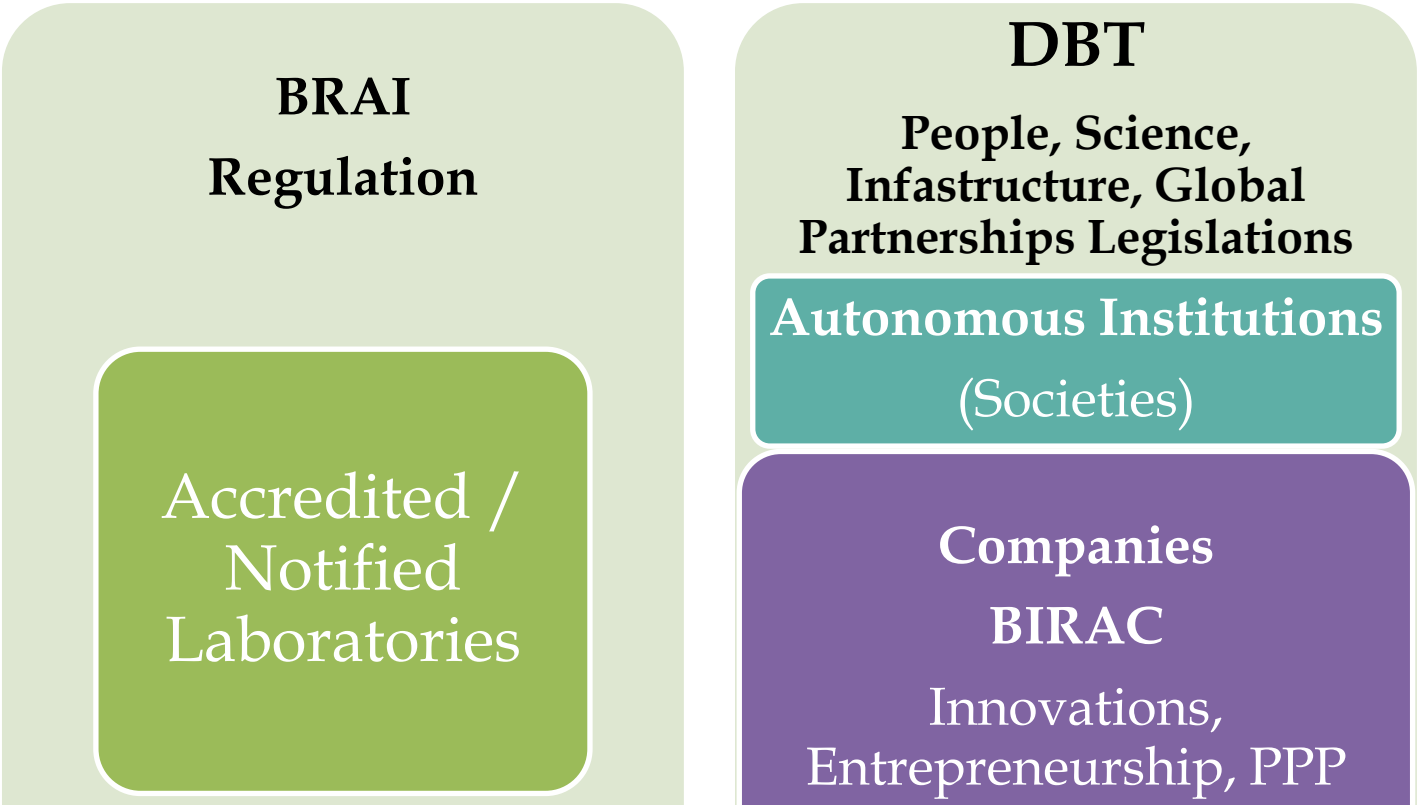
Report of the Working Group on Biotechnology 12th Plan (2012-2017)



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Government of India

Department of Biotechnology
Ministry of Science & Technology
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FOREWORD

The Department of Biotechnology completes 25 years of its establishment by the end of 11th Plan. Biotechnology developments during this period experienced five distinct phases: initial foundation phase followed by capacity building; research and development; institution building and promotion of innovation and excellence. The main strategy of last phase or of the 11th Plan period was to take science in this sector to the next higher level, to push new frontier areas in interdisciplinary manner, to create such tools and technologies that address the problems of largest section of the society, provide products and services at affordable prices through synergistic efforts of public and private sector and make India globally competitive in the emerging bio-economy.

Overall implementation of proposals of 11th Plan aligned to strategies formulated in the National Biotechnology Development Strategy, 2007 has brought about paradigm shift in the ways and means biotechnology programmes and projects formulated and supported. Strong beginning has been made to create an ecosystem of innovation in biotechnology. More than 90% of the initiatives committed have been implemented. Higher budgetary allocations (Rs. 6389.00 crores) for the 11th Plan as compared to 10th Plan (Rs. 1653.00 crores) made it possible for major expansion of programmes: seven new autonomous R&D institutions, 10 translational research centres and platforms, grand challenge mission mode programmes, 50 centres of excellence, more than 2400 R&D projects in priority sectoral areas involving more than 3000 investigators and 6000 research personnel, 100 public private partnership projects and key global partnerships involving high investments. Industry experts acknowledge these major government initiatives for exponential increase in biotech industry revenues from Rs. 8541.00 crores in 2006-07 to Rs. 17249.34 crores during 2010-11.

While the progress is impressive, a critical scrutiny of India's position in global context reveals several gaps and barriers keeping in view of future requirement for growth. Indian life science enterprise is small compared to competitive countries like USA, Japan, South Korea and China. The overall strategy of 12th Plan proposals therefore is to "accelerate the pace of research, innovation and development to advance biotechnology as strategic area by taking India's strengths in foundational sciences to globally competitive levels and expanding the application of biotechnologies for overall growth of bio-economy within the framework of inclusive development".

Therefore, emphasis is now to sustain investments for scale-up and augmentation of schemes of 11th Plan focused on promotion of innovation and excellence, public-

private partnerships, research resources and specialized centres, technology platforms and service facilities, existing autonomous institutions, major R&D programmes and networks for technology development. At the same time, during 12th Plan, new centres, platforms, institutions, bio-clusters and grand challenge programmes addressing national priorities of health, agriculture, energy, climate change, environment and industrial growth are proposed with higher investments. Establishment of Biotechnology Industry Research Assistance Council for facilitating growth of starts-up and SMEs and Biotechnology Regulatory Authority of India for streamlining regulations would be priority. New governance models and management with respect to hiring, partnerships, monitoring and networking shall be put in place for maximizing the returns. Together with this wish list and carefully articulated strategy, it is expected that Indian biotechnology sector would expand by 3 folds by the end of 12th Plan.

With the foundation laid and various strengths and weaknesses identified, it is the time now to increase the pace in terms of activities, actions and investments. We share these strategies through this report to encourage the stakeholders of biotechnology sector to discuss and debate further and provide feedback on plans, programmes and implementation modalities for continuous improvement. Our goal is an industry of $20 billion annually by 2020 with a string of new companies having strong impact on health, agriculture and nutrition security of the country and a scientific base that can discover and innovate for the 21st century at world class level.

I thank all the members and the convener of the working group, DBT scientific officers for their time and valuable inputs.

M.K. Bhan
Chairman
12th Plan Working Group on Biotechnology
Planning Commission

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Executive Summary

The Working Group on Biotechnology constituted under the Steering Committee of S&T, Planning Commission reviewed and assessed the 11th Plan physical and technical progress of the Department as against the proposals. The group also examined the implementation of National Biotechnology Development Strategy of the department prepared in consultation with several stakeholders and which formed the basis for 11th Plan proposals. Parallel to this exercise, the department constituted 12 experts committees to formulate Vision and Strategy for 2025 in niche areas of national importance. To supplement these efforts of the working group, DBT autonomous institutions were also asked to conduct regional meetings involving various stakeholders from academia and industry.

The final recommendations contained in this report are based on synthesis of all these inputs involving more than 300 experts in different areas of biotechnology education, research and development and promotion of innovation and excellence. The recommendations also integrate appropriately the salient features of 12th Plan approach paper for S&T in general published earlier by the Planning Commission. We will soon send a report on the vision and strategy 2025 to provide a more detailed background for the 12th Plan.

Review and assessment of 11th Plan

The main strategy of 11th Plan was to take science in this sector to the next higher level, to push new frontier areas in interdisciplinary manner, to create such tools and technologies that address the problems of the largest section of the society, provide products and services at affordable prices through a synergistic effort of public and private sector and make India globally competitive in the emerging bio-economy. It was important to globalize our R&D efforts and make them nationally relevant through collaborative innovation.

Accordingly, the focus was on cross-cutting issues such as human resource development, smarter re-entry for our scientists abroad, new and varied models of creating innovation-friendly micro-environments, R&D in small and medium size companies, newer ways of collaborating with large companies, establishing centre of excellence, remodeling life sciences departments in universities/institutions, promoting dynamic biotech regional clusters, interdisciplinary networks, academic and industry interface, infrastructure development, lab and manufacturing, promotion of industry and trade, expansion of autonomous institutions and establishment of new

institutions uniquely designed to have both science and transitional capacity, biotechnology parks and incubators and regulatory mechanisms.

The 11th Plan thus was aimed at laying a foundation for progress in basic and translational work in sectors such as agriculture, food and nutritional biotechnology, industrial biotechnology, medical biotechnology, bio-engineering, nano-biotechnology, bio-informatics and IT enabled biotechnology, energy, bio-resource mapping and prospecting, environment and its preservation, intellectual property & patent law, international cooperation and, of course, in meeting the basic needs of the society for affordable technology .

Our whole enterprise was designed previously to support good competitive science but not mid level innovation. We have worked on several fronts towards this goal: need-analysis and idea generation strategies, innovation-centric training, promotion of translational research, diversifying human talent, innovation relevant infrastructure in an accessible manner, national and global connectivity for collaborative innovation, public-private partnership and regulation.

An assessment of first four years (2007-2011) has been undertaken for measuring indicators of performance. About 2410 projects have been implemented under various R&D schemes costing about Rs. 1600 crores. Among the sectoral areas, 26% (535) of the projects were in the area of medical biotechnology covering vaccines, diagnostics, human genetics and host pathogen interaction followed by 22% in agriculture and allied areas of biotechnology; basic research and emerging areas (20%); bioresources and bioprospecting (19%) and 12% in capacity building (International collaboration/bioinformatics and HRD). In terms of expenditure, the trend was similar.

Translational R&D in sectoral areas was an evident priority in 11th plan while substantial importance was given to advancement in basic science and emerging research areas such as nano-biology, chemical biology, RNA biology and systems biology. In terms of manpower, a total of 5887 research personnel were supported in R&D projects and through HRD programmes in the categories of Junior Research Fellows (1768), Senior Research Fellows (1844), Research Associate (1060) and 70 professorships. In addition, about 2142 post graduates students in life sciences and biotechnology were given biotechnology industry training fellowships involving 200 industries; about 30% of these trainees were provided employment in the same industries. This scheme creates finishing experience as well as placement.

As we had committed, the estimates so far revealed that Universities received 50% of projects and funds followed by research institutions and public private partnerships. Our approach to universities, though laborious, provided support based on in depth analysis of strengths and weaknesses and as contracts with quantitative outcomes for continued support. This has resulted in a balanced strengthening of infrastructure accessible to students, new hiring of young people by merit, expansion of the PhD programme, improved governance and branding of these universities as multi departmental life science centres.

In order to assess the performance of extramural research projects, relevant information was collected across projects and institutions. It was recorded that there were a total 1104 publications of impact factor 5 and above; 312 patents (national/international) were filed and 110 patents have been granted; 105 technologies developed, 21 transferred to industry and 5 commercialized. A large number of technology transfers are in process. Healthcare technologies dominated in technology development compared to agriculture. This is because of limited information or under estimates but indicate the quality push that was desired. Our competitive grant system is totally online and from 2012, detailed analysis will be available on the performance of the extramural system at any time.

The 11th Plan also witnessed major expansion through launching of variety of schemes for promotion of excellence and innovation, promotion of bio-industrial activities, establishment of new institutions in critical areas of national importance, translational research platforms and incubators. Programme on Centres of Excellence around innovative leaders and institutions with 15 category I centres. 35 programme supports and 11 individual projects resulted in of 200 publications with impact factor >5 published including journals like Nature, PNAS; 33 national patents filed and 24 granted; 37 international patents filed 26 granted; 10 research leads and 1 technology transfer. This Centre of Excellence scheme has been rewarding for basic science and elating our image abroad.

Ten translational research centres and platforms established for clinical development service, GM crops translational research, energy biosciences, Bio-design for implants and medical devises, Stem cell research, drug discovery, Primate Research and veterinary biologicals. A new International Depository Authority for Microorganisms at NCCS Pune established besides, continued support to IDA at IMTECH, Chandigarh. Novel DBT partnered governance models in existing institutions for management of these translational and technology platforms are an important innovation in itself and expansion of these DBT partnered centres across the country is a cost effective way of achieving translational excellence in the country.

Seven new autonomous R&D institutions namely (i) Translational Health Science and Technology Institute, Faridabad; (ii) Regional Centre for Biotechnology, Faridabad; (iii) National Agrifood Biotechnology Institute, Mohali; (iv) National Institute of Biomedical Genomics, Kalyani; (v) Institute of Stem Cell Biology and Regenerative Medicine, Bangalore; (vi) National Institute of Animal Biotechnology, Hyderabad, were set up. In all the institutions interim facilities have been established, directors and staff recruited, research work initiated, land was acquired and construction is ongoing. Several of these institutes are embedded within clusters which apart from several institutions of different agencies, will have incubators, parks, entrepreneurship development centres, SME support technology platforms, all under cluster boards. The shared governance models of these emerging clusters have distinctly advanced our collaborative abilities.

Emphasis on public private partnerships schemes such as Small Business Innovative Research Initiative (SBIRI) and launching of new scheme Biotechnology Industry Partnership Programme (BIPP) paid rich dividends in terms of promoting R&D in small and medium bio-industries. About 100 PPP projects have been launched so far. SBIRI scheme resulted in 6 Indian patents and development of 16 technologies in agriculture, health care and instrumentation. 60 projects supported under BIPP scheme benefitted 51companies (27 small, 12 medium and 12 large companies). H1N1 vaccine developed in BIPP supported project was recently approved by Drug Controller General of India (DCGI) for marketing and pneumococcal conjugate and HPV vaccines are making rapid progress.

SBIRI and BIPP are providing a major boost R&D in small and medium companies in areas where there were little activity when we began these schemes: Bioenergy, implants and devices, gene discovery, molecular breeding, basic platforms for diagnosis and bio instrumentation. The schemes have also triggered strong activity in development of off patent biogenerics at affordable price. High risk innovation and affordable technology development have received balanced attention. Excellent, widely respected processes for assessment and management of PPP projects have been established and these should serve us well as we scale up. As BIRAC becomes fully operational, we hope to catalyze large scale movement in innovation and new company formation.

Major global partnerships were fostered to add value to the national priorities and initiatives. The welcome trust-DBT partnership biomedical fellowship programme to attract scientists of Indian origin to take-up research assignment in the Indian institutions and universities was successful with more than 50 scientists receiving the

fellowships. Stanford biodesign programme in collaboration with Stanford University provided needed support for domestic biodesign initiatives for implants and medical devices and bioengineering. New collaboration with Canada, Australia, Denmark, Sweden, Finland, UK and EU resulted in high quality publications, patents and technology transfer.

The Biodesign training followed by innovation project concept has been internalized to our country after originating from an international collaboration. The Biodesign process initially developed for implants and devices has now been extended through a national alliance to diagnostics and drug delivery systems for which we observed this process to be very helpful. An international partnership has catalyzed a national movement involving industry, medical schools and engineering schools. Expansion of this scheme could potentially produce hundreds of young innovators and entrepreneurs, affordable products and companies. The governance of this national alliance, as we scale up, is a challenge to be met. Strategic alliance for affordable solution has been established with NIH, Gates Foundation, WHO, DFID and multiple bilateral country programmes.

Major translational research initiatives through grand challenge schemes and network programmes in the areas of agriculture and health care resulted in several technological developments. Vaccines for malaria, dengue, cholera, and rotavirus are at various phases of clinical trials. Rota viral vaccine is in phase-III trials and may be commercialized by the end of 11th Plan. Public-Private-Partnership projects with novel technology transfer arrangements facilitated by DBT will ensure availability of the world's cheapest vaccines against pneumococcal pneumonia, rotavirus, HPV, chikungunya and Japanese encephalitis. The public sector contribution is focused on difficult to make vaccines and industry led partnerships will handle product development when science is not limiting. A balanced strategy has thus evolved during the Plan.

Public sector developed GM crops such as insect resistant chickpea, rice, brinjal: drought tolerant groundnut, sunflower: mustard with hybrid vigour are in regulatory pipeline. Accelerated molecular breeding programme in rice, wheat, corn, mustard have been launched and protein rich maize is already commercialized. Similarly, technologies for food fortification, bioremediation of environmental pollutants, biofuel production are in advance stages for technology perfection and transfer. The potential of this sector based on current research is excellent if public policy issues can be handled.

