NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY-2014

(BIOTECH STRATEGY II)

Department of Biotechnology
Ministry of Science & Technology
Government of India
NATIONAL BIOTECHNOLOGY
DEVELOPMENT STRATEGY-2014

(BIOTECH STRATEGY II)

SECTION – I

EXECUTIVE SUMMARY
NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY-2014

(IN FULFILMENT OF BIOTECHNOLOGY VISION 2020)

MOVING AHEAD FROM STRATEGY-I of 2007

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 focused 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. The strategy sought to address a number of challenges in terms of R&D; creation of investment capital; technology transfer, absorption and diffusion; intellectual property regime; regulation standards and accreditation; tailor-made human capital for science and innovation and public understanding of biotechnology.

Most of the new initiatives announced in the 2007 Strategy are in place as can be seen in the Annexure.

Further, new and novel institutional mechanisms inspired by the government, but functioning outside it, have been put in place to facilitate a march towards genuine world-class technological competence, biotech innovation and increased national impact. While recognizing several accomplishments, it should be pointed out that one of the major challenges, still requiring attention, is the issue of biotechnology regulation.

Meanwhile, 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. In light of this, it is important to redefine the paradigm of relationship between government, academia, industry and civil society. This is critical for the new era of science-driven, society relevant innovation and entrepreneurship. Newer instruments of connectivity are continuously needed. Scale up and sustainability are important for novel efforts and approaches to make institutional mechanisms of
innovation empowering. Human resource policies have to be reshaped to bring in breadth and depth as accelerated growth is propelled by both a highly skilled workforce 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. Regulation, standard setting and support of infrastructure for all this require attention on priority.

The implementation of Biotech Strategy 2007 has provided an insight into what works and what does not in the national context. A new Strategy must reflect on error-correction and redesign in consonance with the new higher benchmark for performance and societal impact. It should also seamlessly build on the earlier Strategy to accelerate the pace of growth of biotechnology sector. 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-2014 (hereinafter referred to as ‘Strategy-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 consultations have resulted not only in identifying guiding principles that will drive Strategy-II but also in detailing the instruments through which these principles will be implemented. These are outlined below.

**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 toward 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; and bio-manufacturing;

- **Empower**, scientifically and technologically, India’s incomparable human resource;

- **Create** a strong infrastructure for research, development and commercialization for a strong bioeconomy;

- **Establish** India as a world class bio-manufacturing hub for developing and developed markets;

**TEN GUIDING PRINCIPLES THAT WILL DRIVE STRATEGY-II**

Consultations with stakeholders have identified the following 10 guiding principles that shall drive the renewed mission through Strategy-II and these can be applied to R&D, innovation and solution finding for scientific excellence in education, agriculture, health, energy, environment and bio-manufacturing:

1. **Build top-notch competence in technologies directly relevant to the growing bioeconomy**

   - Existing technologies (e.g., genetic engineering, high throughput systems for DNA and RNA analysis, mass-spectrometry)

   - Emerging technologies (e.g., synthetic biology, systems biology, bioinformatics for data-intensive discovery, advanced proteomics, advanced imaging)

   - Effectively linked fundamental science with other sciences and technologies for novel bio-applications (e.g., nanoscience, material science, chemical biology, physical biology, ICT)

   **Instruments for implementation:**

   ✓ New, multiuser, accessible Regional Advanced Technology Platforms with preferred university location, linked to incubators.
New centres on the lines of Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore for all bio clusters.

Advanced technology platforms linked to Inter-institutional Centres

2. Continue to provide strong support to basic, disciplinary and inter-disciplinary sciences

- Sustained support to basic sciences is critical

- Encourage multi-disciplinarily research in biology and integrate it with quantitative and engineering perspective at every level; attract non-biologists to address biological questions

- Complement individual excellence with mission and team-driven approaches to transform basic findings into applications.

**Instruments for implementation:**

- **Set up Centres of Excellence and Innovation**

- **Grand challenge, network programmes to be supported.**

- **Inter-institutional and DBT partnered centres to be set up**

3. Encourage use-inspired discovery research

**Building on what has been accomplished**

- New schemes and mechanisms will be added to build on existing strengths:
  - 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 will be created for placement of industry workforce in academic environments.
  - New mechanisms will be put in place for transnational public-private partnerships.
  - Wherever appropriate, technologies will be globally sourced.
  - Special units for ‘Intelligent Ideas for Innovation’ (III-Units) will be set up.
This should have an inherent potential for translation into new or novel applications

Research focus needs to be linked to major problems with early identification and filtration of leads

New institutional mechanisms are needed that facilitate nurturing of promising leads and taking them to a logical conclusion.

Innovation cartography expertise is necessary to identify the tools to be developed that can facilitate design of solutions.

**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.

The illustrative programme of this nature will include human microbiome, molecular understanding and signature of premature birth, new drugs target for cancer through chemical biology, enigma of fatol 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.

4. **Increased investment in R&D directed in such a manner as to improve economic and social impact**

**Creating a pipeline of socially relevant products**

- Innovation for socially relevant biotech products in the areas of food and feed, human health and wellness, animal productivity, energy and ecological security, and bio-
manufacturing requires a top-down approach, global consortia and critical resources. Other essential factors include:

- Diversified human resource for early translation, pre-clinical and clinical studies
- Strong technology platforms that are widely accessible
- A two-way approach to idea generation: bench-to-bedside and bedside-to-bench (or lab-to-land and land-to-lab)
- Establishment and nurturing of open innovation centres
- Network of clinical sites or testing facilities as appropriate.

➢ Affordable innovation is a key requirement for sustainable systems for all sector related to food and nutrition, health, environments and natural resources. Demand creating policies and measures are required by multiple stakeholders.

➢ Policies and investments need to be strengthened to promote R&D innovation for development of affordable products for Indian and global market.

➢ Investment has to be increased to critical levels and models of public R&D funding have to be diversified for ensuring success of innovation and entrepreneurship.

➢ Investment in R&D to be so directed towards enhanced turnover of biotech sector, creation of jobs, creation of affordable products, and human impact of biotech product.

**Instruments for implementation:**

✔ *Put in place appropriate policy instruments to create demand*

✔ *Incentivise R&D in affordable innovation, demand forecasts ahead of time by government agencies, facilitate wide use of safe, effective technologies, support public-private partnerships, pricing mechanism to balance consumer interest and innovation by local stakeholders.*
5. Promote connectivity in R&D through national or regional alliances

**High-powered consortia for better coordination**

- High-powered, multi-stakeholder consortia will be set up:
  - To implement biotech missions ensuring agricultural- and food security of economically weaker sections, enhancement of animal productivity, health and wellness of vulnerable populations, and environmental safety;
  - To bring about better coordination and enhance synergy; and
  - To address cross-cutting issues and remove bottlenecks, if any, in this regard

**New paradigm of connectivity**

- It is important to create a new paradigm of connectivity between government, academia, industry and not-for-profit organizations dedicated to quality innovation.
  - Enabling and empowering strategies will be linked to financial support.
  - Advanced technology platforms will be made accessible to SMEs and start-ups.
  - New schemes and principles will be used through consortia-based approach.
  - Connectivity has to be promoted within public academic space, within private sector, within government agencies, and also across sectors.
  - It is critical to create new concepts of public-private partnerships and entrepreneurship to make India an innovation and entrepreneurial hub.
  - The talent pool, research resource and disciplinary strength is often spread and effective team based long term collaboration is difficult to achieve. National consortia and alliances focused on grand challenges, functioning autonomously and with long term support to be established in key areas.
Global partnership need to be strengthened to leverage the interdisciplinary skills and competencies.

**Instruments for implementation:**

- Inter Institutional Centres, DBT Partnership centre and national alliances as key institutional model to be supported with autonomously functioning governance system.
- 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.
- Promote and strengthen establishment of bio-clusters to ensure connectivity.
- Build upon existing global partnerships and develop new models of multilateral alliances involving public, private and non-governmental organisation.

6. **Build world class translational capacity**

**PROMOTING INNOVATION LANDSCAPE**

- Translational capacity has to be embedded in all major research centres and programmes.
- Capacity includes relevant talent creation and retention, institutional mechanisms that make research tools and resources accessible, backed by rapid training possibilities for many.
- World class translational capacity is achievable in the medium term only if it is valued enough at the national level as a complement to other components of research.

**Nurturing bio-entrepreneurship**
In order to enable Indian biotech enterprises to enjoy sustainable competitive advantage to deliver affordable products, the following measures will be taken:

- Strengthening of the existing Ignition grant scheme through Biotechnology Industry Research Assistance Council (BIRAC)
- Support will be provided to business incubation infrastructure, technology validation and scale up infrastructure.
- In a bid to create technology capabilities at the institutional level, about 150 Technology Transfer Organizations (TTOs) will be set up across the country.
- A technology repository will be created for a broad spectrum of assets (e.g., biomaterials, with focus on acquisition and access for commercial and social engineering.

**Instruments for implementation:**

- 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 on moving head. The Translational Accelerator would help to complete preclinical work, clinical trials, field trials of modified crops/organisms, compliance with regulatory requirement and production as per Good Manufacturing Practices (GMP) standards.
- Use BIRAC (through its regional centres) to create and sustain ‘Translational accelerators’ in key location.
- Creation a scheme to popularize technology transfer training.

7. **Strengthen Regulation, Accreditation, Validation And Standards**
It important to build a world class regulatory system that is science based, transparent, efficient and dedicated to the safety of consumers and environment

**Biotechnology Regulatory Authority of India**

- A Biotechnology Regulatory Authority of India (BRAI) is proposed to be set up as an independent, autonomous, science-based and professionally-led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes.

- DBT was entrusted with the responsibility for setting up of the Authority. A draft Bill is currently pending in parliament in this regard.

- Existing mechanisms, however, would continue till a full-fledged body is created with the required infrastructure and fully functional autonomy.

- Such a system will build confidence among the civil society, farmers, consumers and the scientific community alike

- A rigorous but transparent regulatory system will also boost the confidence of the industry in investing in the biotech sector

- Regular flow of new technologies will also be ensured

**Strategy and Instruments for implementation:**

- Establish Biotech. Regulatory Authority of India through appropriate legislation.

