of health claims such as in treatment of obesity, diabetes, inflammatory bowel disorder etc. Identification of prebiotics and development of synergistic combinations of probiotics and prebiotics

Shelf life extension of foods

- Development of newer technologies and methods for shelf life extension such as high pressure processing, edible packaging material, nanotubes, nanostarch, nanoclay and enterocins for inhibition of microbial contamination.

Food safety for prevention of food borne diseases and health hazards

- Development and or establishment of newer, cost effective, sensitive and simple methodologies to quantify the potential toxic agents in food, feed and water and also development of sensitive methods for detection of genetically modified foods

Bioresource utilization, management and biodiversity

The environmental strategy that DBT would prioritize is utilization of biotechnological agents (microbes and their products) for promoting ecofriendly processes, ecorestoration of habitats and impact assessment of climate change for preserving this unique biosphere.

Bioprospecting

Bioprospecting is being practiced by mankind for centuries for applying the useful processes and products in nature. But with progress in science, the active ingredients that were once directly obtained from their source are now being synthesized in laboratory more so with strides in genetic engineering.

Value-added Biomass & Products from Natural Resources

To enable sustainable utilization and enhance the intrinsic value of natural resources, research efforts on value-added products from nature would be supported.

- Commissioning study to find out the global markets and priorities for various natural products, market intelligence on natural products to be an integral component
- Launch a National Mission on Bioprospecting and Product Development from Lower & higher plants, Fungi & Lichens, Seabuckthorn, Phyto-pharmaceuticals
 - Microbial prospecting for industrially important compounds
 - Prospecting and product development of non-timber forest product- Gums, resins, tannins, mucilages
 - Phytomedicinal Research
 - Biomaterials and Bioplastics
 - Gums, resins, dyes, tannins, mucilages, essential oils, natural foaming agents

A National Natural Products Repository has been proposed for extracts, phytochemicals and botanical references for plant-based drugs (section 3.4.1).

Marine Resource: The non-food sector of marine biotechnology offers phenomenal opportunities for process and product development. The emphasis would be to study the uniqueness of the marine ecosystem and its diversity of life forms for critical source of products that would include food, bioactive compounds, and biomaterials having medical and industrial applications.

- Biofuels from marine algae
- Extremophiles
- Novel microbial enzymes
- Biomaterials
- Metagenomic approaches to bioactive molecules
- Whole genome sequencing of native commercially important aquaculture species.

Environmental management

Eco-restoration- Biodegradation of toxic and waste effluents and bio restoration of habitats

Metagenomics

- Exploitation of the biosynthetic and bio catalytic capacities of the microbial communities in waste management and pollution mitigation.
- Development of treatment strategies based on metagenomic knowledge
- Prospecting of catabolic genes from Common Effluent Treatment Plants
- Metagenomic of biofilm/ community in removal of Volatile organic Carbon
- Metagenomics of anaerobic niches

Biodiversity

Enhance quality and refinement of inventory & monitoring of plant and animal biodiversity through biotechnological tools.

- Impact assessment of climate change on biodiversity and characterizing biodiversity elements for ameliorating climate change impact and sequestering atmospheric carbon
- Standardization of tissue culture and other micro-propagation techniques, and re-introduction of the plant species.

Industrial biotechnology

Technologies for clean energy

With a vision to utilise biotech research opportunities for bioenergy production for ensuring energy security in the face of threat from renewable resources, the technologies for green and clean bioenergy would be strengthened.

The experiment with first generation biofuels has opened the debate of fuel versus food and food security could be jeopardized in search of energy security using such fuels. Hence there would be a paradigm shift in our support to second generation biofuels, which are made from food crop residues or industrial wastes as well as from non-food crops, which do not compete with food or fodder.

The DBT intends to achieve cost efficient, commercial scale technology for production of biofuels from algae either through harvesting and oil transesterification or direct conversion to bio-oil. With this larger vision, Department would support basic research projects on feedstock improvement and on algal biofuels (microalgae and macroalgae).