Overall implementation of proposals of 11th Plan aligned to strategies formulated in the National Biotechnology Development Strategy has brought about a paradigm shift in the ways and means biotechnology programmes and projects formulated and supported. As envisaged, a strong beginning has been made to create an ecosystem for innovation in biotechnology. About 90% of the initiatives committed in the biotech development strategy have been initiated. The DBT-Welcome affordable health initiative is in progress. Biotech Regulatory Authority legislation and full operationalization of BIRAC are expected to happen soon. However, the critical scrutiny of strengths and weakness of biotechnology developments in public and private sector revealed that:-

- While human resource in basic life science and biotechnology education has been generated, there is acute shortage of people with expertise for high- end disciplinary and interdisciplinary research and scientists and professionals relevant to mid-level innovation. The gap areas include: interdisciplinary bio-pharmaceutical professionals, technology transfer professionals, translational scholars in all fields, science background project managers, statisticians working in genomics and computational sciences, clinical bio informatics experts, toxicologists, quality assurance lab mangers for regulation relevant laboratories, physician scientists and regulatory professionals. The steps initiated in this Plan must be scaled up in the 12th Plan for us to product innovation.

- While drug development has a unique approach, vaccine development, diagnostics, implant and drug delivery requires need and opportunity analysis to drive product profiling and development because we have an extremely heterogeneous market. Units capable of need and opportunity analysis and product profiling can be enormously valued for SMEs and Public Sector institutions.

- There is also an acute shortage of some key research resources for translational work: animal models of disease including knockouts, new drug screening systems for different diseases, toxicology labs, large animal facilities, assay validation labs and many others. Most institutional scientists who have interested leads are unable to seek guidance for how to negotiate the translational pathways. A clinical development service agency has been established in New Delhi on a pilot basis and such units across the country can help decide what is translatable and how to progress ahead.

- The positive impact of all that has been done is that our quality PhDs are being produced in larger numbers, young people are getting innovation experience, translational research has gained a new respect in the country. The strategies for how to overcome existing gaps and barriers have been developed through experimentation, trial and error. This puts us in a strategic position for acceleration during the 12th Plan.

Recommendations for 12th Plan (2012-2017)

Keeping in view of the above inputs from various stakeholders and experts, success and lessons learnt in implementation of "Biotechnology Development Strategy, 2007" which formed the backbone of 11th Plan (2002-2007), the wide range of programmes and projects implemented during the last 3 years of 11th Plan and their spillover effects in terms of programmes, objectives and investments, the recommendations for 12th Plan have been made.

The overall strategy of 12th Plan proposals is to "accelerate the pace of research, innovation and development to advance biotechnology as strategic area by taking India's strengths in foundational sciences to globally competitive levels and expanding the application of biotechnologies for overall growth of bio-economy within the framework of inclusive development".

This strategy of 12th Plan complementing the foundations laid during the 11th Plan shall be achieved through focused investments, policy support, reforms in governance and management of projects around the following goals:-

(i) **Expand available pool of research scholars and scientist at all levels (Ph.D, PDFs, young faculty) in biological and interdisciplinary space by 3-5 folds:** a thorough, major programme based support for expanding biological/life science departments and clusters in universities, IITs, medical, veterinary and agriculture and pharmaceutical universities/departments, centres of excellence, existing and new DBT/DST/CSIR biology institutions. This would also involve disciplinary, more important interdisciplinary bio-based science linking to quantitative sciences (chemistry, engineering, physics) and expanding biological and interdisciplinary sciences in human, animal and plant science systems to achieve greater translatability of knowledge with feasible model system.

(ii) **Connecting and augmenting existing competences across institutions and universities for bio-economy and social impact**: Inter departmental and institutional centres overall and extramural centres of DBT institutions supported with a novel

contractual career path for faculty and scalability to connect existing competencies will improve interdisciplinary science, use inspired and translational research. This approach is impactful and cost effective but requires standardization of management. Few examples of such connectivity are: Biosciences with chemical sciences and Synthetic biology for next generation biofuels; Nanoscience; chemical sciences and pharmaceutical sciences with clinical research for novel drug delivery, novel diagnostic and medical image, engineering-medicine-biology and medical science for implants and devices, chemical biology, physical biology.

(iii) **Expanding, diversifying career paths with a linkage to high-end interdisciplinary sciences, innovation, translation and entrepreneurship**: involving support to centres of excellence , incubators, programmes for expanding existing research and human resource capacity by 3 folds through increase in current areas of relative strength such as molecular and cell biology, structural biology, immunology, neurobiology, bioengineering and promoting career paths in clinical and translational research, regulatory sciences, IP technology transfer and knowledge management, entrepreneurship and education etc. The challenge here is how to create rapid expansion over a five-year period under existing administrative norms.

We propose expansion, redesign and creating extramural and inter institutional centres as a cost efficient process of scale up utilizing the existing best people with some additional younger people. The IIT system offers a unique opportunity over a substantially large inter connected and effective bioscience, inter disciplinary science, bio and other engineering science linked to technology innovation in almost all areas of biotechnology relevant to the country. This should receive high priority and use the instruments defined above for connectivity and for conversion of early leads to meaningful solutions and products. The foundational work for this flagship effort has already been done in the 11th Plan with the IITs and their domain institutional partners.

(iv) **Strengthening regulatory science and infrastructure**: It involves establishment of Biotechnology Regulatory Authority of India; central agency for regulatory testing and certification laboratories" with some core activities and network of testing facilities in public sector laboratories; promotion of regulatory science research units; and human resource development.

(v) **Expanding existing autonomous R&D institutions and establishment of new institutions in emerging areas of critical national needs:** The expansion aims at expanding current strengths of researchers and scientist by 3 folds at all levels through on-site expansion or establishment of second research campus; setting-up of

extra mural research centres on or off site to promote translational science, launch mission programmes or to advance interdisciplinary science area and expanding physical infrastructure including technology platforms. It is proposed to adopt a system of intramural institutes and extramural centres for each of our 14 autonomous institutes as is the model in the developed world. These extramural centres could be located in medical schools, state agricultural universities, engineering schools and so on with about 10-12 principal investigators at each extramural centre. We have developed a contract career path that is attractive and respectable for use exclusively in the extramural centres. Even if each of our 14 institutes created 4 such centres for each, about 500 scientists additionally can be supported with existing leadership and anchor role by the autonomous institutes. The approach has been piloted, tools and processes have been developed, it is practical today and not Utopian. This will also strengthen translation of created knowledge.

Governance models for new Centers:

We propose 4 types of Governance models for new centres hiring: (1) Grants-in-aid receiving centres in existing universities or institutions around thematic areas; (2) Grant-in-aid receiving inter institutional centres for interdisciplinary research and focused translational work; (3) Time bound centres which can be either closed or absorbed by the host institute or converted into Grants-in-aid receiving centres based on external review and need over time. Initial support for five years, extendable by 4 years, has been shown to work well globally for such centres and (4) National virtual alliances and networks linking multiple institutions with a strong coordinating centres. The biodesign alliance pilot model is a good example. These networks can be programme based and in some instances be like national institutions. These models can be used in the clusters or in DBT partnered units as below.

Proposed new institutions: Two institutions proposed during 11^{th} plan each on marine and microbial biotechnology and bioinformatics and computational biotechnology will be taken up for necessary approvals. Three new institutions such as (i)Institute of Biodesign, Bioscience & Bioengineering (includes Medical Centre) (ii) Institute of Chronic Disease Science & Biotechnology (iii) Infectious Science & Biotechnology Institute in North East (linking to THSTI as partner for training & Education)

(vi) **Expansion and commissioning of bioclusters at Faridabad, Mohali, Kalyani and Hyderabad**: Adding new programme based centres at each cluster: academic centres, medical centres, bioengineering centre, contract labs, GMP units, animal model resources, novel platforms for therapeutics for sharing by SMEs,

technology incubators and parks of entrepreneurship training centres and offices for technology transfer and management and to provide connectivity for innovation. This potential for integrated development of science, innovation, entrepreneurship, domain connectivity and business is now possible with the foundational laid in the 11th Plan at Faridabad, Mohali, Bangalore, Hyderabad and Kalyani, Kolkata.

(vii) **Establish DBT grant-in-aid or partnership research and translational centres through long term (EFC) support** in 10 best universities/institution in atleast 10 areas of interest: for example: Agriculture sciences and innovation for pre-breeding, GM technology and molecular breeding; veterinary science and technology for animal productivity and health; Biopharmaceutical sciences and health technology; Chemical biology and synthetic biology.

(viii) **Reorient "Grand Challenge Programme" scheme of 11th Plan to address national priorities** in various developmental sectors through bottom-up approach and also encourage discovery led innovative ideas: These are 8 Mission mode programmes with separate governance, management, milestones with inter departmental participation and global partnerships and bottom-up idea based competitive grants for R&D and innovation or network projects with several partners along the biotechnology value chain. Some examples include: Science and technology for safe pregnancy and child birth; Climate change and agriculture productivity; health technology for improved quality of life: vaccines, diagnostics and cell therapies: grand challenges in new basic sciences – genomics based new drug discoveries, nano-biotechnology based drug delivery system, biomarkers for personalized medicine, synthetic biology and advanced biofuels.

(ix) **Rejuvenate existing and establish new research resources, facilities and services**: A National Life Sciences Resource Centre (NLSRC) with specialized research staff, informatics support and data bases to network all research resources, training for skill development activities and organize a systematic information access management facilitating biology research community. New facilities and resources proposed include: low end virtual supplies for small organizations example micro array, knockout mice; Validation and prototyping, safety testing technology platforms/centre for implants, devices, cell therapies; large animal resource centre; viral testing facilities; Genomic and proteomic facilities ; New generation sequencing service units etc

(x) **Leverage international collaboration for partnerships in cutting edge areas of research, education and technology development, access and acquisition:** The experience with exiting global partnerships with countries and international agencies

will be leveraged to bring about directional change in partnership strategies. Towards this objective focus shall be on establishing joint centres of excellence; graduate schools across universities; forging 2X2 international involving industry and academia on either side, 1X1 partnership among SMEs projects; Linking DBT autonomous institutions with international institutions and universities; Joint development industrial biotechnologies with global organizations. Global consortia of industries and public institutions will be promoted on the lines of the Indo-US Bio-energy initiative in other areas, such as molecular breeding, cell therapy and regenerative medicine etc.

(xi) **Continued and Sustained support to public private partnerships with new innovative funding schemes**: Besides continuing with some reforms in SBIRI and BIPP schemes operations innovative funding schemes such as : Ignition Grant Scheme available to individuals or a team of individuals– in partnership with private investment agencies; Schemes for creating and nurturing startup for early stage technologies; Provision of "bridge funding" firms to function between successive private equity funding or planning for IPOs; funding for technology access and acquisition and licensing and special investment incentives to industry for building more biotechnology/pharma SEZs. Biotechnology Industry Research Assistance Council (BIRAC) would become fully operational in 12th plan to assess and facilitate bioindustry as per its mandate and mange funding through PPP schemes. Through BIRAC, appropriate expansion of incubators and parks is an important need given our sustained 20% annual growth.

The affordable health technology initiative with Welcome Trust will be launched. It will have a pro-poor bias, focus on mass health impact and enhance our abilities to access technology from overseas in addition to from within the country. In this way, we have created a diversity of schemes to promote academia-industry interaction. Healthy competition across the schemes will aid performance with each addressing a different phase of discovery to commercialization path ways.

(xii) **Promoting discovery led innovation and strategic investments in priority sectors**: The department has been funding investigator –driven R&D projects across areas of basic agriculture, health care, environment, animal health and reproduction, bioresource utilization and food science and technology etc. During 12th Plan it is proposed redesign sectoral strategy in such a way that every sector utilizes more than one mechanism or modality, linkages, partnerships and alliances and platforms that are required for successful development of both science and technology. Therefore, the sectoral areas are bifurcated into Basic and use Inspired Research and Translational Science and Strategic Research. The later involves discovery-to-market

approach along the biotechnology product development value chain combined with effective project management and monitoring mechanism for achieving the targets in time bound manner. Some examples for strategic research approach is applied for development of new generation vaccines and diagnostics development; next generation bio-fuels Bio-design for implants and devices; GM technology and Molecular crop breeding by design; Biopharmaceuticals and drug discovery; bioremediation and biofortification.

A system of mapping intellectual property and translational knowledge generated by our universities and institutions has to be put in place across the country to prevent a large opportunity arising from our growing investments in basic science. We have to harness the leads we generate, the ideas we create for bio-economy.

(xiii) **Promoting new generation biotech industries:** Innovative funding schemes and incentives within the frame work existing mechanisms shall be extended to develop capacity for setting up of new bioindustries such as bulk/specialty chemicals/biochemicals; Food and nutrition technologies; Biotech led/enabled services – engineering, components and equipment manufacture; nano-bioindustries etc. Reengineering the economic model for biotechnology product/industry development:

(xiv) **Technology acquisition, transfer and licensing for product development**: Although some beginning has been made in 11th plan, some major initiatives will be taken up in 12th plan such as Establishment of III (Intelligence and Innovation Idea) units to serve as "think tanks" in life sciences and biotechnology to imagine the future and prepare for the future to analyze needs and opportunities and create product profile for products that will really be usable and marketable; technology acquisition fund with legal process and mechanism technology and IP management centres particularly DBT partner universities and institutions

(xv) **Communication platform/system for creating awareness and public understanding of biotechnology**: To address this issue it is proposed to set up Centre for Biotechnology Communication for content creation and coordination; Communication units in universities and institutions and commissioning regular programmes and publications in electronic and print media an constitution of authorized communication expert groups for crisis management and response

(xvi) **Expedite legal framework and legislations:** Biotechnology Regulatory Authority of India Bill has been tabled in parliament for introduction. The other bills

dealing with Public sector funded IP Management; DNA Profiling; Regional Centre for Biotechnology will be followed up for logical conclusion.

(xvii) **Strengthening and consolidation of major 11th plan initiatives**: Keeping in view ZBB exercise certain projects and programmes which have outlived their relevance will be phased out. At the same time, successful schemes shall be strengthened through stringent project management and scale up. Schemes in this category belong to promotion of innovation and excellence; public private partnerships Research resources specialized centres, translation platforms and service facilities; Innovative human resources development programmes and major R&D programmes and networks for technology development

(xviii) **Promote policy research and analysis in biotechnology**: Policy research and analysis has become an essential ingredient of biotechnology development due to IPR, regulations, public concerns and technology options/alternatives , affordability, access and trade issues: Besides general capacity building through workshops, training and research, centres/units for health and agriculture biotechnology policy research will be supported along regular policy dialogue among stakeholders through special meetings and seminars.

Indian life science enterprise is small compared to competitive countries like USA, Japan, South Korea and China. During 2010-2011, Indian Biotech industry recorded 21% growth and touched US$4 billion mark. The Industry analysts forecast that sustained support through government sponsored R&D in discovery led innovation and access to loans/grants, technologies and services for next 5-10 years is essential to reach a respectable market size of US $ 10 billion mark.

The experience gained in implementing National Biotechnology Development Strategy and 11th plan so far has been that the department has to make adequate future plans to defend the efforts, extend the efforts to build competitiveness in emerging areas of life sciences and Biotechnology and value add to the ongoing efforts for sustaining the benefits.

To achieve this goal, in future of the department should strengthen and nurture "Three main pillars" of biotechnology innovation and development viz.

(a) **Biotechnology research and education** through promotion of excellence and innovation in all its programmes/schemes under human resource development, centre of excellence, research resources, facilities technology platform and services, university life science programmes, multidisciplinary R&D. This role should be

played exclusively by DBT through its extramural and intramural activities. This role must extend to medical, agricultural and veterinary and science institutions /universities nationally and to international alliances.

We need a new breed of domain professionals trained in science and innovation and able to pursue a predominantly research based career. This particularly in the medical sector is a huge challenge that must be addressed in the next Plan. The Scientists and professionals in areas where there are deficiencies identified in our analysis of the 11th Plan have to be created in appropriate numbers to built a strong base and allow for about 15% expansion every year.

(b) Establishment, strengthening and expansion of **"Biotechnology Industry Research Assistance Council (BIRAC)**" which exclusively serve as DBT interface agency for industry-academia interaction and also help in promoting and sustaining start-ups small and medium enterprises and facilitate high level discovery and innovation respectively in large industries through various public –private partnership schemes such as SBIRI, BIPP etc. BIRAC must be a highly specialized agency with world class processes, and opportunity creating and problem solving mechanism through collaborative innovation skills.

BIRAC is to be nurtured as an innovation and entrepreneurship support system, as an enabler, a connector, a risk reducer for daring innovators, in addition, for funding PPP. It will require extreme specialization in domain areas to be successful with affordable technology.

(c) **The Biotechnology Regulatory Authority of India (BRAI)** as an independent and autonomous regulatory agency to provide comprehensive food and environmental safety assessments. Regulations have to be science based transparent and predictable for promoting discovery led innovation and translation.

Considering this long term vision of the biotechnology development, three fold scale up, an investment level of Rs. 17887.81 crores has been recommended for 12th plan (2012-2017) which includes Rs 8087.81 crores for 14 ongoing autonomous institutions and 6 new institutions including BRAI, Rs 9800.00 crores for extramural funding to universities, institutions and industry related activities.

Since 2004, DBT has established a record in terms of physical and financial performances, after exceeding targets set for expenditure in a given timeframe and challenges of rules and procedures. Higher allocation in this Five Year Plan (2012-17) than in the past will help to scale-up the activities 3-folds.

Finally, DBT would continue to perform in future through clearly laid out targets and activities to build a strong biotechnology enterprise, institutional and universities capacities, infrastructure and resources for making India self-reliant, globally co-operative and competitive.

In summary, we believe that based on wide but careful experimentation and learning during the 11th Plan, we have the tools and processes and carefully piloted schemes that will allow for the accelerated expansion of the biotechnology sector by at least 3-folds in the next Plan, as proposed in the Vision 2025 consultation. The science should move to a higher orbit and the country should be recognized globally for its product innovation proves. Affordability of solutions, creation of new companies and jobs and strategic impact in health and agriculture could help us grow to the realizable goal of a 20 billion dollars a year turn over for the biotechnology sector by the year 2020.