- Improve existing Biotech. Regulatory system based on RCGM and GEAC to make it scientifically strong, professionally competent, conflict free and transparent and backed by sound validation infrastructure

- Embed training and re-training of regulatory professionals for regular and periodical skill up-gradation within the system

- Regular oversight by inter-ministerial committee

- 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 decision by concerned Central/ State Ministries.

8. Investing In World Class Human Capital - Nurture An Outstanding Workforce As Well As Leadership For R&D In Both Public Sector And Industry

New Schemes to address gap areas

➢ Several measures have been contemplated:

• Web-based portal for study material in biotechnology for easy access to students and teachers

• New courses to be included

  o Dual degree (3 years) in MSc/MBA in bio-enterprise management, agri-business management and pharma-business management

  o MSc programme for physicians

  o MSc programme for veterinary professionals

  o MSc programme in Medical Bioinformatics

  o MD/PhD programme for physicians (with Fellowships)

• Current capacities for short-term training will be transformed to make it more skill-based

• Separate Overseas Associate Fellowships for Undergraduate- and Post-graduate teachers

• Establish 5 EMBL (European Molecular Biology Laboratories)-like centres in the country
Expanding the Star College Programme

- Access to quality undergraduate education is very critical as it lays the foundation for a lasting and productive science career. It is intended to expand the Star College scheme to 1,000 colleges across the country

- This has to cater to the needs of discovery, translation, manufacturing, commercialization and diffusion into markets and public systems

- Bioscience, inter discipline science and biotech programme in 25 selected universities to be strengthened as ‘A’ Star programme

**Instruments for implementation:**

- Measures to be attract higher quality students to bioscience and biotechnology. Master and Ph. D level branded programmes in bioscience/biotech for domain programme in medical veterinary, agriculture, forestry and engineering domain. 20 such centres to be established in existing institutes as DBT partnered centre

- More ‘Finishing schools’ to be set up in partnership with industry

- Involve industry in curriculum preparation and in actually teaching courses

- New scheme to be launched to increase mobility of industry professionals into academic institutions and vice versa

- Promote bioscience and biotech higher education and research programme in engineering system.

- 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.

9. Strengthen Institutional Capacity with redesigned governance models
• To cater to the research needs and meet the requirement of discovery based innovation driven translational research, new institutional capacity is critical.

• Institutional redesigning in terms of new governances models needs to be explored to allow for new research models to be implemented.

• Institutional capacity strengthening can be at universities, research institutes, private sector and non-governmental organisation.

**Instruments for Implementation**

- DBT – partnered Centres of Excellence
- Inter-institution centres
- Virtual network centres

10. **Create a matrix of measurement of process 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

- Put in place a built-in mechanism of reward and penalty

Announcement made in the National Biotechnology Development Strategy (2007) and action taken on the same

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<td><strong>REGULATION</strong></td>
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<td>Biotechnology Regulatory Authority of India (BRAI) to be established</td>
<td>• A draft document for establishment of BRAI was placed in public domain for suggestions from concerned stakeholders.</td>
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<td></td>
<td>• Process of inter-ministerial consultation completed. Bill is likely to be introduced in the Parliament soon.</td>
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<td><strong>INTER-MINISTERIAL COORDINATION</strong></td>
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<td>High-powered Inter-ministerial Coordination Committee to be set up</td>
<td>• Committee set up Inter-ministerial coordination issues discussed.</td>
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<tr>
<td><strong>PROMOTING BIOTECH INDUSTRY</strong></td>
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<td>Small Business Innovation Research Initiative (SBIRI) to be strengthened.</td>
<td>• Under SBIRI scheme over 134 R&amp;D projects have been funded in SMEs at a total cost of <code>390 crore (DBT contribution </code>190 crore, company contribution `200 crore).</td>
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<td>Biotechnology Industry Partnership Programme (BIPP) – to be launched</td>
<td>• BIPP launched after Cabinet Approval in Nov., 2008. So far 112 projects approved; 102 Agreements signed; 93 Companies involved, 15 start ups, 60 SME’s, 28 Academic partners. A total of investment of <code>797 crore has been committed with </code>298 crore as BIRAC/DBT contribution &amp; `499 crore as company contribution.</td>
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<td>Biotechnology Industry Research Assistance Council (BIRAC) - to be set up</td>
<td>• With the approval of Cabinet, BIRAC has been established as a not-for-profit company (under Section 25 of the Companies Act) which was incorporated in 20th March, 2012.</td>
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### BUILDING WORLD-CLASS HUMAN CAPITAL

| "Star Colleges" in life sciences to be set up | • Scheme has been launched. Already 55 colleges supported across the country. |
| Re-engineering of existing university departments to be taken up | • BUILDER Scheme launched and nine universities supported so far (University of Hyderabad; Osmania University; MS University; Banaras Hindu University; Madurai Kamaraj University; Institute of Chemical Technology; Karnatak University; University of Rajasthan; University of Calcutta). More under consideration. |
| Regional Centre for Biotechnology (RCB) to be established (in partnership with UNESCO) | • RCB already set up; it will be co-located at Faridabad with Translational Health Science and Technology Institute and other institutions in a Bioscience cluster. Construction is happening in full swing at the Faridabad campus. In the interim, the centre has been functioning from Udyog Vihar, Gurgaon. |

### ACCENT ON YOUNG SCIENTISTS

| New schemes to support young scientists | • Innovative Young Biotechnologist Award (IYBA) scheme launched  
• Scheme for Rapid Grant for Young Investigators introduced  
• Biotechnology Entrepreneurship Student Teams (BEST) Awards scheme introduced and is being implemented through Association of Biotech-led Enterprises  
• Khorana Program in partnership with University of Wisconsin and Indo-US S&T Forum to encourage young and budding scientists  
• Under the Women Bioscientists Scheme (BioCARe) an Early Career Fellowship grant |
### ATTRACTING SCIENTISTS FROM OVERSEAS

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<td><strong>DBT-Wellcome Trust Fellowships</strong></td>
<td>DBT-Wellcome Trust Biomedical Research Career Programme launched. 4-tier post-doctoral fellowships (Early-stage, intermediate, senior and Margadarshi) are being awarded. Nearly 80 Fellowships awarded so far.</td>
</tr>
<tr>
<td><strong>Ramalingaswami Re-entry Fellowships</strong></td>
<td>A re-entry fellowship to attract high-calibre scientists of Indian origin to work in Indian labs. So far 85 fellows in position; 50 more have been selected.</td>
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<td><strong>International Biotechnology Chairs</strong></td>
<td>International Biotechnology Chairs have been created to attract leaders in biotechnology and biosciences to Indian institutions.</td>
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<td><strong>Energy Bioscience Overseas Fellowships</strong></td>
<td>Fellowship Scheme launched with same pattern as Ramalingaswami fellowship. 8 Fellows selected.</td>
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### CREATING WORLD-CLASS RESEARCH CAPACITY

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<td><strong>Centres of Excellence in Biotechnology</strong></td>
<td>So far 15 Centres of Excellence supported. Additionally, 35 applications that did not meet the centre requirements were given Programme Support.</td>
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<td><strong>Reinforcing biotechnology infrastructure</strong></td>
<td>New incubators, biotech parks, GMP scale-up facilities, testing facilities for GMOs/LMOs, GM crops and BSL III/IV labs are being setup.</td>
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### CATALYZING SYNERGY AND INNOVATION

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<td><strong>Technology Clusters</strong></td>
<td>Three clusters – Punjab Agri-food Cluster (Mohali), the Biotechnology Science Cluster (Faridabad), and the Biotech Cluster (Bangalore) are rapidly taking shape.</td>
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## NEW BREED OF INSTITUTIONS

**New breed of institutions to be set up in critical areas**

- 6 new institutions have been established: Translational Health Science & Technology Institute, Faridabad; Institute of Stem Cell Biology and Regenerative Medicine, Bangalore; Regional Centre for Biotechnology, Faridabad; National Agri-food Biotechnology Institute and Food Bioprocessing Unit, Mohali; National Institute of Biomedical Genomics, Kalyani; National Institute of Animal Biotechnology, Hyderabad.

## NEW LEGISLATION

**Protection of IP in public-funded R&D**

- Draft legislation on “The Protection and Utilization of Public Funded Intellectual Property Bill. 2008” was introduced in the Rajya Sabha and examined by the Parliamentary Standing Committee. Based on the modifications, a new Bill is likely to be introduced.

**DNA Profiling Bill to augment and transform forensic investigation and criminal justice delivery system**

- Inter-ministerial consultation is completed. Bill to be introduced in the Parliament shortly.
NATIONAL BIOTECHNOLOGY
DEVELOPMENT STRATEGY-2014

(BIOTECH STRATEGY II)

SECTION – II
SECTORAL PRIORITIES
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### SECTORAL PRIORITIES

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Biotechnology is defined as

“The application of Science & Technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services”
1. **Disciplinary and interdisciplinary Basic Sciences**

**Vision 2020**

To support to continue Basic, Disciplinary and Interdisciplinary Science

- **Transforming Research Areas:**

  **Goal:** Our basic molecular and cell biology excellence should reach critical mass: It should undergo 3 doublings in 10 years. Include chemistry, physics, engineering and medicine etc.

  - To develop multidisciplinary biology – integrating with quantitative and engineering perspectives in Biology at every level. Encourage programmes where non-biologists address questions in biology.
  - Build on Current strengths: Molecular, cellular, structural biology, immunology, neurobiology, computational and informatics
  - Mission and Team driven programs: coordinated activities on a large scale. Global Alliances: to transform basic biology into applications.

- **Building Research Resources:**

This can be achieved by

  - Clustering of institutions
  - Resources for technology platforms should be organized
  - Partnership in global initiatives on research resources
  - 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
2. Agriculture and Food Productivity

1. **Vision 2020**: To achieve higher productivity and better quality food while reducing resource inputs.