For achieving commercial production of Biofuel from different feedstocks for 20% blending, technologies and research on Biofuel would be promoted including bioethanol, commercially viable lignocellulosic ethanol from agricultural and forest waste, green diesel, algal biofuel, biobutanol, biohydrogen, biochemicals and fuel cells.

Bioenergy centers would be supported (also refer to Section 3.1.1) for promoting commercialization of biofuels.

In addition research on enzyme and protein engineering, metabolic engineering and synthetic biology; system biology, downstream processing and bioprocessing engineering, bio refinery approaches and life cycle assessment would continue to be prioritized for support.



Bioenergy constitute the thrust area in synthetic biology and DBT would support the initiatives in this area. Synthesis of drop-in biofuels: synthesising pathways for production of higher alcohols, fatty acids and hydrocarbons in *E. coli* and yeast; synthesis of aminoacids, biobutanol; synthesis of furanics from biomass; Metabolic Engineering of *E. coli* for biobutanol; Metabolic Engineering of *Saccharomyces cerevisiae* for co-fermentation of glucose and xylose; ethanol fermentation using

bioresources including rice straw; and engineering algae for growth improvement and lipid content would all be prioritised for support.

Biosystems and bioprocess engineering

Innovative and efficient solutions are required for the development and improvement of sustainable bioprocesses of commercial interest, taking into account the environmental requirements and constraints involved in large scale production processes. Hence DBT would support interdisciplinary approaches towards analysis and synthesis of complex cellular systems based on the hierarchical structure and decomposability of biosystems. It would also aim to integrate recombinant technology and process design, as well as in silico modelling and process systems engineering for efficient bioprocesses development.

- manipulation of biosystems
- metabolic engineering to provide novel enzymes, pathways and cells
- bioreactor operations
- bioconversion and separation processes
- integrated bioproduction systems for chemicals, fuels and pharmaceuticals from renewable materials
- design of synthetic enzymes/cells for improved production of bio-products, process analytical techniques for bioprocesses

Silk biomaterial

- To focus only on addressing newer and emerging development in silk biology and its applications
- A new DBT-CSB joint programme on silk as biomaterial to be initiated. This area is an emerging field having immense potential since India is a producer of all four major types of silk.
- Post-harvest technology development towards improving the quality of silk
- Multi-locational field trials of transgenic silkworms resistant to grasserie disease caused by BmNPV to be supported in collaboration with CSB institutions and state sericulture departments
- Technology development in marker-assisted selection in breeding improved varieties of silkworm and mulberry

Genome engineering technologies

To make genome-wide analysis and engineering technologies accessible and affordable for wider use in Life Sciences, the department has initiated the new area “Genome Engineering Technologies”. Emerging technologies like Genome Manipulation, Editing and Interference by CRISPER, TALENS and RNAi; Nucleic Acid Chips for genetic variations and chromatin remodeling; Single Cell Genomics and Mass-Cytometry etc. are proposed to be established. The focus would be to create a larger user base and enable it to address important basic questions:

- Applications in the study of emerging diseases
- To manipulate/engineer genomes
- Develop transgenic systems
- Develop genome-based diagnostics

Nanobiotechnology

Today's scientists and engineers deliberately make materials at the nanoscale to take advantage of their enhanced properties such as higher strength, lighter weight, increased control of light spectrum, and greater chemical reactivity than their larger-scale counterparts. The science, engineering, and technology conducted at the nanoscale is gaining rapid attention and biologists are increasingly adapting it to understand the biological machinery and for developing technologies to create solutions in the areas of health, agriculture, food and environment. Nanobiotechnology requires a multidisciplinary research approach bringing physicists, chemists, biologists and engineers on a common platform for engaging in knowledge exchange towards targeted innovations.