With the foundation laid and barrier identified, it is the time now to accelerate. The goals are the same, the approach and mechanisms will be different.

2.0 HIGHLIGHTS OF ELEVENTH FIVE YEAR PLAN (2007-2012)

2.1 Observations of the Working Group

The Working Group was presented the detailed account of 11th Plan proposals and achievements during 2007-11. Reviewing the progress made, the working group made following observations -

- The overall progress of 11th Plan has been highly impressive. There has been a paradigm shift from routine biological research to translational research, innovation and technology development.
- The promotion of excellence and innovation achieved so far with the implementation of the scheme "Centres of Excellence" has paid rich dividends in terms of state of quality research, high impact publications, patents and technology leads. The programme should be continued with establishment of more Centres of Excellence.
- The concept of creating biotechnology as a separate branch or department or course in Universities/ Colleges/Institutions is far from achieving its objectives. There is a need to institute diverse fellowships, career development awards and finishing schools to remedy the situation and provide employment opportunities.
- Convergence and multi-disciplinarily of sciences and emerging technologies require range of interventions and special schemes of HRD, infrastructure and centres.
- DBT has been active in establishing several biotech facilities since its inception. With the emerging needs of technology, legal framework of regulations and IPR, there is a need to establish new research resources, facilities and service centres for researchers and industry through a coordinated and network approach.
- The public private partnership programmes initiated during the 11th Plan should be continued with more opportunities for starts-ups and encouraging scientist to become entrepreneurs.

2.2 Major Programmes and Strategies of 11th Plan

The 11th Plan proposals of the Department were based on 'National Biotech Development Strategy' formulated through wide ranging consultations involving various stakeholders. The overall vision was to "**Create tools and technologies**

that address the problems of the largest section of the society, provide products and services at affordable prices and make India globally competitive in the emerging bio-economy" with following programmes and strategies -

- Human Resource Development.
- Establishment of Centres of Excellence and innovation for basic research, translational research, technology development, in collaboration with various institutions / universities, industry and non-profit organizations.
- Establishment of biotech facilities and infrastructure to serve for research and services facility to public and private sectors in fulfilling the needs of technology validation, product development and formulation, regulatory tests along with providing research resources, genome library and databases.
- To launch Grand Challenge Programmes on vaccines development, breeding crops by design, microbial prospecting and bioengineering, medical devices and nutritional technologies.
- To re orient sectoral R&D programmes in emerging areas towards translational and product development areas in agriculture, animal sciences, vaccines and diagnostics, stem cell biology, bioengineering, nano-biotechnology, RNAi technology, biofuels and bioenergy, bioprocessing and scale-up.
- To attract young scientists from India and abroad for taking research in Indian Institutions / Universities.
- To establish new breed of institutions in critical areas of National importance in the areas of translational health research, stem cell biology, technology and innovation, agrifood technology, marine biotechnology, animal biotechnology, seri biotechnology, and biomedical genomics.
- To establish technology clusters biotechnology industry incubators, parks and industry platform for promoting academia –industry interaction and process and product development.
- To launch major public private partnership programme for proof-of-concept research, research on futuristic technologies and provide assistance and facilitations to SMEs for accelerating biotechnology industrial growth.
- To develop processes and products that is affordable, good in nature and accessible with equity both public /private.

2.3 Factsheet on 11th Plan major proposals, achievements and outcomes

Major Proposals	Achievements	Outcome
1.0 Human Resource Development		
(a) Introduction of new JRF scheme	Biotechnology Entrance Test (BET) scheme launched.	19346 applications received and 404 JRFs awarded
(b) Improvement of undergraduate life science education	Star College Competitive Grant Scheme launched	112 applications received and 56 colleges awarded grants
(c) New PG courses in applied disciplines	12 new PG teaching programmes launched	Human Resource in IPR, regulations, bioprocess development, medical biotechnology (with MD/MS), neurosciences and food biotechnology generated.
(d) New Post Doctoral Fellowships (PDF) programme	PDF programmes for North East and others launched	1058 applicants screened and 394 awarded PDF and 19 in North East.
(e) Attracting scientist from abroad	2 new schemes: Welcome Trust-DBT fellowships for biomedical sciences and Ramalingaswami fellowships	A total of 160 scientists from abroad took-up fellowships in universities and institutions for research and education
(f) Support to young scientist and researchers	Rapid Grant for Young Investigators (RGYI) scheme for working scientist and Innovative Young Biotechnologist Award (IYBA).	A total of 150 young scientist and researchers benefited and could serve as potential investigators pool for future.
(g) Schemes for gain full employment of women scientists	Biotechnology Career Advancement and Re-orientation Programme for women scientist (Bio-CARe) started in 2010-11.	50 women were awarded fellowships to bring them back to life sciences research. 4 eminent scientists from abroad took positions.
(h) Renewed industry training programme for PG students	Biotechnology Industry Training Programme (BITP) with contingencies to industry and fellowships to students launched.	15135 students applied and 2223 selected for training and up to 30% were absorbed by the industry.
2.0 Promotion of Excellence and Innovation		
(a) Establishment of Centres of Excellence and innovation for basic research, translational research and technology development	The scheme was launched in 2007-08	Out of 618 proposals 61were funded which included 15 Centres of Excellence, 35 programme supports and 11 individual projects. A total of 20 publications with impact

		factor >7 published including journals like Nature, PNAS. 33 national patents filed and 24 granted. 37 international patents filed 26 granted. 10 technology leads obtained; 1 technology each transferred to industry and commercialized. 12 sophisticated facilities set-up
(b) Setting-up of translational research centres and platforms.	Launched Centres/Platforms: (a) Clinical Development Service Agency, THSTI, Delhi (b) Platform for Transgenic Translational Research, ICRISAT, Hyderabad (c) ICT Centre for Energy Biosciences, ICT, Mumbai (d) National Bio-design Alliance with IIT and AIIMS Delhi. (e) CMC-DBT centre for Stem Cell Research at CMC, Vellore (f) Translational platform for verterinary biological, TNVASU, Chennai (g) Drug Discovery Centre, ICGEB, New Delhi (h) Primate Research Centre, NII Faridabad (i) International Depository Authority (IDA) for Micro organism at NCCS Pune	All these Centres are already operational and would help in validation, technology perfection, clinical/field trials and product development in the areas of vaccines, GM crops, energy and implants and devices. The ICT centre for energy has developed Competitive Cellulosic Ethanol technology using rice/wheat straw, bagasse and cotton stalk. First pilot plant based on ICT Technology for 10 ton biomass/day being put up by India Glycols Ltd
3.0 Bioinformatics		
Restructuring Bioinformatics to take-up R&D and computational biology.	R&D scheme launched in computational biology and linking bio-informatics with wet Lab data	Out of 137 projects, 57 projects funded with 50 publications of impact factor >7 and development of 25 data basis and 25 software for open domain use.
4.0 Research and Development During 2007-2011 about 5750 R&D proposals received and 2410 (41.9%) proposals approved/ongoing with 16% annual increase in publications, a total of 1104 publications having impact factor 5 and above; 312 patents (national/international) have been filed and 110 patents have been granted; 105 technologies developed, 21 technologies transferred to industry and 5 were commercialized.		
Orient sectoral R&D programmes in emerging areas towards	R&D schemes started for laying foundations in HR and research	**RNAi technology:** 120 projects covering medical

translational and product development	capacity in the areas of RNAi technology, nanotechnology, molecular breeding, bioengineering, Stem Cell and regenerated medicine biofuels and bioenergy, metabolomics, genomics and proteomics.	/agricultural/ environmental applications funded resulting in 3 US patents, 100 SCI Publications, training 150 researchers and leads in developing disease/pathogen resistant crop and understanding cancer and tuberculosis **Nanotechnology:** 90 projects funded covering applications in medical / health care, agriculture, aquaculture and allied sectors and environment resulting in 90 SCI publications, training of 100 researchers with lead in improving the efficacy of drugs for important diseases like cancers; new generation pesticides with better health and environmental profile; water filters etc. In **Molecular Breeding** utilizing already available markers 20 projects for important traits in major crops launched and with commercialization of protein rich maize. In **Bioengineering** 75 projects implemented in the areas of biomaterials, biosensor, biomedical instrumentation and tissue engineering involving 75 institutions/universities, 60 research personnel resulting in 3 national patents, 1 international patent and development of 4 technologies. In **Stem Cell Biology** over 40 institutions and hospitals were involved with leading publications, patents and Phase III multi-centric clinical trials supported on acute myocardial infection &

		pilot study on acute Ischemic stroke In **Biofuels and bioenergy,** 15 projects launched with algal biofuel network.
5.0 New Institutions		
Establish new breed of institutions in gap areas of critical importance	The following new institutions were set-up (i) Translational Health Science and Technology Institute, Faridabad, Haryana (ii) Regional Centre for Biotechnology, Faridabad, Haryana (iii) National Agrifood Biotechnology Institute, Mohali, Punjab (iv) National Institute of Biomedical Genomics, Kalyani, West Bengal (v) Institute of Stem Cell Biology and Regenerative Medicine, Bangalore, Karnataka (vi) National Institute of Animal Biotechnology, Hyderabad, Andhra Pradesh	In all the institutions interim facilities have been established, directors and staff recruited, research work initiated, land acquired and construction is going on. National Institutes of Marine Biotechnology and Seri-biotechnology proposed could not be set-up due to pending EFC clearances
6.0 Public Private Partnerships		
To launch major public private partnership programme for proof-of-concept research, research on futuristic technologies and provide assistance and facilitations to SMEs for accelerating biotechnology industrial growth	SBIRI programme launched from 2007 for proof of concept and pre-proof of R&D concept in SMEs. Biotechnology Industry Partnership Programme (BIPP) for industries to fund ventures in futuristic high risk technologies.	531 projects received and 91 sanctioned resulting in 6 Indian patents and development of 16 technologies in agriculture, health care and instrumentation. Since 2009-10, 16 rounds announced, with 7 special calls 600 proposals received and 71 projects cleared with 60 projects supported benefiting b 51companies (27 small, 12 medium and 12 large companies). The DCGI has approved this H1N1 vaccine to be marketed as two dose schedule. A patent has been filed with IPO, New Delhi

	A pilot Biotechnology Industry Research Assistance Programme launched and based on that, a fully fledged "Biotechnology Industry Research Assistance Council" was approved by EFC and Cabinet approval to establish section-25 company is pending.	BIRAP started activities with Innovation funding; Capacity Building and Mentoring Programme; Technology Development Programme; Initiating Technology Acquisition Landscape Analysis and Technology, Mapping and Support Services for policy and analysis etc.
7.0 Promoting Global Partnerships and Alliances		
Leveraging international collaboration for value addition and quality Human Resource development	New bilateral collaboration with Canada, Denmark, Finland, Australia, Germany, Sweden, Switzerland, EU, UK and International Agencies like Welcome Trust, Bill Gates and Melinda Foundation launched.	More than 150 projects funded with 200 publications with impact factors >4 and development of 7 technologies, 21 patents and technology transfer of insect resistant chickpea, biopesticide to industry. A Welcome Trust – DBT programme on development of affordable health care products with a commitment to invest ₹ 165 crores jointly for 5 years. Stanford-India Biodesign programme launched with two batches of joint training in biodesign and 6 prototypes have been developed
8.0 Streamlining Biotech Regulations		
Development of new guidelines and formulation of Biotechnology Regulatory Authority of India (BRAI) Bill.	Guidelines, SOPs and regular conduct of RCGM meetings	RCGM published SOP for field trials, protocols for food and feed safety assessment of GE crops, revised guidelines and handbook for institutional biosafety committees, prepared guidelines for preclinical evaluation of similar biologicals (2011) and revised simple to fill application formats for various clearances. Two dedicated websites launched.

		3506 applications processed with decisions, 51 meetings were held in 48 months.
	Formulation of Biotechnology Regulatory Authority of India (BRAI) Bill.	A new bill formulated, stakeholder consultation organized and Inter Ministerial consultation completed with Cabinet approval. The bill was tabled in the monsoon session 2011 for introduction in Lok Sabha.
9.0 Launching Mission Mode Projects		
To launch major initiatives in technology development in agriculture and health care	Five major Grand Challenge Programmes involving R&D, technology development, validation, clinical/field trial launched in the areas of • Vaccines • Implants and devices • Bio-prospecting for bio-molecules • Molecular breeding • Food and nutrition	Vaccines centre and pediatric biology centre launched alongwith vaccine grand challenge programme for development and clinical trial of rotavirus, cholera, malaria, TB, JEV, DNA based rabies (animal, human), Vi-polysaccaride typhoid, HPV, HIV/AIDS. Clinical trials of Rotaviral vaccine is in phase-III, Malaria in Phase-I: Implemented six Clinical Training Research Centres in various parts of the country. In food and nutrition education and research strengthen in 4 colleges and ulta-rice, zinc dispersible tablets have been assessed and distributed in States. In Bio-prospecting 2,30,000 microbes screened. The extract of these isolates found to possess anti-infective, anti-cancer, anti-diabetic and anti-inflammatory properties. An International Depository Authority (IDA) established at NCCS, Pune. EFC on Crop Genetic Enhancement Network through molecular breeding

		ready for circulation.
10.0 Programme for Northern Eastern States		
To spend 10% of GBS on Northern Eastern Region.	73 R&D twining projects with other parts of country, 25 Bioinformatics facilities, 42 Biotech hubs, infrastructure support in 11 medical colleges, setting-up of five STAR colleges, Biotech park in IIT-Guwahati and NER-Delcon project for digital access of journals, 20 DNA clubs launched.	More than 500 researchers /students benefited A major DBT-Assam Agriculture University Centre for Agriculture Biotechnology launched for breeding crops and HRD 14 conferences and seminar held with 300 participants Early results show 15 SCI publications

2.4 Detailed Area-Wise Achievements

2.4.1 Human Resource Development

The Department is implementing an Integrated Programme of Human Resource Development in Biotechnology to generate adequate and appropriately trained manpower required for overall development of Biotechnology in the country. Some noteworthy achievements are:

Education & Teaching: Sustained support at M.Sc./M.Tech level

The Department has continued support to a number of M.Sc./M.Tech. Teaching programmes in biotechnology. The universities / institutions have been selected on the basis of existing expertise and infrastructure, ongoing R&D. Collaboration with Agencies like University Grants Commission, Ministry of Human Resource Development and respective State Governments ensured that the faculty positions are taken over after the plan period. The Department has provided critical inputs like infrastructure, equipment and grants for consumables, visiting faculty, studentship and faculty salaries.

During 11th plan, 22 post graduate teaching programmes including M. Tech. programmes in biochemical engineering, bioprocess, marine, food biotechnology, and pharmaceuticals were supported. In these courses, the students are selected on the basis of Common Entrance Test (CET) conducted across the country. In addition to PG courses the Department also supported PG diploma courses in IPR,

Biosafety and Regulatory Affairs, Regulation in Agricultural Biotechnology, Genetic Engineering and Bioprocess development, Molecular and Biochemical Technology and Certificate course in Medical Biotechnology for clinicians. The programme has an inbuilt component of visiting faculty and provision of studentship and summer training for students. Interactive sessions are organized to evolve model curriculum to be adopted by all participating universities. Realizing the need to upgrade the skills of mid career scientists 10-12 short term training courses for 12-16 participants for 2-4 weeks supported every year.

New JRF Scheme Launched: To fill the gap between PG teaching courses and post doctoral fellowship (PDF) programme of the Department, JRF programme has been started. 100 JRFs may be selected through Biotechnology Eligibility Test (BET) conducted by University of Pune, Pune. Till 2011, 472 students availed the fellowship and 23 students have completed their Ph.Ds.

Biotechnology Career Advancement and Re-orientation Progamme for Women Scientist (Bio-CARe): The scheme launched in 2010 and has two components - Research Grant Opportunity (RGO) and Career Re-orientation Fellowship (CRF). The objective of RGO is to encourage the women scientist to undertake independent R&D projects especially for women scientist employed full time in universities and small research laboratories or unemployed women scientist after a short career break.

2.4.2 Biotech Facilities

Department has established about 35 facilities during 11th plan for biological material , access to high end sophisticated equipments and regulatory requirements which are available to scientists, industries and students at nominal costs. The facilities also conduct regular training programmes for capacity building in areas of instrumentation, handling of small animal houses, bio-processing, microbial taxonomy and molecular biology.

- For the first time, International Depository Authority (IDA) was established at IMTECH, Chandigarh for patent deposits. It is the first such facility in India, 7th in Asia and 34th in the World. The Departmental supported Microbial Culture Collection (MCC) facility established at National Centre for Cell Sciences, Pune for maintenance and long term maintenance of

microorganism is now fully operational. The MCC has been recognized as an International Depository Authority (IDA) from April 9, 2011.

- A National Certification system for Tissue Culture raised plants has been evolved. DBT has been notified as the Certification Agency under the Seed Act vide Gazette of India. Notification dated 10th March, 2006. An Accreditation unit, 6 Accredited Test Laboratories and two Referral Laboratories for virus indexing and genetic fidelity testing have been set up. Guidelines for 6 crops have been notified. Seventy Six tissue culture industries have been recognized under this system.
- At DBT-ICRISAT platform for translational research on transgenic crops operations began for facilitating contract R&D on validation, regulatory tests and commercialization of agri-biotechnology products for public and private sector.
- Synchrotron X-ray beam line (BM14) time was acquired for 6 years at European Synchrotron Research Facility, France in partnership with Medical Research Council, U.K and European Molecular Biology Laboratory for macromolecular crystallographic services to 130 Indian scientists and training of the field. 600 crystals have been tested solving 15 structures.
- A Primate Animal Research Facility supported for setting up of NII, Faridabad Campus for services to new institutions of DBT, ICGEB and other research institutions in Delhi involving preclinical trials.
- National Plant Gene Repository' at NIPGR, New Delhi to serve as long term storage for plant genes, promoters, vectors and ESTs in the form of DNA clones and libraries cloned/developed.
- A core immunology laboratory to evaluate vaccine elicited immune responses in HIV/AIDS at ICGEB has been established. Assays like cell proliferation using CFSE, Elispot assays and Intracellular Cytokine assays are in place. This platform can be useful for HIV/AIDS research.