2. **Critical areas which need attention?**

   - Strengthening Pre-breeding programmes
   - Transgenic crops for resistance against biotic & abiotic stresses
   - Pre-breeding research utilizing genomics information and interfaces with wide hybridization, molecular mapping.
   - Acquisition of critical technologies: a massive exercise needs to be carried out for analyzing globally available technologies – transgenes, markers, germplasm etc. for every major crop grown in the country. A clear strategy in collaboration with BIRAC for acquisition of such technologies to be worked out.
   - A couple of 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.
   - Heterosis Breeding
   - Basic Research
     (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
     (f) Introgression and pyramiding useful genetic loci in diverse germplasm.

3. **How to achieve this Vision?**
   **Declare agricultural biotechnology and breeding as a strategic area of research**
   - Establish Translational Centres for Agri Biotech partnered with SAU.
   - Establishment of COEs for pre-breeding-to discuss the matter with 6-7 SAU’s who have basic strength, material and manpower.
   - Establishment of centres for transgenic work
   - New modes for catalyzing public-private synergy
   - Acquisition of critical technologies
• Organizing basic work on biotic stresses and other areas
• Grant-in-aid status institutions like, RCB, NABI etc.
• To identify few agricultural universities for research as advanced agricultural biotechnology resource centres; an MoU in this regard to be signed with them.

**Governance model**: Policies and governance models need to be developed to establish and drive more Research Parks in food and agriculture. These should efficiently catalyse and facilitate knowledge utilisation, corporate investments, agricultural community participation and lead to spin out and start-up companies.

**Biotech communication**: To improve the understanding of agricultural biotechnology and how its products contribute to personal well-being, a strategic plan for public communications is important. There is need to identify some specific objectives for public communication: make evident to decision makers that modern biotechnology can be an effective tool for increasing agricultural productivity, and thereby economic growth, without imposing unacceptable risk to the environment or human and animal health; and enable members of the public to make informed decisions about appropriate uses of biotechnology by providing accurate information about benefits, risks and impacts. Some not for profit organizations could be engaged for this purpose.
3. Human Health and Wellbeing

A. GENOMICS AND HEALTH

A Vision for 2025 is to convert 50% of hospitals currently engaged in treatment of human diseases to hospitals for prediction and prevention of diseases using genomic tools. Concurrently, to engage in genetic epidemiological research for increased understanding and identification of genomic factors in human health and disease, and their interactions with life-style and/or environmental factors. It is envisioned to provide all available genetic screening tests to general public in each city.

Specifics and Tasks that are required to achieve this Vision include:

1. **Translational Genomics**: Taking Genomics from research laboratories to Clinics by increasing the use of genomic information in disease prognosis, diagnosis, prediction and making appropriate choice of drug. **Pharmacogenomics** is an active research field wherein drug choice and dosage is optimized on the basis of patients’ genotype in order to attain maximum efficacy with minimum adverse effects. Initiatives from Department would pave way for introduction of pharmacogenomics in patient treatment as an early application.

2. **More Widespread Genetic Testing Services** should be provided for diseases with chromosomal aberrations or disorders where underlying culprits are highly penetrant genes. Such diseases are less commonly observed in population studies. It is required to identify accurate Publicly-funded institutions that should be able to timely discover and make appropriate intervention. There should be one such dedicated centre in each city for providing genetic testing services at affordable prices. These tests and technologies should be transferred to private service-providers for providing Quality assurance.

3. **A far Greater understanding of mechanisms of predisposition, initiation and progression of diseases** that have multiple low-penetrant genes as underlying causes is required. Generally, these diseases may have environmental influence, that is, environmental factors also contribute and potentiate to such disease progression. These diseases are found to be more prevalent in populations.

- In order to better understand the mechanisms, we need to move away from single genes to Genomic pathways. **Systems biology approach** should be devised to generate Gene networks
- To explicitly focus on environmental interactions, **cohort studies** should be conducted. Paediatric cohorts should be systemically and separately studied for congenital disorders
• **Expression profiling** studies could be undertaken on Blood and other tissues in order to understand the impact of somatic mutations, to define biomarkers and therapeutic targets

• Another approach for better understanding of genetic disorders includes **Small molecule screening and Synthetic biology**:
  
  (a) Sub-classification of impact of these molecules based on genomic information
  
  (b) Genomic information could be used to design and test synthetic peptides and RNA blockers for vaccination and treatment
  
  (c) Some molecules and even marketed drugs have been withdrawn because of adverse events in some patients. However, the adverse events may be specific to genomic-backgrounds of the patients. It is possible to resurrect disapproved or withdrawn molecules using genomic information

(4) Epidemiology and Genomics

A sincere effort should be made in the direction of genetic epidemiological studies. A step forward towards realizing this includes:

• Maintenance of electronic medical records in hospitals, including relevant genomic information. A good starting point for this could be urban hospitals, moving further to district hospitals and finish with Primary Healthcare Centres. It is advisable to use mobile telephones for information transmission

• Collection of epidemiological data from rural areas, primarily, through the National Rural Health Mission

• This should be followed-up longitudinally by deep phenotyping and correlating with cellular, molecular and cytogenetic data for in depth breadth and coverage of analysis

(5) Genomics Education

A well-trained workforce is required for better implementation of genetic principles in clinical studies and enhancing Genomics research. Efforts should be directed towards this end by:

• Introducing training programs in Clinical Genetics in close collaboration with Medical Council of India (MCI) & National Board of Examinations (NBE) for physician scientists and Geneticists

• Providing Genomic education to clinicians and health-care professionals

• Conducting workshops for medical and paramedical personnel at all levels
(6) Institutional Mechanisms for Human Genome Research

It is imperative to advance the field of Genomics in the Country from Drug Discovery perspective. It is important to prioritize diseases of National concern where Genomics could play a spearheading role in devising appropriate intervention and treatment. To achieve this, the following strategies could be employed:

- Common Cancers most prominent in Indian Context include cancers of Cervical, Oral, Lung and Breast origin. Genomics research in these diseases is likely to accelerate biomarker discovery. This would lead to identification of surrogate and clinical endpoints for designing appropriate treatments and therapeutics
- Setting up of Clinical Bioinformatics Units in strategic locations across the Country
- Dedicated centres to conduct association studies and Correlative Biology Research

(7) Creating Genomics Awareness in General Public and Healthcare providers

- In the light of public awareness, shared decision should be taken by doctors and patients. Clinicians should discuss with patients after interpreting results of genetic tests with sensitivity, accordingly take decision and monitor the outcome carefully.
- Encourage participatory genetic research by involving families and communities
- Inter-ministerial efforts be coordinated towards conducting Public Outreach Programs aimed at educating people regarding genetic basis of diseases
B. VACCINES:

VISION 2020

No One Should Suffer From Vaccine Preventable Diseases
To accomplish the vision for 2025 the strategy comprises of strengthening (i) Fundamental tools for vaccine development (Basic and applied R & D) (ii) Product Development, Manufacturing, Regulation & Marketing capabilities (iii) Human Resource; for availability of affordable, safe & effective vaccines for children, adolescent & adults. To achieve the same the strategic approaches are:

Strategic Area I: Fundamental tools for vaccine development

Strategy:
- To support vaccine research to develop new vaccine candidates and improve current vaccines by advancing the science of neonatal and maternal immunity, host immunity, immunization and the development of immunological models to evaluate protective immunity.
- To improve efforts to develop, refine, and validate new biomarkers and correlates of immunity by creation of enabling infrastructure i.e. animal testing facilities, Bio repositories through Public Private Partnership.
- To support development of improved vaccine related technologies such as gene-based vaccines, virus-like particles, plant-derived vaccines, novel adjuvants and delivery systems to create safer, affordable, more potent vaccines.
- To establish surveillance systems or network studies to better assess disease burden in specific target populations for future vaccine development.

Strategic Area 2: Indigenous product development, manufacture, tools for evaluation and licensure of vaccines.

Strategy:
- To support applied research to develop rapid and cost-efficient production, and optimize formulations and stability profiles of currently available vaccines.
- To develop technologies to make vaccines easier to use by minimizing the need for refrigeration and needles.
- To support research and development of novel cell substrates, multi-use technologies such as platforms, and quality testing procedures (e.g., potency and safety testing).
To develop and improve methods to better assess vaccine efficacy and safety including assessment of new technologies by development of better animal models.

To improve access to pilot manufacturing facilities that produce clinical grade material for evaluating promising vaccine candidates by creation of Pilot Plants (PPP model).

To strengthen clinical trial infrastructure in diverse demographical settings.

To harmonize regulatory framework in compliance with global standards.

To support companies to set up efficient regulatory departments well versed in GCP, GMP and GLP to liaise well with regulators & provide the guide map to the industry.

To determine barriers for availability of each licensed vaccine recommended for immunization.

**Strategic Area 3: Human Resource to support vaccine development**

**Strategy:**

- To establish effective functional alliances for overseas exchange and clinical training programme in the area of vaccinology.

- To generate clinical, laboratory, genetic, statistical, bioinformatics, experts to conduct clinical research studies.

- To establish overseas “Centers of excellence for vaccine research” to rope overseas talent to facilitate research on vaccines difficult to develop.

- To implement Educational Fellowships for interdisciplinary translational research (e.g. infection biology, immunology, evolutionary biology, ecology, epidemiology and mathematical modeling) to create new research paradigms.

**GOAL:** To develop vaccines in key areas: Diarrheal diseases, malaria, dengue, TB, cancer, pneumonia, influenza, JE and HIV.
Short-term:

To develop and commercialize vaccines against the following diseases:
- Rotavirus
- Cholera
- Typhoid
- Rabies human (DNA based)

Mid-Term:

To take into pre-clinical and clinical development new vaccines against:
- Malaria
- Dengue
- Tuberculosis
- Japanese Encephalitis

Long-Term:

To investigate new approaches for development of affordable vaccines against:
- Cancer (HPV)
- Polio
- Pneumococcus

To support research for the development of effective vaccines against:
- HIV

Development of improved vaccines: Conjugate vaccines, live vector vaccines, subunit vaccines, DNA vaccines, needle free & refrigeration free vaccines
C. INFECTIOUS DISEASES:

The “Vision” in the domain of infectious disease is to “safeguard public health in the face of threat from emerging pathogens”. To realise this vision into reality, progress needs to be made broadly in the following realms:

- Preparedness for rapid detection, precise identification and appropriate monitoring of emerging infectious diseases in the country
- A better and in-depth understanding of the host, environmental, pathogen factors that influence the emergence and spread of pathogens
- Development of effective intervention strategies for prevention, control and containment of existing and emerging infections

The following “Strategies” would be devised in order to achieve the above-mentioned Vision:

1. Molecular Epidemiological aspects of disease surveillance: breadth and depth of coverage

   It is proposed to take proactive role in promoting the implementation of comprehensive system of surveillance for infectious diseases of national concern. DBT has a prominent role to play in accelerating the development of cutting edge technologies for molecular identification, characterization and typing of systematically collected clinical materials from Bio banks. This can be immediately initiated in a fast track mode in collaboration with ICMR/DHR/M/o HFW. The role of participating ministries or departments or agencies would be collection of clinical specimens, maintenance of electronic medical records in order to carry out deep phenotyping for longitudinal follow-up.