DBT would continue to engage in advancing research and fostering innovations in the areas such as:

- Designing of new therapeutics and targeted drug delivery vehicles for cancer, arthritis, neurological and other important diseases
- Novel formulations to enhance the efficacy of existing drugs and expand their therapeutic spectrum
- Nano carrier systems for siRNAs therapy
- Diagnostics and imaging for early disease detection
- Design and development of smart nanomaterial for bio separation, tissue engineering and other medical applications
- Sensors for detection of chemicals and pathogens in food and crops, Nano carriers system for pesticides, pheromones, nutrients /fertilizers
- Nanoparticles-mediated gene or DNA transfer in plants for development of pest-resistant varieties, and improving the nutritional qualities of food and smart packaging system etc.

Inclusive development

To develop and adopt biotechnologies focussing on improving quality of life and living of the rural and the marginalised sections of the society including human health and employment opportunities.

In line with the Government's principles of ensuring economic and social equality, DBT is committed in upliftment of the marginalised sections of the society through biotechnology. DBT would continue to prioritise societal and NER programs for ensuring inclusive development.

Societal programmes

The societal programme has three components i.e. women, rural community and SC/ST population. The primary aim of the programme is the economic upliftment of the community through application of biotechnology.

Focused support would continue to be extended to research endeavors on health and sanitation, environment and biodiversity, animal husbandry, dairy and fisheries,



integrated farming, multi-institutional, multi-agency driven integrated networking projects on sustainable use of bioresources, product / process development and value addition all envisaging societal upliftment.

In addition, efforts would be directed in documenting farmer/ community innovation, enabling farmers in patenting innovations and traditional knowledge, establishment of centers of rural entrepreneurship development and rural bioresource complex/ hubs. Initiatives would be taken for cooperative efforts through networking of institutions, individuals, NGO, Krishi Vigyan kendras and others working on similar lines.

Promoting biotech in the North Eastern Region (NER)

As per mandate 10% of DBT's annual budget is earmarked for promoting development in the NER comprising eight States viz, Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura.

The Twinning R&D program for NER was initiated in the year 2010-2011 towards developing core competence and core capacity in different areas of biotechnology viz., agricultural, veterinary, pharmaceutical, biomedical engineering, bioinformatics, food and nutrition, health care including alternative medicine, nanotechnology and environmental biotechnology, through joint venture, between two or more institutes, where one of the institute is from North East India. This collaboration is expected to play a crucial role in upgrading the skills of R&D activities of scientists working in NER.

The DBT would continue its support for research in the region through twinning program.

In addition, biotech hubs, infrastructure and capacity building activities already initiated would be pursued.

Bioinformatics, computational and systems biology

Apart from being a platform technology for research in the fields of medicine and agriculture, bioinformatics as a discipline is being supported for R&D. The areas to include are: NGS data analysis, computational genetics, metagenomics, design of functional molecules, understanding nucleic acid, chromatin, protein structures and their interactions, marker assisted breeding, secondary metabolites, genome and proteome analysis.

Nurturing Entrepreneurship - Intellectual Property Landscaping, Technology Transfer, Incubators, Entrepreneurship, SME Support Systems

DBT has been promoting bioscience education and research since inception. Since the last few years DBT has been pursuing commercialization of technologies arising out of the research activities for the benefit of the society. The major achievement in this was PPP schemes like SBIRI and BIPP which initiated funding to biotech enterprises.

With the establishment of the Public Sector Undertaking Biotechnology Industry Research Assistance Council (BIRAC), many more new initiatives had been commenced to meet the industry requirements for seed and developmental funds and nurturing the innovation ecosystem.

DBT has a key role to play in the areas of transfer of technology, licensing, validation and in creation of infrastructure and training for the above requirements for commercialization of technologies. Without entrepreneurs the bench results would not meet the market and hence nurturing entrepreneurship continues to be a mandate. Hence entrepreneurship programs would be supported on priority and the current 'biodesign' program would be expanded in other IITs, medical schools and institutes across the country.