2.4.3 Centres of Excellence and Programme Support

The Department has initiated this programme to augment and strengthen institutional research capacity and to promote excellence in interdisciplinary sciences and innovation in selected areas of biotechnology through support for establishment of Centres of Excellence.

Till 2011, 15 Centres of Excellence have been setup in areas of agriculture (3), medical (8), bio-informatics (1), basic biology (2) and sericulture (1) in different parts of the country. The COEs created in areas such as genetic and genomics of silk-moth, tuberculosis, novel inhibitor designing, high throughput allele determination for molecular breeding, hepatitis, basic and translational stem cell research, molecular basis of heterosis, computational and system biology, epigenetics research.

The programme support is given to identified institution / department to create and strengthen research capabilities at university and institutional level for categorical research. Under 'Programme Support' mode, 35 major programmes have been supported in various front line areas of life sciences. During 2006-07, four proposals have been found to be supported as Centre of Excellence and five proposals have been recommended for support in 'Programme Support' mode.

Publications: Over 200 publications in high impact factor scientific journals emanated so far from the programme including in journals *such as Cell, Nature, Nature Protocols, PNAS, Nucleic Acid Research, Biochemistry, JBC, Protein Science, PLoS etc.*

Patents Filed / Granted: More than 50 patents (both national and international) filed / granted.

Some Early Translational Opportunities / Technologies Developed:

- Novel host-factors identified as therapeutic targets for design and development of anti-tubercular drug (ICGEB).
- Novel inhibitors have been designed against infectious agents – *Mycobacterium tuberculosis* and *Plasmodium vivax* (NII). Technology for anti-malarial agents transferred to an industry.
- New derivatives of therapeutic proteins – Streptokinase (SK) and Staphylokinase (SAK) developed. Several novel biomaterial scaffolds and gels developed for cartilage tissue engineering and osteochondral tissue engineering (Sree Chitra Tirunal Institute of Medical Science & Technology, Trivendrum).
- Small anti-viral peptides against Hepatitis C virus developed (Indian Institute of Science, Bangalore).

- A novel small interfering RNA (siRNA) targeting the Human Papilloma Virus – 16 enhancer region leading to down regulation of the expression of viral RNA identified (AIIMS, New Delhi. Several novel biomaterial scaffolds and gels developed for cartilage tissue engineering and osteochondral tissue engineering (Sree Chitra Tirunal Institute of Medical Science & Technology, Trivandrum).
- Small anti-viral peptides against Hepatitis C virus developed (Indian Institute of Science, Bangalore).
- Transgenic silkworm lines resistant to baculovirus (BmNPV) through RNAi approach developed at CDFD, Hyderabad. Laboratory trials in progress in collaboration with sericulture centres of Central Silk Board and state Governments.
- Groundnut transgenics expresing helicase (PDH47) and transcription factors (DREB 1A, DREB 1B, DREB 2A) found to be promising as drought tolerant. Approval obtained from RCGM for field evaluation (strip trials) of these transgenics (UAS, Bangalore).
- Two markers linked to Mung bean Yellow Mosaic India Virus (MYMIV) resistance in *Vigna mungo* developed and employed to identify MYMIV-resistant germplasm in *Vigna mungo* and *Vigna radiata* (Bose Institute, Kolkata).

2.4.4 Bioinformatics

An extensive Bioinformatics Network, covering 65 institutions, spread geographically all over the country, has been established. Dedicated High Speed Network for the BTISnet-VPN and a Super Computer Facilities for Bioinformatics have been established. With the minimum speed of 512 Kbps for the Sub-DICs and 2 Mbps for the DICs and COEs 12 major institutions inter-connected through high speed Network in the form of VPN (Biogrid India).

For Human Resource Development, Department started network programme at M.Sc./M.Tech/Ph.D. in Bioinformatics in MKU Madurai, Pondicherry University, Puducherry and Anna University, Chennai on consortium basis with video conferencing and virtual class room facilities. Trainees of these programs have been absorbed by various organizations including industries and many of them have started their own companies in Bioinformatics.

Around 400 short term training courses has been organized in different areas of Bioinformatics, training more than 4000 researchers & scientists.73 New R&D projects have been supported during the 11th plan period in the area of Bioinformatics. 200 software packages for addressing the biological problems has been developed by the Centers. 26 copyrights have been received for the products developed.

2.4.5 Research & Development

2.4.5.1 Agriculture & Allied Areas

A. Crops Biotechnology

The ongoing efforts are on basic and strategic as well as on application oriented research. The main emphasis during 11th Plan was on product development and their delivery. Closer interactions between DBT, ICAR institutions, SAU, other universities and private sector were developed to realize the objectives.

Besides Plant Molecular Biology programmes, the Department supported important programmes on rice and wheat genome sequencing, functional genomics, development of tolerant to drought and salinity, yield under biotic and abiotic stress, bio-fortification with zinc, iron and vitamin A.

The programme on maize includes rapid conversion of normal maize inbred to quality protein maize through marker assisted selection. Other major projects includes transcript profiling of drought stress millets, development of marker assisted selection breading for developing high zinc high bio-availability of pigeon pea, genomics programme on chickpea, developing *mungbean Yellow Mosaic India Virus (MYMIV)* resistant varieties of soybean, genomics of tomato and development of high oil yielding varities of oilseeds such as sunflower. Crop biofortification have been initiated for enhanced Iron and Zinc contents and reduced phytates, in wheat, rice and maize through marker assisted breeding/ transgenic approaches.

Under Indo-US collaborative programme, two network projects have also been taken up – one on development and evaluation of salt and drought tolerant transgenic rice, and the other on fruit and shoot borer resistant eggplant. Some of the salient achievements are:

Plant genome sequencing capacity built-up: India has successfully decoded the genome information of the rice chromosome number 11. The rice genome has been shown to have 37,544 genes, of which 1443 genes are identified in the region sequenced by Indian scientists.

Transformation Technologies for Rice Developed: The Indian initiative on Rice Genome Sequencing provided a good opportunity to learn and train large number of our scientists, research fellows and technical personnel. High level competence and infrastructure in Plant Genomics developed and utilized for genome-wide research on other important crops like tomato, sugarcane and wheat.

Under Salinity and dehydration stress tolerance network project in rice – the glyoxalase 1 and II genes have been transferred in the Pusa Basmati 1 and recently in IR 64, and also sodium proton antiporter gene has been cloned under the constitutive promoter as well as ABA inducible promoter and both the genes constructs have been transformed into Pusa Basmati 1 at ICGEB. Screening of these lines in the next generation at CSSRI, Karnal, revealed that some of these lines are promising in terms of early vigour, spikelet fertility and overall yield than the control non-transformed IR64 in saline and sodic conditions. 15 different Agricultural research institutes in collaboration with International Rice Research Institute (IRRI), Manila are involved in development of high yielding varieties of rice by incorporating genes for flood drought and salt tolerance. IRRI is providing advanced breading lines and technical knowhow to the Indian partners.

Groundnut stem necrosis disease (GSND) caused by the *Tobacco streak virus* (TSV) has emerged as a serious problem on groundnut causing enormous economic losses necessitating the use of transgenic technology for the development of GSND-resistant groundnut varieties. In pursuing this goal at ICRISAT, Hyderabad over 112 putative transgenic events of popular groundnut cultivars was generated.

Similarly, major advancement has been made towards mitigating the disastrous effect of Banana Bunchy Top Virus (BBTV). BBTV is a pathogen causing banana bunchy top disease of bananas. It is transmitted by the aphid vector, *Pentalonia nigronervosa* and is considered to be the most economically destructive of the virus diseases affecting bananas worldwide. Tamilnandu Agriculture University, Coimbatore developed a transgenic line of banana showing resistance to BBTV

infection under laboratory conditions. After regulatory approval, these transgenic lines have huge market especially in Southeast Asia.

Next generation challenge programme in chickpea genomics was initiated at NIPGR for sequencing the nuclear genome of chickpea for detailed structural and functional annotation, transcriptome sequencing, marker discovery, generation of saturated linkage and development of web resource, chickpea genomics data.

Transgenic Virus Resistant Tomato Ready for Regulatory Tests: In tomato for developing leaf curl resistant transgenic line and transgenic lines against an insect *H. armigera.* A high level of resistance observed with single gene insertion. The progeny analysis of these plants showed mendelian pattern of inheritance. The work is being pursued further to develop more transgenic lines and determine the spectrum of resistance under field conditions.

In sugarcane a reproducible method ensuring very high frequency of direct shoot regeneration from various explants established for three varieties for developing transgenic to red-rot disease resistance.

Technology for Double Haploids in Cereals: A new system (*wheat* x *Imperata cylindrica*) of chromosome elimination technique has been developed for making double haploids. The new system has certain advantages over wheat x maize system.

Molecular Diagnostics for Bacterial Disease of Cotton Developed: A sensitive molecular diagnostic tools for rapid detection and differentiation of races *Xanthomonas campestris* pv. malvacearum, causing bacterial blight of cotton has been developed at CICR, Nagpur.

B. Plant Biotechnology

Major programmes have been supported on vegetable crop genomics and metabolomics, forest genetics and tree breading, plantation crops, horticulture. The thrust is on application of tissue culture for regeneration of high quality economically important plant species through national certification system, demonstration of large-scale plantation and validation of proven technology; germplasm characterization, improvement of crops through molecular biology tools, basic research, genomics initiative; host pathogen interaction, resolving of

taxonomic problems by molecular interventions etc. Some of the achievements are:

Genomics and Metabolomics: Department has taken Solanacease (SOL) Genomic Initiative of tomato as a network project among University of Delhi, South Campus, IARI and NIPGR. The sequencing of the whole genome of tomato has been achieved to 5X level in collaboration with a major land group. The studies will address the important issues of disease resistance mainly against Tomato Leaf Curl Virus (ToLCV), shelf life and nutritional quality of tomato. Based on the leads obtained under the SOL programme a national network on metabolomics has been initiated on various important crop plants like Tomato, Rice, Potato, Maize, Arnebia and Curcuma. The goal of the metabolomics profiling is to improve the fruit, aroma and quality.

Micropropagation and Transformation Protocols Developed: Studies has been carried out for developing/standardization of micropropagation protocols of important tree species. Under the horticulture crops, post harvest studies for improved shelf life of Tomato, Grapes and Banana has been supported. Transformation systems have been established. Transgenics of tomato are undergoing field trial. Improvement of selected spices (black pepper, cardamom, ginger, vanilla) through biotechnological tools has been supported concentrating on germplasm characterization and conservation and screening for disease resistance, developing improved varieties through transformation and mutation breeding.

Large scale successful field demonstration:

- Large scale production and demonstration of tissue culture raised black pepper was also taken up. 100 ha in 5 states have been covered so far.
- A Mission programme on field Demonstration of quality planting material of Bamboo was initiated with a target of covering 1000 ha in 12 States.
- Field demonstrations of bamboo plantations supported in Uttaranchal, North Eastern India and Southern India have covered around 200 hectares.

Micropropagation Technology Parks (MTP's)/ Field Demonstrations: Two MTP's and 6 regional hardening facilitates has been supported. More than 15 million plants of important species have been produced and field planted. Protocol

of Apple and citrus root stocks multiplications have been perfected and are currently being demonstrated. Nearly 15000 plants each have been field planted.
To ensure quality of planting material in terms of virus indexing and true-to-type a National Facility for Virus Diagnosis and Quality Control has been set up with 6 satellite centers.

Solanaceae Genome Initiative launched: An International Solanaceae Genome Initiative (SOI) has been launched with the aim of creating a coordinated network of knowledge regarding the Solanaceae family and address various key issues. The long-term goal of the SOL programme is to create a network of map based resources and information and address key questions in plant adaptation and diversification through this International effort. India joined the International 'SOL' programme and has taken up sequencing of chromosome 5 (12 Mb). Functional Genomics has been supported for three traits of importance – Nutritional Quality, Disease Resistance, Fruit Ripening.

Mission programmes for North East: The department initiated a mission programme in North East for setting up of quality farm and demonstration of quality planting material in NER. The objective of the programme involves production and supply of quality planting material produced either by tissue culture or other vegetative means from the selected quality mother stocks of horticultural crops such as Citrus, Kiwi, Banana, Edible Bamboo, Black Pepper, Cardamom, Strawberry etc. Till 2011, 794 hectare of demonstration plot of quality planting material involving 1250 beneficiaries has been established.

Horticulture and Forestry: Department has initiated genomic platforms for Apple, Mango, Potato and Cashew nut research. The main goal is to increase fruiting laterals, nut weights and shelling percentage for cashew nuts, morphological characterization of the germplasm identification of micro satellite markers in apple, reduction of reducing sugar (glucose + fructose) levels with concomitant increase in sucrose level at all the stages of cold storage in potato, assessment of genetic diversity in mango cultivars using DNA markers, gene targeting in Brinjal for resistance to shoot and fruit borer.

New Capacities in Molecular Taxonomy built: Molecular taxonomic studies have been supported on important plant species to resolve taxonomic confusions. Fingerprinting studies helped in segregating populations of plant sps. like *Acacia*

catechu, *M. latifolia*, *Solanum melongena* species in *Cassia*, *Trigonella*, *Cajanus species*.

Plant Architecture: Plant architecture is a new paradigm in plant sciences to address scientific issues in forestry, horticulture and agronomy such as modeling plant plasticity, analyzing the determinants of interaction between growth & production, flowering and root differentiation. Project supported to understand the function and behavior of battery of genes involved in controlling flowering & seed setting, root differentiation, function and morphology.

Transformation system & genetic events and intergenic gene: The ability to efficiently introduce foreign genes into plants is the key to success of the plant biotechnology. Programmes are supported to study efficiency, reproducibility of transformation systems for increasing number of events of gene integration by knock out and mutant approach.

Chemicals from plant cell culture: For continuous production of pure biochemcials from rare plants, cell and tissue culture in suspension systems on a large scale through genetic manipulation and bioprocessing would be an advantage. Projects on this subject needs to be carry forward in 12^{th} Plan to get the optimum benefit of the investment made in 11^{th} Plan.

Network Programmes: Tree Improvement for specific traits may be initiated for understanding Genetic Diversity Estimation for improving productivity and conservation; Improvement of complex traits by Association Genetics in Teak, Rose wood and Sandalwood; Breeding for increased metabolite content by productive engineering; Generation of tolerance to biotic and abiotic stress in *Casuarina equisetifolia, Eucalyptus tereticornis* and Identification of tissue specific promoters for pathway regulation for differentiation.

C. Biological Agents in Crop Management

The programme on biological agents such as biofertilisers and biopesticides had been implemented since the inception of the Department. The objective of the programme is to control major pest and diseases of important crop, vegetable and other plants of economic importance. Several of these agents have been already marketed by the industry through technology transfer. It was recommended therefore to consolidate the existing programme and launch new initiatives in

focused manner particularly addressing requirements of organic cultivation, integrated pest management and export crops requiring chemical free certification, besides the support to the following:

Biopesticides and Crop Management: Field trials for pest management in grapes, sugarcane, mango, banana has been done. The field trials against various pest and micro-organisms found very promising and the successful scientific field trials may lead to technology transfer for different biopesticide agents such as includes enzymes, neem based isolates, different micro-organisms. The efficacy and safety of these biological agents needs to be evaluated before translating them commercially. Simultaneously *In-silico* methodology for predicting the bio-activities of different biological agents has been validated.

Pheromones: Pheromones are organic compounds released by insects for establishing the communication among each other. Four sex pheromones and three aggregation pheromones have been identified from both male and female species of *C. serratus.* The synthetic pheromones may be useful in the development of an ecofriendly and environmentally safe pest management strategy. The field trials of laboratory synthetized pheromones have been demonstrated in Tamil Nadu and Uttar Pradesh. These pheromones may be applied for managing the pest during storage of valuable grains such as green gram, black gram, chickpea, cowpea.

Biopesticides based IPM demonstration: A major programme on IPM as a component of INM for increasing agricultural productivity in cropping ecosystems of various agro-climatic zones has been supported at 14 centres in 12 states. Effective modules/ packages of practices, which are cost effective, sustainable and eco-friendly in different ecosystems, were developed. The cost-benefit ratio of IPM/ INM modules worked out at large scale trials showed significant tilt in favour of adopting the technology by farmers for different crops.

Integrated Parthenium Management: A multicentric programme on the management of *Parthenium* through integrated approach has been initiated for its economic utilization, effect on human health and to observe its distribution through remote sensing.

Website on Biopesticides Launched: A comprehensive website on biopesticides compiling the achievements made in the major programmes supported by DBT on biological control of plant pests, diseases and weeds. Salient achievements have

been extracted from 120 completed projects for the benefit of scientists, entrepreneurs and other users community including progressive farmers. This website has got a resource directory and linkages with national and international websites. Further details may be seen on the website www.dbtbiopresticides.nic.in.

Network for toxicological tests established: In order to facilitate the commercialization of biopesticides, the Department has taken a proactive step for the generation of toxicological data of potential biopesticides. In the first phase, ten biopesticides have been taken up for the generation of toxicological data both for primary cultures as well as for their formulations. Data have been generated for almost all the biopesticides by the two identified centres viz., ITRC, Lucknow and RRL, Jammu.