2. Establishment of Disease specific Network:

   It is important to identify priority areas of National Concern. These may include: HIV/AIDS, Tuberculosis, Influenza, Chikungunya, Dengue, Enteric Diseases, Respiratory Tract infections (upper/lower), and newer emerging infections like CMV, opportunistic infections in immuno-compromised subjects. It is imperative to provide greater attention to develop appropriate diagnostic tools for above-mentioned infectious diseases. To achieve this, disease specific networks should be established across the country. This would involve:
   - Providing basic research infrastructure facilities to Medical colleges and hospitals in Infectious Diseases area
   - The Department to forge networking between public health institutes and hospitals or medical colleges in order to harness the expertise available across the nation
   - It is imperative to encourage interactive research activities at all three levels including basic, translational & clinical through a multidisciplinary approach
3. Regulatory reforms and requirements in Infectious Disease Area

The Current timelines and regulatory steps 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.

It is important to establish customised experimental animal resources in strategic locations across the Country to facilitate the process. Also, the Department should take initiative to create infrastructure in the areas of pre-clinical toxicology and conduct of clinical trials.

4. Strengthen basic research in Infectious Disease Area

Basic research initiatives are important for the understanding and treatment of infectious diseases. In particular, recent advances in Genomics, Transcriptomics, Proteomics and Metabolomics would play a pivotal role in understanding pathogenesis, virulence factors, patterns of transmission, host susceptibility, and development of new technologies and counter-measures for disease detection, diagnosis, and treatment. The following broad areas have been identified to increase our understanding in National perspective:

- Environmental factors that facilitate emergence, maintenance and transmission of infections: Study 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

5. Meeting the needs for Translating basic Infectious Disease Research

Despite the remarkable advances in basic knowledge of Immunology and microbiology, proportional translation of these findings to development has not yet taken place. Appropriate strategies need to be developed for translational research in ID area identified as:

- 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 by priority pathogens of National concern
- Host and Pathogen Biomarkers discovery research for novel interventions: Availability of validated biomarkers would accelerate the crusade against ID in terms of rapid diagnosis and better therapeutic management as well for rational drug and vaccine discovery
• Development of assays for high-throughput screening for use in probe and pre-therapeutic discovery: Establish a stream of scientifically and technologically outstanding novel assays that can be automated for high-throughput screening and can be used for further studies that lead to interesting and important new biology. This would also ensure Indigenous production of quality laboratory reagents

• Development of new diagnostic tools that can support rapid and accurate diagnosis even in field conditions

6. Interdisciplinary Infection Science Research Centres

Interdisciplinary Research Centres should be developed to promote a multidisciplinary approach in Infectious Diseases arena to address alarming microbial threats to health. The proposed centres would cater to the following needs:

• Fostering Interdisciplinary, Multidisciplinary Research projects with focus on high priority public health problems and leveraging expertise across multiple organizations

• Serve as a training venue to provide exposure for young scientists in order to develop future leaders to work across boundaries to control new and emerging microbial threats to health

It is proposed to establish Infectious Disease Science Research & Training Centres in strategic locations across the Country.

A twining institute between North-East Region and Faridabad for Collaborative research and training of scientific personnel would be a good starting point. This could be achieved in collaboration with North East Cell of DBT. The education, training and research provided by this centre would be a much-needed resource for the North Eastern region and the entire Country.
D. CHRONIC DISEASE BIOLOGY

Areas Covered in Chronic Disease Biology

- Cardiovascular & Metabolic Disorders
- Cerebro-vascular & other Neurological disorder including dementia
- Chronic Lung, Kidney & Liver disease
- Autoimmune
- Cancer

VISION 2020

- Preamble: Existing Institutions are designed around cell/molecular biology
- Need at least 3-4 New Organ-based Disease Biology Centers with strong association between basic biologists and clinicians
- Change from the concept of the generalized to personalized medicine for indications such as Diabetes, Hypertension, Stroke, MI & Cancer using Genomics/Proteomics tools and associated knowledge
- Focus on new drug development in cancer using novel drug targets

Gaps in the current status

- Lack of Prioritization
- Shortage of Quality/Number of Human resource
- Lack of Comprehensive infrastructure/ COE for organ-based diseases
- Limited R&D base in the industry
- Lack of Collaborative Culture
- No policy on preventive medicine in CDB
- Limited reliable data on disease burden

Sub areas / critical areas needing attention

- Converting therapeutic approach to preventive medicine
- Creating large R & D infrastructures/ New Institutes/COEs for public-health relevant Chronic Diseases i.e. Cancer, Diabetes/Vascular biology, Neurosciences & Lung-Liver-Kidney to do research on Public-Private Partnerships models
- Involving appropriate bilateral partnership in developing R & D infrastructure

Strategy for next five years

- Prioritization
- Scaling up infrastructure/Setting-up Centers of Excellence/Institutes for 2-3 Chronic Diseases of national relevance
- Developing Human resource in these areas by collaboration- fellowships, sabbatical etc.
- Reliable data on disease burden
- Prospective cohorts for chronic diseases with Bio-banking

Cardiovascular & Cerebro-Vascular
• Early diagnosis & Optimal management of hypertension (including community based)
• Affordable and non-invasive diagnostics / imaging
• Understanding vascular biology & Revascularization
• Point-of-care interventions to prevent/minimize hypoxic tissue damage
• Devices & Non-Pharmacological interventions
• Management of heart failure including cardiac- transplantation
• 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
• Understanding & modifying vascular complications
• Beta-Cell regeneration & transplantation

**Cancer**
• Tobacco related cancers will continue to predominate in males & Breast in females
• 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; MAbs, Small Molecule Inhibitors
  • Targeted Therapies
• Affordable & quality assured diagnostics
• Major focus on Biosimilars

**Mental Illness & Neurological Disorder**
• Need for understanding pathogenesis by basic R & D
• Development of animal models
• Develop new pharmacological & non-pharmacological therapies, including cognitive retraining paradigms
• Affordable and non-invasive diagnostic approaches including structural, functional and molecular imaging
E. STEM CELL RESEARCH AND REGENERATIVE MEDICINE

1. Vision: To achieve a leadership position in the areas of developmental biology, disease models/drug development and regenerative medicine.

2. What are the sub areas/ critical areas which need attention?
   i. Developmental biology
   ii. Disease models and Drug development
   iii. Regenerative medicine

3. How to achieve this Vision?
   i. Developmental Biology:
      - Innovative models for studying developmental biology in models such as Drosophila – lower animals/higher animals, cell based models (ESC/iPS)

   ii. Disease models and drug development:
      - Innovative disease models in higher animals (farm animals/non-human primates)
      - Disease specific cell based models for cancers/hereditary genetic diseases (ESC/iPS)
      - Cell and tissue banking/repository

   iii. Regenerative medicine:
      - Cell therapy – Clinical trials with adult stem cell based therapies (early and advanced)
      - Tissue engineering – To explore the potential of adult stem cells for tissue regeneration and repair

4. Goals and Targets:
   i) To set up Centres for regenerative medicine/cell based therapy/bioengineering in existing or new medical schools, engineering schools and institutions.

   ii) Inter-disciplinary interaction for stem cells research with clinical science, basic science, engineering/informatics and veterinary sciences to answer unresolved questions in biology and problems in health care or animal husbandry.
iii) To initiate measures to increase exponentially the number of skilled/trained manpower:

- Training for physicians in basic science
- Training for the basic science in clinical research
- Opportunities for carefully selected young scientists from India to go the best labs in the world fully funded from here for 1-4 years, depending on their needs and goals.
- Establish collaborations and spend shorter durations in selected labs overseas, if needed.
- Create environment for selected senior scientists from overseas to come to India for 3-5 years and set up labs here with appropriate Indian collaborators.

iv) Encourage public-private partnership in these ventures.

5. Strategy for next five years

i) Establish centers for regenerative medicine/cell based therapy/bioengineering in the country.

ii) To generate patient specific cell lines

iii) Basic biology of all types of stem cells (embryonic, adult, induced pluripotent stem cells, etc.)

iv) Translational and clinical research using adult stem cells such as haematopoietic stem cells, mesenchymal stem cells, peripheral progenitor cells, etc.

v) Use of stem cell in drug discovery for screening candidate and toxicology

vi) Application of adult stem cells for tissue engineering and repair

vii) To revise regulatory guidelines for research and therapeutic applications of stem cells
F. MEDICAL DEVICES AND IMPLANTS

1. **Vision 2020**: Boosting high order of innovation entrepreneurship for developing affordable implants and devices for the mass of the country.