Support for business incubation infrastructure, technology validation and scale-up infrastructure

- Science and technology park (STP) environment with distributed investment made in 5 zones of the country (North, South, West, East and Central)
- The five clusters may require creation of 40 technology incubators, with average of 8 incubators in each of these clusters providing technology incubation, validation and scale up support to enterprises located within these clusters

Technology Management

Professional development and licensing of technologies for accelerated commercialization

Institutional level capacity creation

Over 150 Technology Transfer Organizations (TTO) to be spread across the country

- with 10 professionals per institution, the need for minimum of 1500 professionals to be developed in the span of next 10 years

- Support to TTOs with funding
- Reward and recognition mechanisms for inventor and technology management professionals

Technology accelerator

DBT would establish/strengthen/encourage domain specific 'Innovation Accelerators' and 'Translational Accelerators' accessible to public- institutions and SMEs to successfully incubate discoveries, and take them through the validation stage, and package them for transfer and licensing. The Translational Accelerator would offer support for preclinical work, clinical trials, field trials of modified crops/organisms, compliance with regulatory requirement and production as per Good Manufacturing Practices (GMP) standards.



Through BIRAC, the Department would create and sustain 'Translational accelerators' in key locations. The facility to include validation and transfer centre for facilitating technology licensing.

Technology repository

DBT to create a centralized repository for technology emanated from research. The repository could be used for depositing technologies developed indigenously and for global acquisitions. The access transaction to be structured by trained professionals for affordable solutions. The repository to include broad spectrum of intellectual assets- biomaterials, patents, data, copyrights and business methods. The facility to include validation and transfer centre for licensing. This has been referred in detail in section 3.4.2.

Nurturing Bio entrepreneurship

It is essential for DBT to enhance its effective engagement in triggering, nurturing and sustaining bio entrepreneurship by creating the interventions indicated above and by intensive outreach efforts that ignites young minds to think adopting science for inclusive development in the country.

- Working with BIRAC to nurture and support the Innovation Ecosystem and Bio Entrepreneurship
- Setting up of technology development centres within existing academic Institutes with focus on biochemicals/biofuels, therapeutic/diagnostic biotechnology, bioremediation. They should be mandated to provide access of their resources to both academia and industry for pilot testing their technology and accelerate commercialisation.
- Establishment of incubator facilities for entrepreneurs to prosper rural industrialization in biotechnology
- Establishment of Rural technological innovation & application center on a sustainable basis
- DBT would also be implementing a new scheme 'Encouraging development and commercialization of inventions and innovations' for DBT scientists of autonomous institutes to explore entrepreneurship.

Public-private partnerships

The DBT's public-private partnership programs were initiated in the year 2007 for research activities involving funds from both government and the private partner. More research programs

are currently being funded by BIRAC, a section 25 company of DBT. BIRAC is a new industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make them globally competitive. BIRAC has initiated several schemes, networks and platforms that help to bridge the existing gaps in the industry-academia innovation research and facilitate novel, high quality affordable products development through cutting edge technologies. Some of the on-going programmes include Biotech ignition grant scheme (BIG), Small business innovation research initiative (SBIRI), Biotech industry partnership programme (BIPP), contract research scheme (CRS), Bio-incubators support scheme (BISS), Grand challenge-India, University innovation cluster among others. DBT would partner with BIRAC in PPP initiatives.

DBT will further strengthen its PPP in diverse areas of research and development including building resources and centres of excellence, imparting education and training especially bio entrepreneurship and in accelerating technology from lab to market. Emphasis will be on:

- Support for business incubation infrastructure, technology validation and scale-up
- Technology management and licensing of technologies for accelerated commercialization
- Improved pilot manufacturing facilities that produce clinical grade materials
- High throughput transgenic platforms to be established. These could serve as a common resource facility to undertake work on relatively difficult crops e.g. pulses, oilseeds, cereals etc. Transgenic platforms available in the public domain can be provided to the industry and transgenics could be developed in a contract research mode.