Biofertilizers: The biofertilizers generally enhance the production of the crop through increasing their nitrogen fixation population in quantity and quality around the roots and in soil to allow them to function in time and space. Important achievements are:

Integrated Nutrient Managements Packages Developed: Bio fertilizers made up of combination of microorganisms for Integrated Nutrient Management (INM) are trusted and sign of critical progress has been observed in after their application in different economic crops and different regions of India. The simultaneous application of both biofertilzers and chemical fertilizers and their cumulative effect needs to be assessed on scientific basis. Some of the notable economic crops where the nutrient management effect of biofertilizer tested on field are Tea, Rosewood, Spices and Oranges. The biofertilizers acts mainly through making the more nitrogen and phosphorus available to plants. Various basic and applied issues have been targeted to have integrated approach to manage nutrient supply to major cropping systems.

Molecular Biology of Biofertilizer Strains: Information for transgenic biofertilizers generated with the objective of developing better nitrogen fixing microorganisms, a network programme involving 12 centres has been supported.

Cyanobacteria: A suicide vector capable of integrating cloned genes in *Anabaena*/*Nostoc* genome has been developed. The gene and the operon have been cloned from cyanobacterial genome and successfully transferred into *Anabaena* strain and *Nostoc muscorum* strain.

Rhizobium: The gene responsible for production of bacteriocin facilitating but more nodule occupancy has been cloned.

Azotobacter: Elite *Azotobacter* strains developed and tested under contained conditions. The genetically modified strains excreted large amounts of Ammonia is indicating that these nitrogen fixing and strains are efficient excretory of ammonia.

Lignocellulose Degradation: Several species of gram-negative bacteria isolated from diverse locations found to enhance the degradation of lignocellulose especially waste of sugar and timber industry the process may reduce the time in production of vermicompost.

D. Animal Biotechnology

Productivity of livestock sector in our country needs to be substantially increased in order to satisfy increasing consumer demand, to more efficiently utilize scarce resources and to generate income for a growing population. Biotechnology has long being a source of innovation in production and processing, profoundly impacting the sector.

Animal Nutrition: Genomic Analysis of Rumen Bacteria: Various rumen microbes such as bacteria protozoa have been detected in rumen of buffalo and sheep. The concentration of these microbes depends upon the fodder and feed. Numbers of plants such as Jatropa, Neem were detoxified to utilize them as animal feed supplement. For large scale bioconversion of lignocellulose residues to animal feed using white rot fungus, a reactor of 1200 liter capacity has been designed and fabricated indigenously. Trials showed that system could degrade up to 30% of the crop residues.

Livestock Reproduction: A nonsurgical technique for permanent gene integration was developed and in process of standardizing in buffalo. In buffaloes pheromones have been detected in saliva, urine, vaginal mucous, other body fluids during estrus cycle. These natural harmones may be useful in development of detection kit for detecting the estrus cycle in buffaloes. 40 embryos of Sahiwal, 10 embryos of Jaffrabadi and 6 embryos of Red Sindhi has been preserved for future use.

Inhibin based synthetic peptides has been found to be effective in increasing the ovulation rate in Indian breeds of sheep manifolds over long periods of time.
A non-surgical uterine flushing procedure of embryos has been successfully established in bonnet monkeys.

Ovum pick up technology for the production of large number of embryos in cattle and buffalo has been standardized by producing embryos and calves. This will help to reduce the cost of Embryo Transfer.

Capacity for Genomics of livestock built: Molecular characterization studies of various livestock breeds have been carried out. Genetic diversity of Indian sheep breeds was quantified in terms of allele and gene diversity. Sequence analysis revealed a total of 194 haplotypes with a high proportion of singleton haplotypes. These studies will be useful for the technological improvement of milk proteins during the heat processing of milk. Multi centric Buffalo genomics programme has been initiated and in phase I, genes of economic importance like fertility and milk protein are being identified.

Trasnsgenic Mice produced as model for livestock: Eighteen lines of transgenic mice have been developed as a model system for various diseases. Embryonic development of transgenic mouse and its transgene expression pattern has been studied which would be valuable for studies related to embryonic development and somatic stem cell biology. Based on the clues expression of green fluorescence protein gene has also been established in micro injected rabbit and goat embryos.

Livestock Products Technology development including leather: Bovine collagen has been chemically modified converted into ophthalmic inserts collagen diskette for using on patients during and post cataract surgery. Collagen ophthalmic inserts were clinically evaluated.

A process for preparation of serum based protein binder has been developed and several batches have been successfully produced at pilot scale at 100 lit batch production.

Vaccines Development and technology transfer: A recombinant Anthrax Vaccine was developed and its technology transferred to the industry. Phase-I and phase-II

human clinical trials of vaccine has been conducted at three centers. Efforts continued to develop another new generation anthrax vaccine using non-toxic mutants of anthrax toxin proteins for better efficacy in animals/ humans.

Recombinant BCG vaccine against in bovines were developed and shown to have promising results for the development of commercial vaccines in calves. Another recombinant vaccine reported against *Haemorrhagic septicaemia.* The vaccine candidate reported to be Omp protein of P. multocid. The research in this direction is going on to evaluate the potency of this immunogen.

Self-replicating DNA vaccine as an alternative to conventional Foot and Mouth Vaccine (FMD) was evaluated and the vaccine found highly promising. Another DNA based vaccine against *Clostridium perfringens* was evaluated for its immunogenic potential in mice. The construct were able to raise good immune response and capable of neutralizing toxic effects of E-toxin. Another multivalent oral vaccine against chicken coccidiosis was under trial.

DNA vaccine having glycoprotein gene rabies virus fused to signal sequences was targeted to respective intra cellular locations. A lysosomal targeted DNA vaccine was found to be highly potent for prophylactic as well as therapeutic applications.

The overall incidence rate of presence of *Salmonella* in poultry egg found to be 0.0087 while highest incidence rate was obtained in Uttarakhand (0.26) and lowest in Delhi (0.0012). These isolates were found multiple drug resistant and most of them resistant to Ampicillin, Gentamycine and Norfloxcin. In three isolates virulence regulatory gene was not present and they may be potential candidates for development of live vaccine of *Salmonella typhimurium.*

Technology for Diagnostics Kits Viral and Bacterial Diseases: For rapid sero-profiling of Newcastle disease virus, viral protein has been cloned and tested for detecting the diseases. The Loop mediated Isothermal amplification (LAMP) was developed for detection of Marek's disease virus of poultry. The ELISA based diagnostic tool has been developed for Classical Swine Fever Virus (CSFV) the relative sensitivity and specificity of the test were 93.5% and 97.4% respectively. The test found to be comparable with commercial kits. Simultaneously, different biomarkers have been identified and developed as an Immunoassay for diagnosis of subclinical Mastitis. Protein based diagnostics kit for *Peste des Petits*

Ruminants (PPR) virus, based on antigen competition ELISA has been developed and found to be more sensitive than PCR based kit.

A novel PCR based diagnostic kit for rapid diagnosis of *Buffalo Pox Virus* (BPV) has been standardized.

ELISA based kit has been developed for monitoring the levels of antibodies in serum samples of *Haemorrhagic septicaemia* (HS) vaccinated cattle and buffalo.

Class specific monoclonal antibodies have been produced against chicken for use in simultaneously monitory the immune status/ diagnosis of recent infections in birds for any viral diseases affecting poultry.

Database and Repository Development: For demarcation of Indian Poultry Virus isolates a DNA database has been developed representing all published Indian sequences and their molecular comparison with vaccine strains.
Serum samples for *Classical Swine Fever Virus* (CSFV) from Meghalaya, Arunachal Pradesh, Sikkim, Maharashtra and Kerala have been archived in the repository. The repository has 455 tissue sample in total of which 302 are from domestic pigs, 146 from pygmy hog and 7 wild pigs. At present 14 CSFV isolates are maintained for future studies. Simultaneously, CSF referral laboratory it was setup and linkages established with farmers/farms/ disease investigation laboratories in Maharashtra and Madhya Pradesh.

E. Aquaculture and Marine Biotechnology

The initiatives undertaken in the area helped in development of marine natural products, novel enzymes, pharmaceuticals, brood-stock improvement, disease diagnostics and prophylactics etc. Some noteworthy achievements are:

- Virus diagnostics developed and technology transferred
- Cell line and Stem cell line development and their application
- Development of aquaculture feed
- Development of pharmaceuticals and compounds against white spot syndrome
- Measures taken on development of vaccines and prophylactics here helped the sector in aquaculture health management to control the disease outbreak.

- Prophylactics and Fish Spawning Agents in Aquaculture

Virus Diagnostics: Development of molecular and immune diagnostic kits for Hypetopancratic Parvo Virus (HPV) in shrimp it was developed. The kit was tested for its specificity and sensitivity. Another diagnostic test was developed for identification of White Tail Diseases (WTD). This method observed more sensitive than RT-PCR method. In addition, Loop Mediated Isothermal Amplification Assay (LAMP) was developed for detection of HPV. The detection limit of LAMP is 0.1 pg. A simple monoclonal antibody (MAb)-based Immunodot kit for detection of WSV of shrimp at the farmers level has been developed as an effective alternative for expensive and complex DNA based tests. Diagnostics developed for WSSV has been commercialized. The kits developed are benefiting aquaculture industry, research and diagnostic labs, hatcheries, shrimp farmers and other academic institutions working on WSSV.

Scientific inputs for development of freshwater pond system: Freshwater pond system has found useful in aquaculture system as a prediction model for pond productivity depending upon certain meteorological and other input variables.

Microsatellite DNA markers and screening of brood stock population from coastal area of West Bengal and Orissa has been carried out along with the prevalence of the disease and viral pathogens in the population studied. The DNA markers disease resistance found useful in identification of disease free aquaculture stock.

Research on Shrimp Genomics Initiated: A Marine biotechnology laboratory has been established at CUSAT. Two projects have been supported as multi-agency network programmes on shrimp genomics. With the objectives to study differential gene expression with respect of infection with viral and bacterial pathogens and salinity in larval and adult stages of development and development of recombinant hormones and their antagonists, development of RNAi technique for silencing regulation of maturation.

Aquaculture Feed: For enrichment of aqua feed with cellulolytic and amylolitic microbes, the bacterial flora from digestive platform brackish water fish was isolated and tested. The parameters required for the growth of these micro floras and degradation of cellulose and amylose were optimized.

Biomolecules: Number of peptide toxins were isolated from various species of cone snails and confirmed for their analgesic effect. Another series of active biomolecules were isolated from marine sponges and screened for anti cataract potential. One of the compounds named aldrin found to be potent in normalizing biochemical alteration induced by UV light in eyes. A list of another compounds from marine actinomycetes were screened for their antibiotic, enzyme inhibition, anticholesterolinic, insecticidal, antioxidant, antifungal, antibacterial, anti algal and anti malarial activities. The immune stimulatory properties of medicinal plant *Achyranthes aspera* was studied on Indian major carp *Labeo rohita* (rohu) larvae. Anti WSSV compounds developed against white spot syndrome and the technology is transferred to Poseidon Biotech, Chennai to conduct field trials and for commercialization.

Bioprocess and Byproduct Development: Waste from the fish industries can be utilized for production of useful products such as lipids and proteins through biotechnological route. Lipids from waste of marine fishes are rich in unsaturated fatty acids such as EPA and DHA. These lipids are very helpful in delaying the possible heart problems in humans and keep them healthy.

A project for process development of collagen and gelatin extraction from fish waste was developed. Both of these products have wider application in food and packaging industries. Collagen and gelatin films also tested for biomedical and pharmacological properties. Fish air sacs were used as a primary tissue for developing cellular biomaterials.

Cell line Development and Stem Cell Applications: For *in-vitro* replication of White Spot Syndrome Virus (WSSV), cell lines from marine shrimp (*Penaeus indicus*) and freshwater crab (*Paratelphusa hydrodomous*) was developed and may be useful in future.

In-vitro culture and characterization of spermatogonial stem cells (SSCs) of Indian major carp *Labeo rohita* (Hamilton) was implemented.

Vaccines: Work is under progress for the development of vaccine against *Vibrio anguillarum*. Molecules such as outer membrane proteins (OMP), lipopolysaccharide (LPS) and extracellular protein (ECF) were evaluated for their use in diagnosis and vaccine development.

F. Seri-biotechnology

The objective is the improvement of host plant relationship, post-harvest silk processing, production and quality of silk, utilization of by products in sericulture. To support the objectives of the programme, Department has initiated several programmes in different Indian institutions. Over the time being, several other small needs at R&D level have been recognized and taken care off.

Mulberry Genomics: The main objective of this programme is the sustainable conservation and enhanced utilization of mulberry trees. Under this programme, various kinds of markers have been utilized for analysis of Mulberry gene bank and construction of dense linkage map. The germplasm conservation and transcriptome analysis of Indian Mulberry has shown good results.

Improvement of host–plant relationship: Mulberry is highly susceptible to powdery mildew diseases, which has a direct impact on growth of silkworm and therefore the overall production of silk. Efforts are made both at the level of identification of susceptible genes and preparation of transgenic Mulberry plants for tolerance to major diseases as well as environmental factors such as draught and other kind of stressing factors.

Silkworm Improvement: Silkworm normally passes through several stages during its development as a full-fledged insect. At any stage, the insect may be infected and the production of silk will suffer. Therefore, it is relevant that the insect must have appropriate immunity/resistance to various infecting agents. The most common infection is BmNPV (Viral). To tackle this and other infections, genetics studies have been carried out in different states and significant progress has been made in this direction. The transgenic lines resistant to BmNPV are under preparation and possibly will undergo appropriate trials in coming plan. Also the studies on different microsporidians infecting mulberry and non-mulberry silkworms is going on with respect to study of their life cycle, cross infectivity, pathogenicity, tissue specificity and transovarial transmission.

Silk Processing: Silk, this natural product has a huge market. Naturally silk is available in limited shades. It is desirable to have silk in variety of different colors to attract the consumers and enhance in the market consumption of the product. Several microbial dyes and pigments have been isolated and tested for their

coloring ability of silk. Some of the dyes are poor in their coloring effectiveness therefore; more research is required to take this ongoing work for commercial utility.

Silk By-product Processing: Industrial waste degumming liquor is a source of Sericin protein powder. A method for application of Sericin to cotton knits to get a valuable finished product at bulk scale is under investigation. The up-scaling of the process at pilot level is ongoing in association with a commercial company through public-private partnership.

Silkworm Hybrids: Three high yielding productive hybrids namely- *Swarnandhra*, *Hemavathy* and *Kalpatharavu* of silkworm have been developed and released to farmers; these have superior quality of silk by adopting a combination of conventional breeding techniques and DNA marker technology. These hybrids are now being used by farmers of Andhra Pradesh, Karnataka and Tamil Nadu.

Similarly, microsatellite markers for tasar and muga silkworms have been developed, which are being used to study population structure, gene flow and genetic polymorphisms.

Joined International Lepidopteron Genomics: India joined "International Consortium on Lepidopteron Genomics" and fulfilled the Indian commitments viz (a) Construction of high-density linkage map of silkworm (*Bombyx mori)* (b) Isolation and characterization of ESTs from non-mulberry silkworms.

Technology for transgenic silkworm: An RNA-interference based baculovirus resistant transgenic silkworm line has been developed. These lines are undergoing laboratory trials.

Web Based Information on Mulberry: A Web-enabled DNA database on mulberry has been developed for the first time in the world encompassing DNA fingerprinting studies carried out on more than 250 genotypes including 50 selected elite genotypes.

Technology for GM Mulberry Developed: Genetic manipulation of *Morus indica* cv. K-2 via *Agrobacterium* mediated transformation using HVA-⊥ gene for abiotic tolerance has been achieved. Evaluation of putative transgenics in mulberry (with HVA-1gene) under transgenic green house condition is in progress. A Multi-

institutional Network project has been launched on identification of DNA markers associated with disease and pest resistance in mulberry (*Morus* spp.).

2.4.6 Bioresource Development and Utilization

A. National Bioresource Development Board (NBDB)

National Bioresource Development Board has been established in 1999 with an overall aim to decide the broad policy framework for effective application of biotechnological and related scientific approaches for R&D and sustainable utilization of bioresources, specially for new products and processes; and to develop a scientific plan of action for contributing to the economic prosperity of the nation through accelerated R&D using the most modern tools of biosciences. The programme performance is reflected in the following indicator:

i.	Number of publications	29
ii.	Patents filed	13
iii.	Patents granted	4
iv.	Technologies developed	13
v.	Technologies transferred	3
vi.	Products marketed	7
vii.	Extent of biodiversity assessment	80% of forest cover
viii.	Number of research leads	11
ix.	Number of students benefited	1200
x.	Number of rural people benefited	3974

Public-private partnership for drug prospecting of microbes: The mission programme has nine academic and Piramal Life Sciences Limited as industrial partner. Till now 2,30,000 microbes screen and extracted. The extract of these isolates have found to possess anti-infective, anti-cancer, anti-diabetic and anti-inflammatory properties. The programme is now entered into phase-II activity i.e. chemical characterization of potent biomolecules.

Indian Bio-resource Information Network (IBIN): Setup to gather, compile and designing the data base for the collected information regarding the bio-prospecting and bio-diversity systems through a single website. The website has two nodes – spatial node, *Jeeva Manchitra* at NRSC, Hyderabad and species node *Jeeva Sampada* at UAS, Bangalore.