2. **What are the sub areas/critical areas which need attention?**
   
i. Medical devices and Implants

   ii. *In-vitro* Diagnostics

3. **How to achieve this Vision? - STRATEGY**

   i) To create replica of biodesign concept at other IITs, medical schools and institutions.

   ii) To promote ideas generation for medical devices innovation and interdisciplinary research.

   iii) Lowering the import of medical devices by indigenous innovation and fast market implementation

   iv) Capacity building for research and generating ideas to facilitate the conceptualization and designing of medical devices and implants:
   - Research interfaces with medical/clinical environment
   - Research interfaces with technical environments
   - Interface with public and community health
   - Technology transfer

   v) Introduce healthcare technologies including biodesign in the curriculum of medical and engineering schools for undergraduate and post graduate programmes.

   vi) Develop infrastructure for: a) product development such as laboratories for animal studies, prototypes development and validation studies of the developed products; and b) manufacturing capabilities such as cluster capability, low volume incentives (tax) and quality certification.

   vii) 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; and c) *Outpatient care technologies and telemedicine*
4. Goals and Targets

i) To develop simple, rapid, indigenous, low cost medical devices and implants by applying 4 components i.e. affordableness, accessibility, availability and appropriateness.

ii) To produce a large number of medical technology innovators.

iii) To expand multi-disciplinary, team-based program across the country to train engineers and physicians for clinical immersion through biodesign process in India.

iv) Standardization and protocol testing of biodesign products.

v) To establish collaboration with various international institutes/universities.

vi) To initiate inter-institutional Ph.D programme, innovation award, overseas fellowships, etc.,

vii) To create quality manpower in engineering school in partnership with medical schools for multidisciplinary research, skilled technicians, manufacturing engineers and regulatory staffs.

viii) Regulatory and policy framework for enhancing innovation

5. Strategy for next five years

i) To establish biodesign inter-institutional Centre at Translational Health Science and Technology Institute (THSTI), Faridabad with large number of faculty, proper infrastructure and facilities such as platform technology, validation unit, pre-clinical, clinical trials.

ii) Expansion of biodesign concept in other IITs, medical schools and institutes across the country.

iii) To create an effective National Biodesign Alliance with the partnering institutions (virtual) with a secretariat at THSTI, Faridabad.

iv) Increase the number of fellows and interns for training in clinical immersion process.

v) To establish/promote graduate school concept at the biodesign inter-institutional Centre.
4. Biotechnology for Animal health, Productivity and Quality

1. Vision

Enhancing the role of livestock including poultry for enhancing food production and productivity through a multi-pronged approach involving breeding, reproduction technologies, nutrition and health care.

2. What are the critical areas which need attention:

(i) Genomics and Genetic Characterization
(ii) Animal Reproduction and Transgenics
(iii) Nutrition
(iv) Animal Food safety:

3. How to achieve this vision; goals and targets

The following strategies would be adopted to accomplish this vision

Genomics and Genetic Characterization : Livestock and Poultry

- By using already developed SNP chips on our stocks we can aim at bringing about faster genetic improvement for production traits/disease resistance. The chip may be developed for indigenous stocks viz. cattle, chicken, buffalo, sheep pigs using high density sequencing of genomic DNA/cDNA for SNP detection and development of SNP array.

  Goals and targets

  - Application of genome-wide marker-assisted selection (GWMAS) for enhancement of production, FCR and disease resistance.

Animal Reproduction and Transgenics

- Sperm sexing technique for enhancing productivity should be a priority. Almost all farmers prefer a female calf because that can provide milk as well as offspring.

- Biopharming for therapeutic proteins has wide ranging applications. The use of recombinant proteins of human origin for therapeutic application has steadily increased during the last two decades. Clinical applications often require large amounts of highly purified molecules, for multiple or chronic treatments. Animal systems can be employed for these.
For fundamental research, transgenesis makes it possible to study the operation of a gene and its regulation. If genes are identified for disease resistance, specially in the case of livestock, they can be used to generate transgenic herds of livestock free from such diseases.

There is a need to develop hormones and biologicals required for embryo transfer of technology. This will reduce the cost of the production of ET calves.

**Goals and targets**

- Sperm sexing technique for enhancing productivity.
- Biopharming for therapeutic 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.

**Nutrition**

The GI tract of animals harbours a variety of microbes which helps in digestion as well as many other physiological functions including biosynthesis of macromolecules, enhancement of immunity, protection from pathogens etc. Metagenomics via culturable and sequence based approach provides an opportunity for studying the microbes and their activities in this niche environment. This approach will be useful for understanding the effects of different feeds and supplements on the native GI flora and the role of different microbes in maintaining health.

Microbes in the digestive tract lack the ability to degrade the lignin. This calls for alternate approaches to tackle lignin degradation. Developing exogenous enzymes suitable for supplementation with feed or for pretreatment of the feeds can help in degrading lignin. This approach is important in our country which generates about 500 million metric tonnes of agro-residues every year.

Studies on nutrigenomics to identify the effects of different nutrients (macro and micro nutrients) or their metabolic products on gene expression (desirable/undesirable) will help explain the genomic level effects of nutrients and assist in designing strategies for controlling gene expression through food rather than drugs. This will help in identifying quality nutrient foods which will enhance animal productivity and product quality.

**Goals and targets**

- 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 issues:

The growing health consciousness necessitates an urgent need for developing convenient and affordable functional animal products including designer egg/meat with adequate food safety and longer shelf life. Research needs to be directed towards finer assessment of microbial risk as well as the use of predictive microbiology approaches to produce safe animal products. Development of simple and quick laboratory methods for detection and quantitative estimation of incriminating factors such as pesticide, heavy metals, veterinary drugs and other toxic residues in animal feed and products and their amelioration techniques for safer food production is necessary. A national database on occurrence of bio- and phytocontaminants may be developed to address safety concerns of animal products and promote their export trade under the WTO regime.

Goals and targets

- Assessment of quality and safety of products
- Establishing traceability protocols for meat and products.

4. Strategy for the next five years:

- Launching a major multicentric programme on generating transgenic animals in livestock
- Generation of transgenic animals for production of biomedically important compounds and pharmaceuticals.
- Development of technologies for degradation of lignin and enrichment of animal feeds based on agro-by product residues
- New programmes for human resource development with a focus on industry requirements and the science of manufacturing.
5. Aquaculture and Marine Biotechnology

1. Vision

To enhance aquaculture productivity and its contribution to food security; development of processes and products using marine biotechnology

2. What are the critical areas which need attention:

   (i) Larval feed and nutrition
   (ii) Breeding and genetics
   (iii) Health
   (iv) Marine biotechnology

3. How to achieve this vision; goals and targets

Indian aquaculture has demonstrated a six fold growth over the last two decades, with freshwater aquaculture contributing the major share. The production of carp in freshwater and shrimps in brackish water form the major areas of activity. In contrast, the development of brackish water aquaculture has been confined to a very few species. With over 8000 km of coastline there is immense potential for the development of mariculture. It is noteworthy to mention that DBT has demonstrated high production of shrimp through semi intensive prawn culture technology by producing 10 t/ha per annum in two crops. This marked a paradigm shift in shrimp aquaculture in the country. In the freshwater sector more than 17 t/ha per hectare per annum was demonstrated through an ICAR institute.

   (i) 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. Nutritional composition of live feed is considered as the most important deciding factor in the success of aquaculture, especially in finfish and shell fish. Industries have been increasingly focussing on the development of feeds for very early developmental stages of the different fish species, to reduce their dependence on live food. Most of these feeds developed and tested only at laboratory scale, experimental conditions, however commercially available micro-diets is really scarce, because of the difficult elaboration process and the high production costs. These aspects are required to be addressed and also the enrichment of aqua-feed with useful microbial enzymes isolated from digestive tract of culture species.

Goals and targets

- 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. The technology being envisaged includes, screening and selection of healthy founder population of brooders based on molecular markers, maturation in grow out systems, completion of maturation in indoor facility wherever feasible, breeding and spawning in controlled systems.

**Goals and targets**

- 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.

**(ii) Breeding and genetics**

DNA marker technology can be used in various species for trait characterization related to growth, disease resistance and salinity tolerance.

The sub-discipline of functional genomics, termed nutritional genomics or nutrigenomics, endeavors to resolve the influence of dietary chemicals upon the genome and to increase our understanding of how dietary constituents influence metabolism. The information can be directed towards enhancing productivity.

**Goals and targets**

- QTL identification through genome wide scanning
- Breeding strategies for productivity enhancement
- Molecular coordinated regulation of reproduction
- Application of nutrigenomics for nutrient utilization
(iii) Marine Biotechnology

The non-food sector of marine biotechnology offers phenomenal opportunities for process and product development. In aquaculture biotechnology relating to environmental applications and topics related to drug discovery and development, genomic and proteomic applications, biomaterials and bioengineering with biomedical applications need to be explored. The untapped microbes having incredible application in food, fisheries, medicine industry and agriculture and for novel compounds need pursuasion. The emphasis is required 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.

Goals and targets

- Biofuels from marine algae
- Extremophiles
- Novel microbial enzymes
- Biomaterials
- Bioremediation
- Metagenomic approaches to bioactive molecules
- Whole genome sequencing of native commercially important aquaculture species.
- Setting up a new institution and centres of excellence

4. Strategy for the next five years:

- A viable strategy for management of WSSV infection in shrimp
- Development of brood stock banks for supply of high quality brood stock
- Diversification of aquaculture based on new species
- Setting of centers of excellence
- Setting up a national institute on marine biotechnology
6. Value-added Biomass & Products from Natural Resources

1 Vision 2020

Enable sustainable utilization and enhance the intrinsic value of natural resources for new products developed through synergistic interaction between industry, academia and Government.