Intellectual Property Landscaping

- Run awareness program on IPRs to raise awareness about their benefits and value to both right holders and public: making scientists and researchers aware of the need to protect to their inventions.
- Build an atmosphere that leads to generation of IPs and their protection, to further stimulate innovation.
- Facilitate commercialization of IPRs by promoting collaborations between R&D institutes, industries, academia and funding agencies.
- Promote exchange between IP offices and scientists.

Biotechnology and society

Biotechnology is widely used for producing drug substances and in enhancing food productivity, both of which are for direct public utility. Hence the Department is committed in ensuring safety of the products and processes generated through biotech research so that they are eventually accepted by the end user for whom it is produced, to gain public acceptance.

Ensuring safety- Regulation of rDNA products

At present, the RCGM functions in DBT to monitor the safety related aspects in respect of all recombinant DNA activities and projects involving genetically engineered organisms/ hazardous micro-organisms and controlled field experiments research in four areas namely human and animal healthcare, agriculture, industry and environmental management. RCGM has also brought out manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research, use and application including

industry with a view to ensure environmental safety. RCGM reviews and issues the clearance for import/export of etiologic agents and vectors, germplasms, organelle, etc. needed for experimental work/training and research through a multi-level process of assessment undertaken by scientific experts.

The BRAI draft bill prepared by the DBT in 2008 had proposed BRAI, a regulatory body in India for utilization of biotechnology products including genetically modified organisms(GMOs). The regulatory body will be an autonomous and statutory agency to regulate the research, transport, import and manufacture of biotechnology products and organisms.

GM crops as food: With the Indian government's approval for field testing of GM crops, the role of the DBT which is part of the RCGM becomes all the more significant. It would encourage and support research on GM crops. To validate GM food, the DBT would establish a toxicological center for testing toxicity, safety and biological contaminants and adulterants.

Encouraging safe processes

The safety of drugs produced through biotechnology rDNA technology are governed and regulated by RCGM as described above. After experimental trials as per RCGM, the products are further reviewed by independent regulatory body for human trials. The current timelines and regulatory steps for the process are not user friendly. A process reform table of current qualitative and quantitative limits, mechanisms and timelines is urgently needed. The Department intends to support regulatory reforms with respect to preclinical and clinical trials for animal and human experiments.

The DBT recognizes that it is important to facilitate safe processes and hence would initiate creation of

- Infrastructure in the areas of pre-clinical toxicology and clinical trial protocols
- Customised experimental animal resources in strategic locations across the country
- Infrastructure in the areas of preclinical toxicology
- Clinical trial infrastructure in diverse demographical settings
- Manufacturing facilities for production of clinical grade material for evaluating promising vaccine candidates through PPP model
- Efficient regulatory departments well versed in GCP, GMP and GLP

In addition, discrepancies on therapeutic applications of stem cells have now been clarified in the new regulatory guidelines for research and therapeutic applications of stem cells brought out by DBT in collaboration with ICMR. To ensure environmental safety in the course of manufacturing of bioproducts, the DBT proposes to implement environmental regulation policy.

Communicating biotechnology

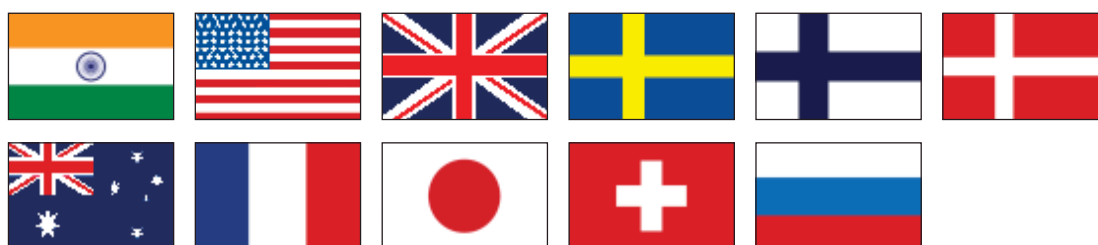
It is important to raise public awareness of the modern tools of biotechnology and how it could improve our well-being, offer food and energy securities and helps in preserving our environment. With this mandate, DBT would engage with not-for-profit and other professional organizations' to clearly articulate scientifically the benefits, risks and impacts of biotech products for easy understanding of society.