DBT and Department of Space jointly initiated mapping of bio-diversity in defined areas using remote sensing and geographical system. The study brought out a spatial data base adding understanding of vegetation formation and natural habitats mapping.

Prospecting of genes and molecules for product development: Prospecting for new genes, molecules has been taken up and potential lead molecules which could be converted to a product have been identified especially for producing biofertilizers and biopesticide formulations. 96 genes for stress resistance have been isolated from plants of fragile ecosystem. Genes responsible for imparting salinity tolerance has been identified from Mangrove plants and transferred to other crop plants including Rice. Limited field trials are being held after RCGM clearance.

In prospecting for natural dyes, more than 400 plant species collected from high altitude ranges of North Western Himalayas (6000-12000 ft above m.s.l.) and tropical areas of Northern Western Ghats (~1200 ft above m.s.l.) screened for presence or absence of colouring matter. Information on distribution, habit and natural colouring matter present for 600 dye-yielding plant species from India has also been documented. Large-scale production of the algae *Dunaliella salina* and *D. bardawil* have been developed and methods have been standardized for isolation of stable and high quality β-carotene.

Prospecting for botanical pesticides has yielded good results; so far ~575 extracts/fractions have been prepared in different solvent systems, from 29 plants collected by different laboratories.

Several compounds of biological origin were evaluated for soluble protein content, shikimic acid content, novel terpenoid molecules, carotendoids. The most promising of these compounds is a novel molecule from lichen, which prevents the colony formation of Multi Drug Resistant (MDR) of *S. aureus.* The discouraging aspect is the minimal inhibitory concentration seems to be high for MDR microbe growth inhibition. Similarly, the peptide anti-biotic from frog skin secretions is tested for its anti-microbial activity.

The technology for preparation of a plant extract based bio-pesticide formulation "TERI-DBT-Bollcure" against cotton bollworm *(Helicoverpa armigera)* has been

transferred. The field application of the technology showed significant production in pest incidences under field trials carried outing five states.

Resource Specific Programmes:

Coffee: The Coffee network programme has successfully concluded with substantial achievements in the area of germplasm characterization, molecular marker development and transformation for disease resistance and improved quality. A network project on Coffee involving CCRI (Coffee Board), CCMB (Hyderabad), UAS (Bangalore), MKU (Madurai) and CFTRI (Mysore) were supported. More than 300 genomic SSR markers were developed and 90 of them were used to evaluate genetic diversity in coffee germplasm. Molecular linkage map of *Coffea canephora* having >379 mapped markers (SSRs, RAPDs and AFLPs) is developed.

Tea: Tea network project involved the genomic analysis to find out the sequences related to various traits such as drought resistance, blister blight resistance and tea quality improvement especially the fragrance and aroma. Tea transgenic lines are prepared by imported genes from other plants such as *Solanum tuberosum.* Procedures of DNA fingerprinting have been evolved for facilitating the work on a common platform. Database for 150 clones in terms of descriptor quality traits and DNA fingerprinting have been established which laid the basis for expanding the database to all clones available in the country. Three important genes have been isolated in relation to regulation of dormancy. Micropropagation protocols and hardening procedures developed have been successfully implemented. More than 2000 accessions are now being characterized.

Seabuckthorn: The mega network projects concerning germplasm characterization of Seabuckthorn from different regions of the country especially the high altitude regions of Himalaya. To prepare a database and for future utility of the germplasm, a germplasm resource center for *Hippophae* has been setup at Lahaul, Himachal Pradesh in collaboration with Forest Department of the State. The genetic characterization of 462 germplasm has been completed and their chemical characterization for bio-active compounds is going on in IHBT, Palampur. The commercial utility of Seabuckthorn berries is very well explode to improve the shelf life of the berries and use of its berry oil as well as its seed oil in preparation of pharmaceuticals formulation. Some of the commercial product containing berry product are under testing for marketing purpose.

Jute: Under the Jute Biotechnology Programme the microbial retting protocol was standardized and tested in the farmer's field at different location. Different microbial consortia have been developed the improved retting process showed decrease in number of days required for retting and increase in fibre quality

Sugarcane: The production of sugar from sugarcane is highly affected by the two major diseases: red rot diseases and smut diseases. PCR based diagnostic kits for red rot and smut diseases have been developed and their validation is underway. A major initiative has been launched for functional genomics studies of sugarcane with special emphasis on biotic and abiotic stress. The SSR markers were developed to facilitate resistance against red rot. 124 sugarcane varieties or genotypes of diverse origin were phenol typed against red rot pathogen for linkage analysis and association mapping. In addition to SSR markers a new class of functional markers called Conserved Intron Scanning Primer (CISP) were used for genomic analysis of different varieties of sugarcane and interspecific hybrids. About 25,384 EST sequences have been submitted to Gene Bank. A total of 432 microsatellite containing genomic clones, 480 microsatellite enriched genomic clones and 240 cDNA clones were sequenced.

Other resources: A project on the development and optimization of processes for value added products from lac has been initiated with emphasis on development of eco-friendly high yield processes for currently marketed products. Programme has been supported for developing novel chemo-enzymatic technology for the food fibre from Guar/Cassia tora gums.

Honeybee: The morphological attributes and taxonomic importance of different species (3) of honeybee in several Indian States have been completed. The results indicate significant differences in key traits among the geographical samples of all the three species. Under the same project, development of the plant based as well as pheromone based honeybee attractant formulations is under evaluation.

Zingibers: Morphological and molecular characterization of 150 cultivars of ginger completed. Under the same project a ginger house was established at TBGRI, Trivandrum for isolation of essential oils and oleoresins. Similarly, from 13 Indian *curcuma* varieties biologically active peptide 'turmerin' was isolated for its commercial utility.

Bamboo: For multiplication of bamboo species a tissue culture technique was used for their enhanced plantation. The marker based study revealed that bamboo species have minimal genetic diversity.

Technology Transfer: Two botanical pesticides and three natural dyes are currently under testing for product formulation. Biofertilizer formulation has been transferred to the industry. 96 stress genes have been isolated and 4 genes have been transferred to rice, which is under limited field trials. Capacity building programmes have helped in creating awareness and more than 1100 school children are benefitted. About 4000 people have been trained in various rural technology packages.

B. Medicinal and Aromatic Plants

A programme on Medicinal and Aromatic Plants (MAPs) is continuing for the conservation, characterization, micro-propagation and development of herbal products, isolation and characterization of novel bioactive agents, genomics and biosynthetic pathway studies.

Four Technology Transfer Agreements: Under a joint DBT Ranbaxy project, a dengue virus inhibitor has been identified from a plant extract. A joint patent has been obtained on this lead extract (CiPa/D1). The lead extract found clinically safe during preliminary studies. Anna University with Ranbaxy, Gurgaon for further screening of compounds (as potential anti-diabetic and immuno modulatory agents) and also to take up already identified molecules for further investigations. Anna University joined with Nicholas Piramal, Mumbai for further investigations on lead molecules / extracts having anti-cancer properties. National Institute of Immunology (NII), New Delhi and Nicholas Piramal, Mumbai partner for further investigations of an anti-inflammatory compound isolated from *Alpinia galanga* .NII, New Delhi and Reliance Life Sciences, Mumbai jointly conduct further investigations of an immunomodulation agent (NII-70) isolated from *Tinospora cordifolia.*

Conservation and Characterization: A Network of four national gene banks on medicinal and aromatic plants at TBGRI, Thiruvananthapuram; CIMAP, Lucknow; NBPGR, New Delhi and RRL, Jammu have been further strengthened. A total of about 8500 accessions of prioritized species are conserved in different forms such as in field bank, seed bank, *in-vitro* repository, cryobank and DNA

bank. A germplasm bank for medicinal plants used in Ayurveda has been set up at Arya Vaidya Sala, Kottakkal, Kerala. An *ex-situ* germplasm bank for conservation of important MAPs of Manipur hills has been recently established at Krishi Vigyan Kendra – Sylvan, Senapati district, Manipur.

Micropropagation and Multilocation Field Trials: Multi-locational field trials to evaluate the performance of tissue culture derived *Pogostemon cablin* (Patchauli) carried out over an area of 32 acres involving five centres. Field evaluation of the performance of tissue-culture raised elite varieties of large cardamom (*Amomum subulatum*) over a total area of 50 acres in Uttaranchal initiated in association with the Spices Board.

Cell-culture Production of Therapeutic Agents: Efforts have been initiated towards protocol development of production of important therapeutic agents through cell culture methods such podophyllotoxin from *Podophyllum hexandrum*, hyoscyamine from *Hyoscyamus muticus*, guggulsterones Z and E from *Commiphora wightii* and comptothecin from *Ophiorrhyza* spp.

Bioactive Molecules: Under multi-institutional project, after bio-activity based *in vitro* screening of 60 medicinal plants (used in Indian traditional system of medicine), a total of 35 lead molecules have been identified so far: Anti-cancer (15); Anti-diabetic (5); and Immunomodulatory (15).Two anti-cancer lead molecules (from *Aegle marmelos* and *Phyllanthus urinaria*) have been patented. A lead medicinal plant extract exhibiting promising osteogenic (bone forming activity) using several *in vitro* and *in vivo* test systems have been identified. The patent for the above is being filed. The capsaicin synthase enzyme (key regulatory enzyme for capsaicin biosynthesis) and its gene (*csy-1)* have been characterized from placental tissues of *Capsicum* sp. Patent has been filed for csy-1 gene.

Agro Technology: A multi-institutional project on development and demonstration of sustainable methods of harvesting of *Nothapodytes ninmoniana* under different agro-forestry systems for optimizing the production of camptothecin and related high value metabolites has been initiated at three institutions: UAS Bangalore, UAS Dharwad and Research and Action in Natural Wealth Administration, Pune. Application of *Pongamia pinnata* oil cake found to be most effective control major against root knot disease and enhanced plant growth as well as yield of patchouli herb.

Genomics of Biosynthetic Pathways: Under this programme, efforts are made to identified the biosynthetic pathways resulting into commercially viable molecules to enhance their production naturally for example an aminotransferase gene responsible for conversion of vanillin into vanillylamine has been cloned from *Capsicum fruitscens* fruits to *Nicotiana tabacum.* Transcriptomics and proteomics approaches have been followed for defining the santalol production in sandalwood (*Santalum album*). A small-scale microarray chip containing all the significant alkaloid biosynthesis-related genes in *P. somniferum* was developed.

2.4.7 Basic Research in Modern Biotechnology

The basic research in any field of science is crucial not only to understand the natural phenomena but also essential to find out the application of these phenomenon for mankind welfare. Department is keen to strengthen the basic research in the country to increase the understanding principles and processes.

System Understanding: The projects supported under this category for understanding the different systems at cellular and molecular level by using different modern biotechnology based tools and techniques. The studies taken at CCMB, Hyderabad have taken to elucidate the strategies that human opportunistic pathogens exploit to survive host niches under extreme pH conditions. Studies are also undergoing to understand the basic cellular and metabolic pathways in different organism and in different institutions for achieving variety of different goals such as identification of peptide antibiotics to treat reproductive tract infections, identification of new class of enzymes useful in biotransformation of compounds, understanding the virulence of microbes understanding the relationships between cellular proteins and the diseases such as crystalin protein and cataract, understanding the signaling mechanism of neurons and profitable functioning of immune system both *in vivo* and *in vitro*.

Protein Engineering: In the projects on production of Streptokinase (SK) and development of technology for expression of Streptokinase in *E.coli.*, a novel mechanism of protein-protein interaction between SK and its 'target' protein, namely human blood plasminogen has been revealed. First time a new substrate specific binding sites in the SK molecule have been demonstrated.

Other Leads: A novel series of phenomenally simple and yet highly efficient non-glycerol based cationic transfection lipids has been designed and synthesized for use in non-viral gene therapy.

Aggregation properties of McrA, a restriction endonuclease has been found to have strong aggregation properties, which are predominantly charge based. This suggests the possibility of using McrA as a candidate fusion protein for selective precipitation of the target protein.

A set of modified CaMV 35S promoters has been developed whose strength was compared with the CaMV 35S promoter per se, using ß-glucoronidase as the reporter gene. The modified promoters have been found to function at par with the 35S and shall be useful for plant transgenics.

Molecular studies initiated on the efflux pumps of both pathogenic and non-pathogenic mycobacterium lead to the identification of the contribution of these pumps in the intrinsic as well as acquired drug resistance in mycobacterium.

Considering the importance of a thermostable Anthrax Vaccine, a study for the production of a thermostable protective antigen of *Bacillus anthracis* by computational and genetic engineering approach was initiated which resulted in mutants more stable than native PA and could be better candidates for anthrax vaccine.

Technologies Transferred

- A technology for production of natural Streptokinase to M/s Cadila Pharma Ltd., Ahmedabad

- Technology for production of recombinant streptokinase to M/s Shasun Drugs and Chemicals Ltd., Chennai.

- Technology for virosome based gene delivery system transferred to M/s Panacia Biotech., New Delhi.

2.4.8 Medical Biotechnology

A. Vaccine and Diagnostics

Department has initiated a Vaccine Grand Challenge Programme (VGCP) for accelerated development of vaccine. Several candidates of affordable vaccines for Malaria, Typhoid, Dengue, Tuberculosis, Cholera, HIV, Rabies and Japanese Encephalities, Rotavirus have been undertaken and some of them are in preclinical or clinical trial stages. Vaccine and Infectious Diseases Research Center (VIDRC) has been established at newly established Translational Health Science & Technology Institute (THSTI) with an objective to conduct multi-disciplinary basic and clinical research on vaccines and biologics development as well as to develop newer vaccines relevant to India.

Rotaviral Diarrhea: The safety and immunogenicity of a live attenuated rotavirus vaccine (116E) manufactured by M/s Bharat Biotech International Limited, Hyderabad induced immune response in approximately 90% of the recipients. No serious adverse effects have been observed in Phase-I and Phase-II trials. Now, the vaccine entered Phase-III trials at three sites in India namely Society for Applied Studies, Delhi, Christian Medical College, Vellore; KEM Hospital, Pune.

Vi-conjugate Vaccine for *Typhoid* has given good leads and technology transfer negotiations have resulted into identification of an industrial partner. Development of vaccine candidates for *Human Papiloma Virus* has been initiated.

Effort are being made to develop safe, efficacious and inexpensive tetravalent dengue vaccine candidate based on fusing ED-III of DENV-124 and -4 to Hepatitis B antigens.

Clinical trials of Zinc as a supplement to children in fighting diarrhea provided evidence for an immunomodulator activity in the treatment of possible serious bacterial infections among infants more than 7 days up to 4 month of age.

Development of new drugs through combinational chemistry and high screening throughput by molecular tools has been initiated. Drug development using modern biological techniques has been identified as a thrust area for Tuberculosis.

Rabies: A DNA rabies vaccine has been developed which provides boost to inoculated animals at Indian Immunologicals, Hyderabad. The formulated vaccine is undergoing trials in Kerala, Chennai, Mumbai, Bhubaneswar and Hyderabad

Cholera: The development of VA1.4 cholera vaccine is continuously supported by DBT. The same vaccine has entered regulatory toxicological studies after approval by the RCGM. A study on the oral cholera candidate vaccine has been completed. 48% had a 4-fold rise or more and 40% had 8 fold rise or more in Kolkata. The rise as marker of protection is comparable to the level raised with other oral recombinant commercial vaccine. Assay validation showed good concordance. A field site for Phase-III trial is being prepared Efforts are being made to transfer the technology as well as to get the clinical grade material to be prepared by conducting Phase-III trials.

Malaria: A joint Malaria Vaccine Development Programme (MVDP) has been established between DBT, MVI, EMVI and ICGEB. The overall objective of the programme is to promote the development of vaccine against *Plasmodium falciparum* and *P. vivax* currently MVDP is involved developmental activities of JAIVAC-1 vaccine for *P. falciparum* and PvDBPII vaccine for *P. vivax*. A trial site has been prepared at Sundergarh District of Orissa by MRC, Rourkela for Phase I studies.

HIV/AIDS: Studies on immunogenicity of HIV-1 DNA vaccine expressing the envelope and capsid antigens of Indian Clade C virus in *Macaca radiata* has showed enormous augmentation of CTL immune response in mice. Monkeys immunized against HIV-1 vaccine constructs responded to immunization.

Japanese Encephalitis: An Indian strain of Japanese Encephalitis Virus (JEV) has been grown in Vero Cells to high titers and formalin-inactivated it. Inactivated virus produced high titers of JEV neutralizing antibodies and protected the immunized mice against lethal JEV challenge. Technologies for high-density culture of Vero cells using microcarriers has been standardized and transferred to M/s Panacea Biotech Limited, Delhi. Parallely, native mice immunized IM with recombinant adeno virus with secretary E proteins has showed complete protection against lethal dose of JEV given intra-cerebral. Adeno-based approach is being negotiated as a platform technology with companies

Tuberculosis: Several antigens of *M.tuberculosis* using different vectors in *E.coli* expression system have been cloned. Genes coding for these antigens tailored into DNA vaccine vectors. Antibodies raised using these recombinant proteins and DNA in prime boost approach in rabbits. Challenge experiments are on.

Mycobacterium wightii: RCT clinical trials adopting ICH-GCP guidelines initiated for testing efficacy of Mw in Category II pulmonary tuberculosis are proceeding well.

B. Human genetics

Functional Genomics: Progress has been made to carry out genetic research in SCA, schizophrenia & bipolar disorder and asthma. High-throughput capabilities and highly skilled manpower developed in the field of genomics and computational biology. Novel mutations and SNP in B-thalassemia patients have been identified. Susceptibility on locus on chromosome 22 for schizophrenia and biopolar disorder in the Indian population has been identified. A nonsense mutation in the synaptogyin 2 gene in schizophrenia Identified. A US patent was filed for a method to detect human spinocerebellar ataxia 2 gene variants.