2 Goals and Targets

- Enhance the intrinsic value of India’s natural resources through discovery,
- Develop human resource expertise in bio-prospecting natural resources,
- Develop state-of-the-art infrastructure in the country to facilitate bio-prospecting of natural resources,
- Facilitate inter-institutional linkages to address issues comprehensively and
- To foster academia-industry collaborations to facilitate translational work

3 Strategy for next five years

- 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

Setting up of a National Centre for Drug Discovery from Natural Products

- To make available multi-disciplinary facility including advanced screening technology platforms to advance drug discovery and developmental programme
- Centre to be designed on the lines of the Natural Product Branch (NPB) of the US National Cancer Institute’s Developmental Therapeutics Programme
- Discovery and development of natural product based drug candidates at pre-clinical stage
- Careful identification of priorities based on market potential and socio-economic aspects
Setting up of 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 Department of AYUSH, Ministry of Health and Family Welfare
- 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
  - To launch a major initiative on “Antiviral Agents (for dengue, influenza, HCV, HBV, HIV) from Plant Sources” involving academia and industry

4 Implementation
A. Strategic Research
   - Mission on Bioprospecting
   - Centre for Drug Design
B. Research Programmes in Other priorities:
   - 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

5. Training and Capacity Building
- To train at-least fifty persons every year in all aspects of Drug Discovery from Natural Sources
- To strengthen existing centres for devising training modules in all aspects for drug development and discovery from natural resources
- Development of analytical facilities and trained manpower for secondary agriculture
- Training programmes in specialized areas such as molecular pharmacology, phytochemistry, advanced and robust screening protocols

6. Infra structure
- Strengthening existing infrastructure in Institutes providing training and degrees in Pharmacognosy to have end to end facility for new drug discovery and development

1. Vision 2020: Create a Biotechnology enterprise equipped with viable green and clean technologies.

2. What are the sub areas/critical areas which need attention?

   (a) **Environment**
   - Eco-restoration
   - Metagenomics
   - Biodiversity conservation
   - Preventive/ecofriendly technologies

   (b) **Clean Energy**
   - Enzyme and protein engineering
   - Metabolic Engineering and Synthetic Biology; system biology
   - Downstream processing and bioprocessing engineering
   - Bio refinery approach
   - Life cycle assessment

A. Environmental Technologies

**Eco-restoration**

Approaches:
1. Major polluting industries to be targeted and tackling pollution through End- of- Pipe Biological Treatment Process:
   - Selection of robust microbes having potential for biodegradation
   - Identification of new microbes through metagenomics approach having potential to degrade an array of toxic effluents.
   - Development of technologies for treatment of waste effluent
2. Conservation of viable habitat and restoration of degraded habitats using the bio restoration technologies.

**Metagenomics**

Objective: Metagenomics for waste management and pollutant 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

Approach:
- Establish a Metagenomic programme that includes few large scale co-ordinated project to characterize the microbial communities and habitat for identification and exploitation of the biosynthetic and bio catalytic capacities of the microbial communities.
- Human resource and infrastructure development.
- Participation in global projects of high importance like Global Earth Microbiome and Global Human Microbiome
Biodiversity Conservation

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

Work Plan

- Ecological Niche Modeling and Metapopulation characterization.
- Species prioritization for conservation, preventing extinction and improving conservation status.
- Impact assessment of climate change on biodiversity and characterizing biodiversity elements for ameliorating climate change impact and sequestering atmospheric carbon.
- DNA Bar Coding of the populations (species with relatively wider distribution and facing extinction).
- Standardization of tissue culture and other micro-propagation techniques, and re-introduction of the plant species.
- Establishment a network of field gene banks in appropriate agro-climatic zones.

Expected Output

- More accurate threat classification.
- Improvement in RED Data Book.

B. Technologies for Clean Energy

1. Goals and Targets:

Clean Energy

- 20% blending of fossil fuel by 2025
- Commercially viable lignocellulosic ethanol produced from Agricultural and forestry waste.
- An economically cost efficient system available for Algal production and also a commercial scale technology for production of biofuels from Algae either through harvesting and oil transesterification or direct conversion to Biooil.

2. Strategy to Achieve the Vision

i. Promote technology innovation by creating an enabling environment through Centre of Excellence and Network program.
ii. Make a strong, long-term commitment to implement cost-effective clean energy as a resource.
iii. Provide adequate, timely and stable program funding to deliver cost effective clean energy technologies.
iv. Implement appropriate policies and regulatory mechanisms.
v. Modify implementation policies to align utility incentives with the delivery of cost-effective energy and modify rate making practices to promote energy efficiency investments.

vi. Creation of infrastructure and capacity building.

vii. Institutionalise enabling mechanisms to promote inter-sectoral collaboration with industry and academia.

3. **Strategy for next five years:**
   - Strengthening existing centres of excellence.
   - Create new centres of excellence in gap areas.
   - Collaborations and strategy alliance building with pockets of excellence - National and Global.
   - Address regulatory gaps.

4. **Implementation Modalities**
   i. Launch a Strategic Research Programme towards achieving the Goal of 20% blending by 2025.
   ii. Set up at least 5 Joint centre on the similar pattern as DBT-ICT and DBT-IOCL.
   iii. Create a Team India of at least 100 scientist in interdisciplinary Research Areas.
   iv. Support Basic Research R&D programmes in different cutting edge science areas, which are critical to provide a detailed understanding of the process involved and modifications which are feasible. This would be networked to the energy centre.
   v. Train at least 100 Post Doctoral Overseas in specialized areas such as Synthetic Biology, Enzyme and Protein Engineering, Metabolic Engineering, Systems Biology etc.
   vi. Attract at least 25 overseas scientists to the centre through Energy Bioscience Fellowship and Institute at least 5 chairs, one in each centre.

5. **Science Programme Strategy**
   I. **Strategic Research Program**
      A. **Commercial production of Biofuel from different feedstocks for 20% Blending**

         Technology for conversion to Biofuel
         a. Biodiesel
         b. Bioethanol
         c. Green Diesel
         d. Algal Biofuel
         e. Biobutanol
         f. Biohydrogen
         g. Biochemicals
         h. Fuel Cells

      II. **Basic Research Science Project**
          i. Feedstock improvement
          ii. Algal Biofuels
             Microalgae
             Macroalgae
B. Implementation and Governance Model

Training and Capacity Building
Considering the points as discussed above, it is recommended to create institutional mechanism for medium to long term training and capacity building in the areas as mentioned above.

- There is a need to establish institutional network and protocol to engage the research and educational institutions, scientific agencies, recognized laboratories and public agencies, to share their scientific information and experience in the relevant field as discussed above.
- There is a need to attract high skilled post doctorate professionals by offering attractive remuneration to encourage them to pursue their research activity in India instead of in overseas countries.
- Workshops, seminars should be conducted in the relevant area to share the international experience among scientific community and to assess good regulatory models among regulatory authorities.
- There is a need to host as well as to participate in technology innovation centres.
- It is recommended to initiate and fund mission mode target oriented projects
- It is required to encourage the existing one as well as to create new research centres for focusing research in relevant field
- Private sectors are required to develop and commercialize the product and process resulting from the program, to support and participate in the collaborative R&D projects, as well as to support for creation of technology innovation centres in order to attract the high skilled talented scientists.

International Cooperation
There is a need to enhance our own capacity to comply with our commitments and to enable our flow of resources. Hence,

- India should participate in major international events to develop network and enhance environmental cooperation
- India should participate in regional and bilateral programmes.
- India need to get involved for availing international cooperation from key regulatory authorities
- It is required to initiate program for exchange of scientific professionals having expertise in the relevant area

Regulatory Compliance
- Environmental compliance should be given greater importance
- There is a strong need to implement proper environmental regulation policy
8. Food and Nutritional Security

1. Vision 2020: Food fortification and biofortification to address micronutrient deficiencies, nutrigenomics of metabolic syndrome, food safety and development of functional foods.

2. What are the sub areas / critical areas which need attention?
   - Food fortification and biofortification of food crops for addressal of micronutrient deficiencies with a special focus on iron deficiency anemia
     - R&D in food fortification and biofortification
     - 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 digestability of food protein under chronic under nutrition conditions
   - Strategies for treatment and prevention of diet related chronic diseases eg. Obesity and Diabetes
     - 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 spoilage organisms.
➢ 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
➢ Human resource development in the area of Food and Nutrition Sciences

3. How to achieve this Vision?
➢ Establishment of at least four centers 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. International collaborations and research fellowships in the above mentioned areas.
➢ Acquisition of critical food fortification and biofortification technologies
➢ Basic research to investigate the casual role of diet in the development of diabetes and obesity.
➢ Establishment of Validation centres for nutrition claims with a focus to collect valid data on the phytochemical components of different Indian foods.
➢ Basic research for identification of probiotics for treatment of disorders such as diabetes, obesity etc.
➢ Establishment of a repository of traditional fermented food microorganisms.
➢ 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

4. Goals and Targets
➢ Generation of a critical mass of well trained food biotechnologists and nutrition biologists by 2025 for nutrition and translational research relevant to agriculture and human health
➢ Fortified foods to tackle micronutrient deficiencies
➢ Functional foods and nutraceuticals with anti-oxidant and immunomodulatory activity

5. Strategy for next five years
Activities proposed with time frame
(i) Establishment of center of excellence for nutrition sciences in agriculture and medical schools
(ii) R & D in food fortification
(iii) Addressal of the incidence of Moderate and Severe acute Malnutrition through indigenous development of formulations along with intervention studies.
(iv) Establishment of Validation centers for nutrition claims
(v) Basic research to investigate the casual role of diet in the development of diabetes and obesity.

6. **Human resource:** Initiating 5 year integrated B.Tech and M.Tech programme in food technology
   
   **Infrastructure:** As given above
   
   **Finance**
   
   • *Training and other skill specialization needs*
   
   • *Global networks / collaboration*

7. **Governance model:** Alliance among DBT and other user ministries like Agriculture, Women and Child development, Food processing industries, Health and Family welfare in the area of Nutrition and health to be established so as to be the technical arm of the “National Nutrition Mission”
9. Human Resources & Capacity Building

Consolidation of ongoing PG teaching programmes and starting specialized courses in gap areas.
- Ranking of DBT supported PG teaching programmes & incentives for performers
- Provision of faculty positions by DBT for teaching programmes on selective basis
- formulation of model curricula.

Use of technology for improving quality of education
- Web based portal for study material in biotechnology for easy access

Dual degree M.Sc./M.Phil, M.Sc/Ph.D, M.Sc./M.B.A., M.Sc./M.Tech, MD/Ph.D.
- M.Sc. with 1st year specialized training in industry/research labs
- Instrumentation specialized training (proteomic, gene sequencing)
- Training of clinicians in molecular immunology, molecular genetics, clinical trials, bioinformatics for in silico drug design.
- Dual degree 3 years M.Sc./MBA in bioenterprise management, agribusiness management, pharmabusiness management

Online courses
- PG dissertation for clinicians – provision of modest grant
- M.D teaching labs
- elite & Innovation niche based activities

The group also felt the need to involve more experts to discuss specialised courses in forestry, veterinary, food & nutrition, forensic biotech etc. and study the existing models to develop dual degree sandwich programmes for collaboration of Indian universities with overseas universities.