The scope of biotech is very wide. The application of tools of genomics for diagnosis is rapidly growing. Hence inter-ministerial efforts would be coordinated towards conducting public outreach programs aimed at educating people regarding genetic basis of diseases and to encourage participatory genetic research by involving families and communities. Data centres would provide a focal point on information about the various biotechnology research impacts for interested public.

Biotechnology Cooperation

Exchange of ideas and information is vital in promoting and sustaining research and development. It helps in innovation and in finding newer solutions to long battled challenges. DBT would continue to encourage research ties nationally and internationally. The collaboration to be included would also include private players for attaining competitive advantage.

International cooperation



There is a need to enhance our own capacity to comply with our commitments and to enable our flow of resources. The need is to make International Collaboration a top priority and ramping up of the existing efforts. DBT would pursue global partnerships with governmental organisations, non-governmental organisations and philanthropic research foundations for multinational projects.

- A strategic environment would be fostered for global public-private partnerships
- Efforts would be made to strengthen the national biotech service sector such that India is the first global choice as a biotechnology service provider in the areas of genomics, proteomics, data-mining etc
- DBT would organise international scientific meetings twice a year to debate and discuss scientific grand challenges
- Collaborations with Asian and African countries would be pursued for improvements in the life and living of rural population including innovative farming system
- Effective functional alliances would be forged for overseas exchange and clinical training programmes

The special focus would be on the following initiatives:

- DBT in collaboration with international alliances would support the establishment of Virtual Joint Centres in Agricultural Nitrogen essentially through a large research grant that has additional flexibility to enable support to deliver the partnership and to enable existing resources to be allocated to the project.

- New multimillion India-UK research centres -The DBT and the UK Medical Research Council (MRC) is proposed to fund three major global research centres. The centres will take a global perspective in tackling some of the largest global health problems of today and foster the next generation of researchers with specialist skills.
- DBT and Bill & Melinda Gates Foundation to address global health and development needs in developing countries through joint funding.
- DBT would also leverage strategic partnerships with global players in the building of the national institutes and in establishing the 'centers of excellence' (discussed in section 3.1.1. and 3.1.3).
- Focus on development of international exchange programmes in the area of clean energy and biofuel for strengthening policy, research & commercial status.

National alliances

Biotechnology is an interdisciplinary science and hence close cooperation with other agencies and departments is foremost in attaining best impact from our research efforts. Inter-ministerial cooperation between the agriculture, health, education, rural mission, women development etc would be forged along with cooperation with state governments and state universities in attaining our goals.

The following would be specifically pursued:

- Specialized clinical courses for biotechnologists in association with MCI
- Translational centres for agricultural biotechnology by partnering with SAU
- Molecular epidemiological disease surveillance to be encouraged with ICMR
- ICMR to be engaged in supporting research and development activities aimed at developing affordable diagnostics and therapeutics of diseases of national concern through networking
- Epidemiology survey from rural areas, primarily, through the National Rural Health Mission
- Establishment of natural resource repository in collaboration with Ministry of AYUSH
- Alliance among DBT and other user ministries like agriculture, women and child development, food processing industries, health and family welfare in the areas of Nutrition and health to be established so as to be the technical arm of the “National Nutrition Mission”
- Establishment and functionalization of BRAI with Ministry of Environment
- Collaboration with BIRAC for nurturing entrepreneurship, technology acquisition and commercialization
- Alliance with Agriculture Ministry including ICAR on agricultural biotechnology research including aquaculture and animal biotech initiatives.
- Partnerships with MNRE for bioenergy projects
- Enhancing functional global partnerships in science through interactions with Ministry of external affairs.
- Establishment of offices of BIOCONNECT at 20 institutions (preferably university locations) to promote forward-thinking interaction and exchange between stakeholders in academia, industry, government agencies, trade, professional services and financial organisations.



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