Human Genome Diversity: India is one of the first countries to take up the project on Human Genome Diversity. A major consortium project has been implemented as a network manner with 14 institutions.

Studies on genetic variation among 53 ethnic population groups (tribal, cast and religious communities) revealed that there is an underlying unity of female lineages in India, indicating that the initial number of female settlers may have been small; the tribal and the caste populations are highly differentiated and that the Austro-Asiatic tribals are the earliest settlers in India. The study also provided evidence of human migration from India to South-East Asia. It was revealed that the expansion of the ethnic population took place about 50,000 years ago.

Post Genome Era Research: Supported projects on microbial functional structural, comparative and computational genomics, clinical proteomics and RNAi. DNA Micro-array facilities at NBRC, Manesar and CDFD, Hyderabad set up to carry out studies on neurological and infectious diseases. The whole genome sequencing of *Mycobacterium wigtii* at 5X sequence has been completed with a sequencing efficiency of 83.93% and total sequence coverage of 5.71 Mb. A major effort in

the area of pharmacogenomics is being undertaken to develop baseline data for genetic response to important drugs for treatment of rheumatoid arthritis, bipolar cardio-vascular and other diseases by involving major research organizations and hospitals.

C. Infectious Diseases

The Department supports the programmes in the basic & translational research aspects of infectious diseases caused by various agents viz. viral, bacterial, parasitic and fungal. The emphasis is to establish and integrated approach for the development of preventive, therapeutic and diagnostic tools for infectious diseases such as HIV/AIDS, Hepatitis, Influenza, Chikungunya, Tuberculosis, Cholera, Malaria and Leishmaniasis.

Tuberculosis: TB is widely distributed infectious diseases in India; therefore, DBT has the intention to promote development of new diagnostic tools and therapeutics. Efforts are made to developed real time PCR and line probe assay for rapid diagnoses of multi drug resistant TB. University of Delhi, South Campus have developed immuno-chromatographic rapid visual test "Crystal TB Confirm" for detection of tubercle bacilli in culture. This test can be performed within 20 minutes and require minimal training. The technology is transferred to M/s Span Diagnostics Limited, Surat for manufacturing the kit.

In an effort to develop novel anti-mycobacterial agents against latent and MDR tuberculosis, research was pursued at M/s Ranbaxy Research Foundation, Gurgaon to design and synthesize novel analogues of J & J compound-TMC-207 & screening of NCEs from proprietary library against *Mycobacteria* using enzyme-based and whole-cell based assays.

Other bacterial diseases: PCR based kit for rapid detection STD related infection caused by *Neisseria gonorrhoeae and Chlamydia trachomatis* developed. Phase I clinical trial studies on safety, acceptability, side effects and vaginal sensitivity of 'BASANT' (poly herbal gel) as a vaginal Microbicides in sexually active HIV uninfected women have been initiated during 2009-2010.Outcome of Phase I clinical trial with herbal BASANT cream has been promising. The cream was observed to be safe and well accepted by the women for application.

HIV/AIDS: Several approaches have been tried such as a new class of specific and tight binders were synthetized which inhibit Rev-PRE interaction in HIV. DBT-ICMR collaborative joint efforts in 19 projects have an objective to develop HIV viral load assay, CD4 assay, design a new vectors and adjuvants formulation, understanding mucosal immunity, developing combinatorial mycrobicide formulations and their pre-clinical and clinical testing.

A call for neurosciences inviting pilot, R & D & organizational proposals including biomarkers was given and more than 250 proposals received. About 100 proposals on basic, applied and clinical aspects of neuroscience approved.
A new Task Force on disease biology of vulnerable groups has been launched for projects on pregnant women, fetal diseases, children and elderly.

D. Stem Cell Research

Stem cell research is being promoted for basic and translational research. The objective of the programmme is the study of basic biology of embryonic and adult stem cell, generation of stem cell lines, establishment of institutions and centers of excellence, manpower training and study of clinical implications and pre-clinical studies. To achieve the goal; "*Human Studies committee*" for evaluation and guidance for clinical research particularly for development of clinical research protocols; "*National Bioethics Committee*" to ascertain rigid ethical guidelines being followed while conducting research on human beings; "*Task Force on Stem Cells*" to evaluate basic research and clinical research; and "*Programme Advisory Committee"* to consider the proposals of Centre of Excellence and infrastructure have been constituted.

Adult and Embryonic Stem Cell (ESC) Research: Department is supporting programme on various aspects of pluripotent stem cells like study of their genetic changes identification of factors leading to cancer, study of human ESCs toxicity and in vitro population, mechanobiological regulation. In the same line to new hESCs from discarded grade-III blastocysts work generated to characterize the markers expression and their stability differentiation capability. Simultaneously, the adult stem cells have been studied to treat different diseases. At LVPEI, Hyderabad, limbal stem cells are being used to repair cornea surface disorders caused by limbal stem cell deficiencies. So far, more than 220 patients have been treated at this Institute.

Preclinical and Clinical Research: Preclinical studies using stem cells have been supported for various diseases such as spinal cord injury, traumatic brain injury, articular cartilage damage in joints and epiphysis, treatment of inflammatory bowel diseases. In clinical trials bone marrow mononuclear cells transplanted in myocardial infraction and acute ischemic stroke to test their efficacy and safety in small group of patients.

"CMC-DBT Centre for Stem Cell Research": A technology has been established at CMC, Vellore for collection, isolation and purification of HSC for haploidentical HSC transplantation.

Other Achievements

- Banana lectins have been isolated and purified that have stem cell preservation activities. A patent has been filed through DBT.
- Stem cell research facilities including clean rooms to handle stem cells have been created at SGPGIMS, Lucknow, PGIMER, Chandigarh, KEM Mumbai and LVPEI, Hyderabad.
- A training centre for embryonic and adult stem cells has been supported jointly at National Centre for Biological Sciences & Jawahar Lal Nehru Centre for Scientific & Advanced Research, Bangalore.
- City cluster programmes have been implemented at Pune and Vellore by involving basic researchers and clinicians. This includes sharing of information, explore collaboration with clinicians and discuss emerging policy issues in this area.
- New initiatives include public-private partnership for large scale production of mesenchymal stem cells under cGMP conditions; national and International training programmes; focused, targeted disease specific basic and applied programmes in this area etc.
- National guidelines for stem cell research are being formulated jointly by Department of Biotechnology and Indian Council of Medical Research.

E. Bioengineering

Bioengineering integrates physical, chemical, mathematical, computational sciences with principles of engineering to study biology, medicine, behavior and health. It advances fundamental concepts, creates knowledge from the molecular to the organ system levels and helps develop innovative, processes, implants,

devices and informatics for the prevention, diagnosis and treatment of disease. The key areas identified are: tissue engineering, biomaterials for therapeutics, medical devices, bioinstrumentation and biosensors.

Bio-sensors: Low cost bio-sensors are required for detection of pathogenic microbes in water, human blood, food, drinkable materials etc. Biosensors against pathogenic bacteria such as *S.typhi* and *C.tetani* was developed successfully using poly acrylonitrile fiber (PAN). A tissue engineered *in vitro* sensor for understanding the osteoarthritis model has been developed with potential in understanding the diseases formation, progression and use in therapeutic screening of potential drug candidate. Biomaterials using Indian tassar silk; reconstruction of epidermal and dermal cells of skin in three dimensional collagen scaffold; development of electrochemical sensor for cholesterol; bioengineered cell sheet for corneal tissue engineering; DNA sequence detection for medical diagnostics; novel biodegradable polymeric materials as functionally active cardiac implant; strip based non-invasive rapid test for diagnosis of new born & childhood sepsis are other research leads.

Medical devices: At IIT Madras, 'Mannequin' based training simulator for 'Acute Myocardial Infarction' (AMI or MI) has been developed with particular emphasis on recognition of the AMI type. At IIT Delhi, Mobile ECG platform was developed which displays ECG signals for regular monitoring and emergency. ECG Patch having an arrangement of three twitch electrodes which when put against a patient can wirelessly transmit ECG signals (for single lead) via Bluetooth to a mobile phone (used as a display).

The other leads include: Development and evaluation of new spectroscopic method for diagnosis of oral pre-cancers and cancers; Indigenous production of low cost medical devices of international standard for new born and child health care; biodegradable scaffolds for tissue engineering of blood vessels; silk based hydrogel wound dressings; biomaterials using Indian tasar silk proteins for biomedical applications; biodegradable hydrogel for controlled drug delivery systems etc.

Implants and Biomaterials: Novel biomaterial such as carbon nanotube based, reinforced hydroxyapatite, polyetheretherketone nanocomposites and titanium based composite materials are under development for number of biomedical applications. Topotecan loaded chitosan based micro spheres and chitosan gelatin

scaffolds were successfully synthesized and demonstrated their potential as promising drug delivery system.

Stanford -India Biodesign (SIB) Initiative: This is a leadership-training program in biomedical technology innovation in India. Through this programme, a group of next- generation innovators & entrepreneurs are being developed who will create new medical technologies. This is a multi-disciplinary, team-based fellowship conducted at Stanford and in India. Fellowship teams include physicians, engineers and entrepreneurs business and other medical device industry experience. First SIB Center has been established jointly at All India Institute of Medical Sciences (AIIMS) in Delhi in conjunction with Indian Institute of Technology (IIT), Delhi. The team has developed some prototypes which have extensive applications in the field of medical science. These prototypes are being refined further.

2.4.9 Environmental Biotechnology

Environmental Biotechnology is the multidisciplinary integration of S&T particularly biotechnology in order to utilize the huge biochemical potential of microorganisms, plants and parts thereof for the restoration and preservation of the environment and sustainable use of resources. The primary role of environmental biotechnology is to develop better approaches for sustainable development and for understanding processes in the natural environment.

Bioremediation: Bioremediation of sludge in oil contaminated soil and water lying at various oil refineries and oil exploration sites in India, the pilot scale facility for Oil zappers has been setup.

For efficient bioremediation of Azo dye, 30 anorexic and 10 aerobic consortia of microbes have been developed for metagenomic studies and screening of clones for azo dye de-colourization. The fungal metalloenzymes also tested for azo dye by remediation using solid state and submerged fermentation.

Paper and pulp industries are sources of high level of toxic contaminants including heavy metals. Different processes involving the removal of contaminants through microbial growth are optimized and their technology is transferred to industry.

Phytoremediation of uranium enriched soil was carried out and the preliminary results indicate that vegetation can successfully mineralize uranium. University of Delhi has successfully demonstrated the utilization of site specific restoration technology at mined areas of SAIL. The restore site soil shows the successful establishment of nutrient feedback loop.

Carbon dioxide fixation and sequestration has been achieved through either immobilized enzymes or using whole cell reactors. The carbon dioxide is sequestered into calcite a natural abundant form of calcium carbonate. In another approach carbon dioxide sequestration through afforestation, forestry and agricultural model alongwith their integration to beneficial microorganism was tested. DBT-NTPC joint initiative on carbon sequestration has been launched

Environmental Meta-Genomics: Screening and characterization of antibacterial peptides and proteases from goat skin surface were performed and two antibacterial proteins have been identified. In another study function based screening of meta genomic library resulted into identification of clones possessing anticancer activity. Additionally, clones have been identified for their de-chlorination activity.

Enzymes based amperometric biosensors have been developed for arsenic detection in drinking water.

Biopolymer: Green nanocomposite from renewable sources such as starch based blends were prepared through melt blending technique and it is concluded that biodegradable blends of PLA/PBAT and its nanocomposite can be prepared with improved properties. Similarly, cost effective production of lactic acid for polylactide (PLA) synthesis was carried out using cheese whey and fruits of *Zizyphus oenophlia.*

The biodiesel industry generates about ~10% (w/w) waste glycerol as main by product a study was carried out to develop a process for the production of polyhydroxy butyrate (PHB) from glycerol by product. Few bacterial strains have been identified which are suitable for converting the waste glycerol from biodiesel industries to PHB and also the process does not require pretreatment of crude glycerol.

Technologies are ready for commercialization

- Bioremediation of mine spoil dumps through integrated bitechnologies approach
- Ecological restoration of degraded ecosystems and wastelands
- Technology for mangrove aforestation through application of classical and biotechnological tools
- Biosensors ('Enzcol' and Enzstrip') for detection of organophosphorus pesticides
- Biotechnology of bioscrubber for removal of obnoxious odours from industrial emissions
- Oilzapper technology for bioremediation of crude oil spills and treatment of oily sludge
- Microbial treatment of Cassava starch factory wastewater
- Chemo-biochemical process for desulphurization of gaseous fuels and emissions
- Eco-technology for treatment of textile dye wastewater
- Process for removal of acid dyes, direct dyes and reactive dyes from the spent dye bath.

In addition few more technologies are in the final stage of development like paper and pulp waste treatment, tannery waste treatment eco-restoration etc.

2.4.10 Food and Nutrition

The main emphasis was to develop novel food products and processes. Efforts focused on: a) food safety ; b) diagnostic kits for detection of various food born pathogens ; c) analytical methods for detection of Genetically Modified foods and products derived there from ; d) Utilization of agricultural residues for obtaining value added products and for developing low cost nutrient food supplements; e) nutraceuticals/ health food supplements/ functional foods; f) bio additives (food colorants, flavors and preservatives); and g) nutrient foods/food supplements.

Probiotics for Human Health: To develop probiotics which can cater the most common deficiencies in India such as iron, vitamin B12, folic acid, etc number of projects supported based on plant products such as antioxidants and anti glycemics and other chronic diseases relevant products. The products are under testing phase and soon will enter into clinical trials phase for testing their safety and efficacy.

Number of metagenomic studies carried out to develop microarray based chip to identify changes in flora between individuals or groups of individuals in the screening of probiotics. Multiplex PCR based detection assays for the trans-genes in transgenic crops like GM brinjal, potato, tomato and cabbage are also developed.

Nutraceuticals: In India the delivery of drugs and their shelf life is a major contributor to the overall cost of the drug. Therefore, it will be desirable to make these drugs available freshly to the consumers through fruits and vegetable in routine use. Many projects sponsored by the Department to enhance the nutritive and pharmaceutical value of common fruits and vegetables.

Food Packaging: Few biodegradable polymers such as chitosan, poly-a-caprolactone (PCL) have been identified and are under development to reduce water vapor permeability to minimize water loss from packaged fruits and vegetables for extending their shelf life.

Food Safety: Rapid detection of live bacteria is an important food safety problem. To detect the bacteria, a microchip was developed which can segregate the nano conjugated cells from plain bacterial and which will be helpful in detecting to kinds of bacterial species.

Adulteration of spices and condiments is a major commercial problem for household consumers. PCR based detection methods have been developed for finding out the adulterants in turmeric powder, pepper powder and chili powder.

Nutrition's Deficiency and Health Care: Studies have been carried out to understand the relationship between vitamin B12, folic acid and neural tube defects. Markers have been identified to correlate the levels of these nutrients and nervous system defects. Several biological compounds of various origin identified and evaluated for pharmacological activity in different diseases such as diabetes, inflammation etc.

Diarrhea Management: Use of zinc is recommended by WHO along with oral rehydration therapy to decrease the incidence and severity of diarrhea. The technology for production of dispersible zinc tablet is transferred from M/s Nutriset, France to BIBCOL, Bulandshahar a public sector unit of DBT. The unit

has supplied more than 60 million tablets to Assam, Bihar, West Bengal and Chhattisgarh.

Food Biotechnology: Several raw materials involved in food industries are expensive and the processes are required to generate them cheaply. The investment in this direction led to the significant improvement of process of certain products such as trehaloes and production of biopolythene. The process for detection for early food maturity has been developed especially for tomatoes via measuring their malic acid content. High malic acid level indicates ripeness of tomatoes.

Performance: Basic research activities resulted in 125 publications in reputed journals.

Out of 19 technologies developed- 8 technologies transferred and 3 technologies commercialized.

Technologies for Health Foods: Low cholesterol egg powder, immune colostrum for use as baby food supplement, large-scale production and processing of oyster mushrooms, and *Spirulina* production (50kg/day).

Technologies for Fruit Juice Processing: Production and Application of Naringinase for Debittering of citrus juices, enzymatic application for peeling, deseeding and fruit juice extraction, and membrane filtration technology for clarified fruit juices.

Technologies for Production of Natural Food Additives: Betalain (Colorant) Production from Cell Cultures of Beta vulgaris, and Production of Xanthan Gum by Fermentation.

Technologies on Oil and Fat Modification: Reduced Calorie Fat and Lyso Lecithin.

Technologies for Ensuring Food Quality/Safety: (a) Diagnostic Kits for rapid Detection of Food Borne Pathogens like E. coli 0157:H7, *Listeria monocytogenes, Bacillus cereus, Staphylococcus aureus, Yersinia enterocolitica, Shigella, Salmonella, Clostridium botulinum, Entamoeba histolytica and E. dispar, Norwalk*

and Norwalk like Viruses like Rota Virus, Aspergillus flavus . (b) Technologies for Rapid Detection of *Aflatoxin B-1* and Rapid Detection of Pesticide Residues.

Technology for Biodegradable Food Packaging

Other achievements

- Various nutrient supplements has been developed utilizing indigenous agri-resources.
- Generated R&D leads in molecular probes for Quercetin, the common food toxicant; microbial bioassay method for detection of toxic metals in foods – estimation of chloride and mercury; technology for degradation of organo chlorine pesticides by microbial culture; biosensor for detection of organo phosphorus pesticides, ELISA detection kits for pesticides; and ELISA Kits for rapid detection of aflatoxin in foods.
- The programme has come up with protocols which will help ‘quarantine‘and boost the export potential of quality processed foods from India.