Policy on UG programmes in biotech and provision for students
- Agency for accreditation of colleges
- Recommendation to UGC to discontinue UG in biotech
- Summer training for undergraduate biotechnology students in DBT institutes/DBT programmes
- Setting up of 1000 Star Colleges (one every district)
Faculty improvement Program
- Separate overseas Associateship scheme for UG and PG teachers
- UG teachers training in 10 institutes involved in DBT PG teaching programmes,
- Fellowship for M.Sc./Ph.D overseas
- Structured workshop for Training of UG & PG teachers in star colleges/PG teaching programmes of DBT
- 4 regional institutes for training on the pattern of THSTI
- Distinguished award for superannuated teachers.
- Recognition for teachers – career development awards
- Provision for training as an integral part of programmes with huge equipment grant such as FIST by DST
- 5 technician training programmes

Specialised Short Term Training Programmes for skill improvement
How to strengthen biology / Biotech / Bioengineering interface
- Recombinant human monoclonal antibodies and production
- Drug discovery
- Stem cell
- transgenic plants
- transgenic animals
- IPR & regulation

Fellowships and project for students
Student research projects
Scholarships for joint Ph.D with industry
for Ph.D. overseas
for M.D./Ph.D

In order to capture researchers at early stage, integrated (MSc + PhD) degree programmes need to built to develop synergy between universities and research institutes. Such programmes could be executed jointly with national or global organisations, depending upon the expertise.
Creating Service Centers for Training personnel which include

- a). Centers for practical training (associated with educational institutions but independent of their administration
- b). Centers of advanced practical training and services
- c). Polytechnic schools for training in using and maintaining tools

- Introduction of internet-based educational programmes
- Training infrastructure in an institute in a collaborative and network manner

Educating and training workforce in

(i) Infectious Disease Area

Skilled workforce is necessary to accomplish improvement in the national capacity to respond to microbial threats must be supported with strong training programs (short/long-term). Department to take initiatives in the following directions to achieve these:

- Initiate new and expand existing teaching and training programmes in two broad areas, viz., basic research and public health oriented clinical research
- Research and training should combine field and laboratory approaches to infectious disease prevention and control: Training programs should include an educational, hand-on-experience at public health departments to expose future and current health professionals
- Introduce fellowships for training personnel specific for Infectious Disease area in interdisciplinary sciences including statistics for biology, toxicology, and biopharmaceuticals.
- Develop and sustain trained and competent personnel at all levels
- A core group of health professionals and other disciplines for efficient surveillance, effective rapid response to outbreaks and better understanding of emerging infections.

(ii) Medicinal and Basic Science

Development of world class human resources

(I) For both medical and basic science students and scientists

(II) Financial incentives – for both medical/ basic scientists to work in interdisciplinary research.

(III) Create additional opportunities for Fellowships/Associateships for training overseas
- Short term for graduate students for 3-6 months
- Long term for post docs/young scientists with bench money for 3-5 years

(IV) Create opportunities for overseas scientists to work in India
- Post docs/Senior Scientists
  a. Collaborative Science Chair (CSC) for 5 years (atleast spend 2/12 yearly)
  b. Post-docs

(iii) Bioinformatics, Computational and Systems Biology

Gaps and Challenges:

1) Lack of manpower with expertise in both bioinformatics and experimental biology.
2) Lack of quality graduates, highly skilled in developing newer computer codes.
3) Lack of trained manpower with know-how of new computational machines.
4) Lack of trained manpower in newer fields of Bioinformatics such as Systems Biology, Association mapping etc.
5) Lack of skilled manpower to analyze huge volume of data now being generated due to advent of deep sequencing technologies
6) Lack of trained manpower catering to the needs of industry
7) Lack of lucrative job opportunities to retain the interest of students in Bioinformatics
8) Lack of high quality teaching resources

Possible Solutions / Recommendations:

A) Training of current generation students and scientists

1. Changes recommended in existing Bioinformatics courses
   a. No more new Bioinformatics courses to be started.
   b. The existing courses must be reoriented to include a major component of biotechnology and wetlab.
   c. Increase the computer science programming component in the course work, and employ hardcore computer science faculty for training.
   d. Every course should have a specialization.
   e. Choice based Credit System for Bioinformatics, Computational and Systems Biology course in MSc Biotechnology

2. Training of Biotechnology students/ scientists
   a. One year diploma course for biology students
b. Hands-on-training for experimental biologists
c. Short-term overseas / national fellowships for PhD students and scientists
d. One year Industry training for students
e. Training of college teachers
f. After BSc, Bioinformatics Technician training program

B) Training of New Generation Scientists with expertise in both Bioinformatics and experimental biology

1. Generating a new breed of scientists with expertise in both Bioinformatics and experimental biology
   a. Start Interdisciplinary 5-year MSc, M Tech and PhD programs with strong Agricultural and Medical Science component.
   b. Partnered centers where MSc and MTech training / projects can be done in a multi-disciplinary area

2. Training of next generation scientists in emerging areas
   a. International collaborations for projects and Dual PhD programs
   b. Visiting Professorship to bring world class faculty to India for teaching in the emerging areas on assignment basis
   c. Attracting NRI scientists working in the field of Bioinformatics-Ramalingaswamy and IYBA like fellowships of DBT

3. Developing high quality teaching resources
   Book writing grant to retired teachers and scientists

C) Retaining human resource in the field of Bioinformatics
   Fellowship like those in the DST-INSPIRE program

(iv) Generating trained manpower well suited for industry requirements

a. Look at the possibility to give Research Associateships to persons for working in the Industry
b. Industry participation in teaching programs to be increased
c. Joint academia-industry PhD programs
10. Societal Development

1. Vision 2020
The vision of Department of Biotechnology in the Social Sector to develop and adopt simple technologies for improving family incomes, nutrition and health and reduce inequalities through use of precision tool and techniques for future creation of wealth ensuring social justice – specially for the welfare of the poor.

2. What are the sub areas / critical areas which need attention?
- Human Resource Development and skill upgradation
- Bioresource Utilization and its sustainable use
- Livelihood and income generation
- Health and sanitation for all
- Vulnerability
- Vocational Training,
- Knowledge Resources and Information Technology,
- Green energy and bio-fuel
- Creation of on-farm/non-farm employment
- Integrated livestock based farming

3. How to achieve this Vision?
In the present supporting system innovative approach is very much lacking. This should be addressed parallely to achieve the goals of social sector. We need to establish an inventory of experiences with technology for social development. This should also include documenting farmer/ community innovation. These experiences will be characterized and need also felt to in built mechanism of product/ technology evaluation with identification for scale up methods. Emphasis on new product/ technology development for impacting societal development would be required which can address short term and long term gains and suitable technological needs to reduce drudgery, migration check and economically viable alternate livelihood options. Also need to identify technology for different social sectors and propagate existing technologies to be taken to communities through diffusion, refinement and transfer using system sciences methods to get different sectors together for social development. There should be a multi-pronged approach to address multi-sectorial, trans-disciplinary and multi-layered issues.

4. Goals and Targets
Short Term:-
- Continue projects/ programme mode support to some extent with certain modification/ revisions of funding guidelines for the social sector.
- Establish centers of Rural Enterpurerships Development.
• Establish Incubator facilities for entrepreneurs to prosper rural industrialization in biotechnology.

Long Term:-
• Make a beginning to explore resources and funding from international agencies for implementation of projects in joint collaborations in livelihood sector.
• Establishment of Rural Technological Innovation & Application Center on a sustainable basis.
• Establishment of Biotechnology Institute on Rural Development for pursuing appropriate innovations/ R&D and skill development at par with DBT institutes like NII, NCCS etc.
• Giving equal sharing benefits to farmers in patenting/ innovations and traditional knowledge.

5. Strategy for next five years

1. Identification of thrust areas

2. Establishing institutional framework
   - Carrying out barrier analysis
   - Establishing Centres of Excellence for social innovation and invention
   - Supporting prominent NGOs for diffusion and evaluation of technologies

3. Leadership development
   - Identifying elite core
   - Repackaging training programs to match private sector.

4. Determinants of technology acceptance by communities / businesses
   - Penetration and coverage
   - Cost-effectiveness / economic evaluation
   - Cultural and social appropriateness
   - Social entrepreneurship
   - Other factors

5. Technology Standardization and accreditation : Developing a regulatory framework

6. Technology Evaluation

7. Stakeholder identification
   - Institutions
   - Individuals
   - NGOs
- KVKs
- PRI
- Others

**Target:** (Client, Region, Specific)
- Rural / Urban poor
- Women
- SC/ST
- Marginalized segments of society

1. Farm-based technologies
2. Health-based technologies
3. Waste disposal and water sanitation
4. Translation of mass use technologies (Scaling at Population Level)
   - Farm and non-farm innovations
   - Instituting management perspective
5. Human Resource development
   - Social Innovations as a theme
   - Retraining floating population
   - Social and behavioral sciences embedded in HR development
6. Social mobilizing and Marketing:
   - For community empowerment
   - Adoption of technologies
7. Committee for setting up Centers of Excellence

**Specific recommendation**

- **Research priorities:**
  - Need to give focus on development of sustainable programme having national and global vision for high impact based activities addressing aspects on the welfare of human life through suitable technological interventions, generate income and employment avenues for the benefit of the target community. The programme should also address the issues of drudgery, migration, productivity, profit and market and towards the overall development of the community welfare. To address the issues broad areas are suggested below:
  - Agriculture and allied Sector
  - Health & Sanitation
  - Environment & Biodiversity conservation
  - 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
- Rural Bioresource Complex/ Hubs.

• **Resources**
  → **Human resource**
  - Need to produce skilled and unskilled manpower required for farm and non-farm trade related activities and creation of self-employment.

→ **Infrastructure**
  - Create rural infrastructure for promoting biotech interventions by the prospective farmers and the entrepreneurs like setting up of incubator facilities, technology resource centers, village knowledge centers etc.

→ **Finance**
  - Create suitable financial institutions and fund support mechanism for promotion of biotech interventions by the entrepreneurs and farmers.

• **Training and other skill specialization needs**
  - Farm based and trade related skilled development among the Youths, Women and Rural folk.

• **Global networks / collaboration**
  - Collaborations with neighboring countries viz. Asian and African countries and others which can jointly be pursued for research innovation, technology development, refinement and validation to suit the basic need of the rural youth and entrepreneurs and innovative farming system to fetch better remuneration and lifestyle improvement.

• **Governance model**
  - It is equally important to adopt e-governance in implementation and monitoring of social sector projects, should be user friendly and easily accessible to others and understandable the percolation of technological know-how, viability, deliverables and success driven goals with accounting.
11. Industrial Biotechnology

Vision:

✓ Produce 20% of India’s bulk chemicals by biocatalysis/bioprocessing technologies.
✓ Create at least 10 companies that have a combined turnover of at least 15000 crores/year based on substantially indigenous IP.
✓ Create 2 million industry ready biotechnology manpower.
✓ Increase DBT’s funding to do Industrial Research to 50% of its budget up to 2020.

How to achieve this vision?

✓ Creation of platform technology centers critical for growth with proper governance structures to enable access.
✓ Specific Requests for proposals and generous funding for large consortiums of industry and academia for targeted product development.

Strategy For Next Five Years

• Set up 5 Technology platform centers.
  Could be achieved by setting up multi-disciplinary centers around existing academic centers of excellence in collaboration with industry. These centers should have clearly defined goals and deliverables and should be mandated to provide access of their resources to both academia and Industry.

• Research and identify products and fund at least 4 large consortium grants.
  This could be envisaged by setting up centers “around” existing academic institutions in collaboration with industry. This should be mission based, should draw existing strengths of academic institutions and industry around it.

• Enable research based grants for industry.
  The goal is to enable more funding in discovery research like SBIRI-Phase I grant. The mechanism of increasing funding to Industry and entrepreneurship activity should be seriously looked upon.

• Create a Technologist/Research (SERVICE ORIENTED) track with a reward system that is attractive and prestigious as Faculty.
  A “faculty entrepreneurship” program may be considered to allow faculty with IP to setup small biotech for doing early translation.
- Set up Technology Development Centres within existing academic Institutes as Section 25 companies with focus on:
  - Biochemicals/biofuels
  - Therapeutic/Diagnostic Biotechnology
  - Bioremediation

- These Centres could be given responsibility of identifying, funding and networking with, several satellite pockets of excellence wherein specific sub-tasks of a given technology can be worked upon depending on the expertise at the pocket.

- The Centres will also work closely with industries and pilot test the technologies, developed by the centres or elsewhere, at a reasonable scale and engage desirous industry to assist them to take the developed technologies to commercialization.

- The 4-5 Centres will be advised/governed by a single central committee set up by the DBT that will decide the technology priorities from time to time.
12. **Intellectual property landscaping, Technology transfer, incubators, entrepreneurship, SME support systems**

**Vision**

Indian enterprises to have sustainable competitive advantage to deliver affordable products through *synergistic interaction* of public and private sector.

**Critical areas**

1. Innovation funding needs
2. Enterprise incubation and technology validation infrastructure
3. Technology management professional development and licensing of technologies for accelerated commercialization

**1. Industry innovation funding schemes**

Currently SBIRI and BIPP provide access to innovation funding

**Proposed initiatives**

- Ignition grant scheme (already being addressed by DBT)
- Funding of technology access
- Nurturing collaborative research in translational validation
- Product commercialization funding

**2. Support for Business incubation infrastructure, technology validation and scale-up infrastructure**

- 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

**3. Technology Management Professional development and Licensing of technologies for accelerated commercialization**

a. **Institutional level capacity creation**

Over 150 Technology Transfer Organizations (TTO) 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

b. **Access policy to focus on tech acquisition and their access for commercial application**

**Technology repository**

• Global acquisition of technologies  
• Access transaction to be structured by trained professionals  
• Access for affordable solutions  
• For broad spectrum of intellectual assets- biomaterials, patents, data, copyrights and business methods  
• Subject to translational validation  
• Transferred to enterprises for commercialization

The bill on ‘Protection and Utilization of Public Funded Intellectual Property’ to provide impetuous to this.

4. **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.
13. Bioinformatics, Computational and Systems Biology

SESSION-1:
Bioinformatics research resources and facilities for services to academia and industry

GAPS and CHALLENGES:
1) Lack of National data policy and a National data center. Very few software tools & databases are developed in India. Most of those that exist are not validated and are highly fragmented.
2) Lack of state-of-art computing facilities to analyze the voluminous data being generated and to carry out research at par with the world.

POSSIBLE SOLUTIONS / RECOMMENDATIONS:
i) Bioinformatics Institute:
   a. Institute should cater to both Services to scientific community and high quality research.
   b. Initially one institute maybe established, and later we can think of four centers across the country that will operate in a highly coordinated manner with the institute.
   c. The institute must be autonomous in nature.
   d. The institute must complement the existing BTISnet system and not replace it.

ii) Need for a National data policy and a National data center:
   a) A National data policy must be developed which will make it mandatory for all databases & tools to be validated by publishing in indexed journals and must reach the National data center, where they will be consolidated and made publically available.
   b) The international databases are reaching their limit for accepting more data, especially due to huge datasets being generated with deep sequencing and other high- throughput platforms. India must have its own data center where the nationally generated database can be deposited.

iii) Strengthening of BTISnet:
   a. The system is vibrant and must be preserved as such, without a major overhaul.
   b. More manpower must be given by DBT, to develop skilled personals and also carry out research.
   c. Subject-specific meeting to be organized through BTISnet centers.
   d. A monitoring system must be established for these centers, and those performing well maybe upgraded.
e. More advanced state-of-art facilities may be given to the centers in the universities and colleges.
f. CoEs to ask for more infrastructure and manpower in a project mode.

iv) Developing world class computing facilities:
   a. Number of supercomputing facilities may be increased
   b. Look at the possibility to introduce Cloud / Parallel computing in the country

v) Establishing service centers in existing institutions engaged in high-throughput experimental research:
   a. Database issues require perpetual attention. Moreover the huge datasets have large variations. Neither universities, nor institutes are geared for handling the voluminous data with huge variations, generated by newer sequencing platforms such as deep sequencing. To take care of these needs, permanent services centers must be placed in the existing centers.

R&D and Mission Mode Projects

Gaps and Challenges
a) High quality research and professionalism lacking
b) We are successful in generating ‘distributed information’ in the form of publications, however we are still unable to get ‘organized information’ that can lead to product development.
c) Need for top down / mission mode interdisciplinary projects
d) Need to evolve projects in newer areas, as most of the projects to date are mainly on drug discovery.
e) Lack of understanding/complementarity between bioinformaticians and experimental biologists.

Possible Solutions / Recommendations:

A) R&D projects
   1) Implementation of a robust mentoring program to improve quality of the R&D projects submitted to DBT for support.
   2) CoEs can apply for R&D grant to get more infrastructure and human resource support. The proposal should have a focused research component.

B) Mission mode projects
   3) DBT to organize domain-specific brainstorming sessions for evolving interdisciplinary Mission mode projects in gap areas.
3a) Some research areas that may be considered are:

- Specialized tools for analyzing next generation sequencing data
- Systems Biology in medical and plant sciences
- Biotherapeutics development
- Computational tools for Synthetic Biology
- Personalized medicine utilizing bioinformatics, systems biology and next generation genomics.

3b) Development of data repositories for promoting translational bioinformatics

- Molecular e-resources based on ‘omics’ platforms e.g. consolidation of small RNA data being developed by many labs across the country
- Health / Medical record e-resources
- Plant trait e-resources
- Clinical trial e-resources
- Bio-safety data e-resources
- Drug and drug target databases

These Electronic records will provide a wealth of information for future research endeavors especially in the field of genome-wide association studies to map complex diseases/traits, personalized medicine, drug development, crop breeding etc.

In line with TB and rice consortium projects, more databases can be developed.

C) **Development of a consolidated database of scientists** in all fields of biotechnology and bioinformatics to bring people together for mission mode projects

**Bioinformatics industry development and future trends**

**Innovation strategies, Models Mechanisms and Alliances**

**Gaps and Challenges:**

1) Bioinformatics industry is still in infancy and thus offers very poor job opportunities. Pure Bioinformatics companies are a failure, and those doing well have a reasonable component of experimentation.
2) Lack of a model to support new entrepreneurs (i.e. without a DSIR recognized company)
3) Bioinformatics industry focus is very narrow i.e. mainly drug development
4) Trained manpower well suited for company requirements are lacking
5) Industry-Academia partnership essential for product oriented research is lacking
POSSIBLE SOLUTIONS / RECOMMENDATIONS:

Industry-Academia partnership
a. Academia – based service centers / market maybe developed to provide unique Bioinformatics solutions to industries e.g. Pharmaceutical Industry
b. Academia – based training centers focused on generating manpower suitable for industrial needs
c. Industry-Academia partnership to be supported under mission mode projects
d. Increase interaction by inviting industry people to Bioinformatics annual meeting

Model to support young entrepreneurs
a. Young entrepreneurship development scheme for Bioinformatics without a DSIR recognized company
b. Incubation centers to be developed

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.

- **Global Partnerships:** India should participate in major international events to develop network and enhance environmental cooperation; for this it is imperative that DBT aggressively pursues global partnerships with governmental organisations, non-governmental organisations and philanthropic research foundations.

- **Participation in Global Initiatives:** DBT should make a concerted effort to increase its participation in the number of multinational projects / initiatives.

- **Public-Private Partnerships:** To encourage innovation and enterprise and to provide a platform for international biotech industry to collaborate with Indian biotech industry, a strategic environment should be created for smooth global public-private partnerships.

- **Global Service Provider:** DBT should strengthen its national biotech service sector such that India is the first global choice as a biotechnology service provider be it in the area of genomics, proteomics, data-mining etc.

- **Human Resource Development:** Collaboration in higher education with the best in the world should be the top priority. The scope of higher education should be interdisciplinary enterprise driven. PhDs and Post-docs with international academic / industry participation should be explored.

- **International Science Meets:** DBT should organise international scientific meetings twice a year to debate and discuss Scientific Grand challenges.

- **Ultimate Goal:** By 2025 DBT international Cooperation should become robust enough such that foreign offices of DBT are required in USA, Europe etc., something like the BBSRC, DFID, Tekes offices.