Human Resource Development: An initiative was undertaken for strengthening of food biotechnology research & training in the country so as the students involved in research at B.Tech/M.Tech/M.Sc./M.Phil/Ph.D courses be benefited through advanced techniques/instruments/Curricula. Six institutions engaged in research and training in the area of food sciences/technology across the country have been strengthened.

2.4.11 Bioprocessing and Scale up

Emphasis has been given to support projects on development of product/process having industrial importance and by using environment friendly techniques. Research leads and technologies developed include:

Optimization of the production and application of industrially important enzymes

- Development of keratinase, pullulanase, cellulase, laccase, solvent tolerant protease and salt tolerant alkaline protease.
- Preparation of endoglucanase, glucosidase and xylanase mixture for biological drinking of the mixed office paper-waste

- Development of a clone having α-amylase, glucoamylase and pullulanase genes for direct fermentation of starch to ethanol
- Technology optimization for production of urokinase having medical application.
- Development of cross-linked crystals of lipases
- Bioconversion by lipases
- Development of an improved protocol for crystallization of lipase from *Pseudomonas, Candida* and *Hemicola*.
- Optimization of the Two phase separation protocol for the easy purification of the serine protease from the detergent preparation 'Savinase'
- GA_3 (plant growth harmone) production at a rate of 10 mg/l/h from a selected mutant at NCL, Pune in 10 L fermenter between 48 and 72 h of fermentation time.
- Demonstration of the effectiveness of cellulase treatment in bio-finishing of denim at a pilot scale by NCL, Pune in collaboration with ATIRA.
- Production of extracellular protease and lipase by a solvent tolerant strain of *Pseudomonas aeruginosa* isolated at IIT, New Delhi

In the Health sector focus was given on

- Preparation of polymeric particles for the development of single dose vaccine formulation
- Complete sequencing of rifamycin gene cluster
- Generation of recombinant antibodies against HBsAg
- Development of nutritionally modified egg
- Development of a process for mass production of targeted delivery of antigens through nanoparticles using Sendai virus system.
- Development of a new molecule to detect antibodies to HIV-O subtype 'C'. Performance is comparable to other USFDA approved rapid test kits.
- Purification of the novel lipoxygenase inhibitor from *Penicillium frequentans.*
- Purification of the recombinant asparginase directly from the culture medium using a rapid two-step purification strategy, which resulted in a recovery of ~70% and a specific activity of ~80% of that of the native enzyme.
- Standardization of the entrapment of ovalbumin in hydrogel nanoparticles made up of cross-linked polyvinyl pyrrolidone.

Wastewater Treatment: Designing and fabrication a pilot scale reactor for a novel high cell density process and its installation.

2.4.12 Nano-science and Nanotechnology

Nanotechnology is an area of priority for health, agriculture, food and environment research. Several products enabled by nanotechnology are in the market. Major areas identified under this programme are drug delivery, cancer therapeutics, diagnostics biosensors and agriculture related product.

Nanodrugs and Drug Delivery System: Nano biotechnology approaches are being actively investigated in the designing of functionalized biodegradable nano particulate drug delivery systems. Nano particles encapsulated siRNA formulations were evaluated for treating various types of cancer. The chitosan nano carrier induces silver nano particle based apoptosis a human colon cancer cells at very low concentration. Similarly, fluorescent gold nanoparticle polythathiophene nano composite was developed for quantitative detection of broad spectrum of pathogenic bacteria. This florescent composite has immense application in detecting very small amount of bacteria. The nanoparticle based delivery of several very established drugs such as antimalarial, anti tuberculi etc. proved extremely useful in reducing their toxic effects as well as to change their bioavailability.

Nanoscience and Life Science Fields: Electro spun nanofibers are tested for their application in food packaging, biofertilizers in biopesticides. Silica based nanoparticles were developed for pesticide delivery and these nano particles are named as dipentox and for this product, patent is taken. The advantage of dipentox is cost effectiveness and effectiveness in highly humid condition.

Nanoimaging: Multifunctional magnetic nanoparticles were developed for combined cancer targeted magnetic resonance/ optical imaging and therapy. Polyacrylate coating was developed to transform gold nanoparticles into functional nanorods. This method is also applied to prepare the probes having plasmonic-fluorescent-magnetic properties. These nanoprobes have been used for dark field imaging, fluorescence imaging and magnetic separation.

Tissue engineering: Combination products of polymer ceramic nanocomposites having bone tissue engineering applications are under development. Similarly,

biomimetic process was developed for in situ self nano mineralization of polymer hydrogels using freeze thaw technique.

Nanotoxicology: The clinical applications of nanoparticles may be hazardous in the absence of sufficient data related to nanoparticles in human system. Therefore, it is necessary to understand the adverse effects of nanoparticles size, surface chemistry, composition, material adsorption and their sticking capability under *in vitro* and *in vivo* conditions. DBT established a state of the art nano toxicology characterization facility at Amrita Centre for Nanoscience and Molecular Medicine, Thiruanantpuram. To harmonise the whole process the guidelines are also prepared for toxicological studies of the nanomaterials.

2.4.13 RNAi Technology

The discoveries of RNA interference and RNA mediated post transcriptional gene silencing have opened unexpected avenues for the regulation of gene expression and knocking down gene expression in organisms and cells. The prioritized research areas under RNAi Biology cover development of tools for research, early translation / product development and translational research related to use of RNAi based approaches.

RNAi in Agriculture: RNAi approaches are extensively used as tool in understanding various gene silencing mechanism and applying them as a tool for the benefit of agriculturally important crops. The use of the technology revealed that the phenomenon of trans-silencing exist in transgenic plants. The same approaches are used in nematode management and delaying in the ripening tomato fruit. Efforts are continuing to develop RNAi based technology for developing resistance against two rice viruses Rice Tungro Bacilliform Virus (RTBV) and Rice Tungro Spherical Virus (RTSV).

RNAi in Medicine: Micro RNA found to be useful in understanding the biochemistry underlying various diseases such as diabetes and cancer. Chemically modified small interfering RNAs (siRNA) found to be the most promising tools for developing RNAi based therapeutics. At IIT Bombay several novel chemically modified siRNAs were synthetized to target drug resistance *P. falciparum*. The efficiency of these chemically modified siRNAs is under evaluation in cellular systems.

2.4.14 Energy Bioscience

Department has a focus on using different feed stocks as a raw material for ethanol and biodiesel production. DBT-ICT (Institute of Chemical Technology) and Centre for Energy Biosciences (CEB) has been established in Mumbai with the primary focus of developing technologies from renewable resources. The overall objective of the collaboration is improved bioethanol production any given biomass and development of other biofuel technologies such as biohydrogen and biomethane.

Technology Transfer: A completely indigenous technology for lignocellulosic ethanol production has been developed. The technology is unique in terms of low capital cost, continuity of the process, suitability to all kinds of biomass and a high yield of ethanol (~90%). To test the technology a demonstration plant by Glycol India Limited, Kashipur has been setup. Similarly, the technology for production of butanol from biomass derived sugars has been developed in collaboration with Purdue University, USA.

Jatropha Biodiesel Mission: Under the Jatropha network programme, 1234 germ plasm are collected and 216 accessions found promising in the basis of their oil content and tolerance to local conditions. Seventeen lakh clonally raised saplings have been developed for distribution amongst various states and institutions as Jatropha genetic resource. Jatropha Germplasm Resource Centres are being developed at different states and institutions.

Algal Biofuel and Repository: The progamme involves collection identification and characterization of algal strains having high oil / lipid content. Under the algal network programme 12 national laboratories / institutions / universities are participating across the country. Till now total of 900 cyanobacteria microgreen algae have been isolated from different ecological habitats and location of north east region of India. Characterization of the identified strain is under progress. The genetic manipulation of few algal strains resulted into high lipid content (30%). To boost the programme national facility for Marine Cyano bacterial Repository for biodiesel feed stock has been setup and currently the repository has ~400 strains.

Human Resource Development: To create skilled & trained manpower in energy bioscience, the department has initiated a scheme “National Energy Bioscience Chair” to have excellent team leaders in the bioenergy area. Additionally, the

department also instituted energy bioscience overseas fellowship for scientist of Indian origin who wishes to pursue high level of research in energy biosciences.

2.4.15 Biosafety & IPR

IPR Awareness and Facilitation: In order to enhance knowledge of IPR, 12 seminars and conferences have been organized in various parts of the country for Indian scientists.IPR awareness programme at National Law School of Indian University (NLSIU) has been supported.DBT patent facilitation services resulted in filing of 144 patents, and 17 patents granted so far.

Biosafety: The Department had re-constituted the Review Committee on Genetic Manipulation (RCGM) to monitor the safety related aspects in respect of ongoing r-DNA projects & activities involving Genetically Engineered Organisms/ Hazardous organisms and controlled field experiments of transgenic crops, in compliance with the Rules-1989 of Environment (Protection) Act, 1986 (EPA-1986). During 2010-11, RCGM considered about 625 applications in 9 meetings in the areas of agriculture pharmaceuticals and industrial project for import and exchange of transgenic material, conduct of preclinical toxicity studies, evaluation of preclinical study data conduct of biosafety research level-1 / event selection trials in confined conditions on several transgenic crops for generation of biosafety data. Till now only one transgenic crop i.e. Bt Cotton has been approved by the government. R&D activities are going on with various other crops rice, okra, brinjal, mustard, tomato, cabbage, cauliflower, ground nut, pigeon pea, chickpea, cowpea, finger millets, sun flower, soybean, bamboo, castor, wheat, black gram, black pepper, chilies, onion, papaya and rubber. Eight public / private institutions / companies were permitted to conduct confined field trials of five transgenic crops namely brinjal, cotton, rubber, corn and mustard.

During 2010-11, in the pharmaceutical sector 18 rDNA products were approved for conducting preclinical toxicities studies. Based on the preclinical study reports, 13 rDNA products were recommended by RCGM to Drug Controller General of India (DCGI) for appropriate phase of clinical trials.

Till now, 538 Institutional Biosafety Committees (IBSC) were constituted in various universities, public / private R&D institutions and industries to monitor the biosafety aspects of recombinant DNA technology based projects. The Department also revised the IBSC handbook and guidelines to strengthen the Indian Biosafety

Regulatory System. Documents on the biology of Cotton, Okra, Maize and Rice were approved and implemented as foundation information for conducting biosafety research trials.

Websites: Two dedicated dynamic and interactive websites on "Biosafety" (http://dbtbiosafety.nic.in) and "Indian GMO Research Information System (IGMORIS)" (http://igmoris.nic.in) aimed to provide information on research work being pursued in Indian laboratories and to facilitate and disseminate the statutory requirements. The details of each application and the organizations pursuing these projects are available on these websites. In addition, these websites facilitate in tracking of regulatory clearances on applications made to RCGM and e-monitoring of IBSCs on personalized web features.

2.5.0 International Cooperation

Internationally scientific collaboration expended strategic bilateral and multilateral cooperation with various countries. The efforts have not only been towards R&D but have also endeavored towards creating opportunities for higher education, training capacity building. Innovation and enterprise So far about 100 joint projects have been implemented.

Indo-Canada: Collaboration with a Canadian agency named International Science & Technology Partnership (ISTP) established to develop novel class of anti-malarials. In another initiative, five Programme Development Activities (PDA) for funded in many applied areas such as development of low cost chip for health monitoring, mobile e-health technology, pediatric neuroimaging. The objective of the PDAs is to allow interaction of two collaborating sites through workshops for possible building of contacts and projects. DBT also made partnership with National Research Council (NRC), Canada for developing high oil yielding varieties of *Brassica*. Efforts have been made to develop comprehensive genomic resources and molecular markers suitable for application in flax breeding towards genetic improvement for oil and other agronomic traits.

Indo-Denmark: The Indo-Danish joint Biotech Steering committee has been constituted. The major areas of collaborations include thematic workshops, one in each country every year co-ordinator on both sides. The first workshop on Stem Cell was held on 20-21 February 2006 at NCBS, Bangalore. Four proposals

have been recommended for funding from both sides and another four are under consideration.

Indo-Finland: A Memorandum of Understanding (MOU) in the area of Biotechnology has been signed between Finland and India. Five projects have been recommended for science related to vaccine development, delivery system, products and processes; diagnostics: development of new innovative diagnostics, using different technologies like e.g. FRET-technologies; drug development: computational biology related to drug development. Efforts are in progress to develop a multiplex assay for the simultaneous detection of anti-HIV, anti-HCV and Hepatitis B surface Antigen (HBs Ag) in human serum samples. In agriculture the focus is on to develop the abiotic and biotic stress resistance crop varieties and microbe based biofertilizer production processes.

Technology Transferred: Under a project entitled "novel in expensive test concepts for sensitive and specific detection of HIV, HCV and HBV infections in a blood bank setting", recombinant antigens were developed for the detection of HIV in human serum. The technology has been transferred to J. Mitra & Company and the product is marketed under the brand name of "HIV TRI-DOT".

Indo-Germany: A joint Indo-German patent has been filed in India entitled "Isolated antigenic polypeptides useful for detection and immunotherapy of aspergillosis". In an exploration project for microbes growing in extreme conditions, two new species of archaebacteria have been discovered from the Lonar Lake. As a part of collaboration project at Bharat Biotech Foundation, Hyderabad and University of Wurzburg, Germany, pre-clinical development of recombinant lysostaphin for the eradication of systemic *S.aureus* infection was completed. New leads were identified for developing a novel multi-epitope vaccine by improvising the existing *S.aureus* vaccine candidate.

Indo-Sweden: DBT and Swedish Governmental agency for innovation systems agreed to cooperate in the fields of biology, diagnosis and treatment of TB. Till now, 4 proposals funded involving different well recognized institution of India and Sweden.

Indo-US: The collaborative effort leads to the development of transgenic monkey through germ cell integration of the foreign gene in primate. This method is ethically superior in terms of no animal sacrifices is required and less invasive. In

collaboration with NIH, a programme is initiated for the development of novel low post technologies for diabetes screening and treatment. An Indo-US Vaccine Action Programme (VAP) is initiated to develop the low cost vaccine against the common communicable and infectious disease such as Malaria, TB.

Indo-France: Under the bilateral cooperation with CNRS, France has agreed to support five Indian scientists for 3 months training in laboratories in France in the areas of pharmacogenomics, bioinformatics, nano biotechnology, neurosciences and immunology.

Indo-UK: DBT ICAR and BBSRC and Bill & Milenda Gates foundation has agreed to established a joint funding initiative entitled "Sustainable crop production research for international development" to increase the food security by understanding and countering biotic and abiotic stresses to facilitate sustainable crop development. MOU was signed in 1998 with the Biotechnology and Biological Sciences Research Council (BBSRC), Government of United Kingdom on co-operation in the field of biotechnology and biological sciences to facilitate broad opportunities for co-operation between the two countries thereby promoting the areas of research of mutual benefit to both countries. Five projects are being processed for funding from both sides. The diagnostic biomarkers for cancer and the possible therapeutic targets for cancer treatment have been given priority.

Welcome Trust-DBT India Alliance: DBT partner with Welcome Trust to launch a three tier fellowship programme for biomedical research. The programme is being delivered by a Special Purpose Vehicle (SPV) for a period of five years. The alliance runs three fellowship schemes: early (for newly qualified Ph.D.), intermediate (those with 4-7 years of post Ph.D. experience), senior (those with 7-12 years of post Ph.D. experience). So far, 8 early career, 13 intermediate and 8 senior fellowships have been awarded.

Indo-EU: DBT and European commission are in agreement to enhance research opportunities in Food, Agriculture and Fisheries. A project called 'New Advances in the integrated management of food waste in India and Europe (NAMESTE) is initiated as result of cooperation. The main objective of the project is to develop innovative, comprehensive and industry relevant approaches for the valorization of citrus, Mango and Pomegranates by-products and Wheat and Rice bran through environmentally and economically sustainable conversion of these by-products into healthy food ingredients, foods and feeds. The second project is to study the

"Impact of agents with potential use in functional foods on biomarkers for induction on age related diseases".

ERA-NET: DBT is a part of the new INDIGO project which is the first European Research Area Network (ERA-NET) in India. The main areas of thrust are biomarkers and diagnostics, bioinformatics for health, structural biology for health. So far, under this programme, 13 projects have been funded.

Indo-Australia: DBT and Department of Innovation, Industry, Science and Research, Government of Australia and recently State Government of Queensland signed MOU for cooperation in cutting edge areas of biotechnology. So far, 30 projects have been supported under different areas.

Indo-Norway: Indo-Norway collaboration was made to foster the vaccine development for commercially viable aquaculture animal species especially for the Fish and Shrimp.

DBT-IAVI Collaboration: DBT and International AIDS Vaccine Initiative (IAVI) collaborative programme has been extended for another five years to take the existing leads further for developing the vaccine against HIV/AIDS. Recently DBTs new Institution i.e. Translational Health Science and Technology Institute entered into collaboration to accelerate the HIV Vaccine discovery program. The key component s would be designing, testing and implementing high-throughput strategies for HIV-1 immunogen screening and prioritization to help discovery and advancement of novel HIV vaccine candidates.

Indo-Swiss: New phase of Indo-Swiss cooperation began in 1999 with agriculture and environmental biotechnology as focus with eight collaborative projects and two large networks involving a total of 47 research groups and more than 120 researchers. In the Phase III (2008-2012) on product development, prototypes of biosensors detection of pesticides residues have been developed. New resistance genes against sucking pests (e.g. aphids and white flies) were identified and characterized. In addition, a synthetic gene encoding for an insecticidal toxin originally derived from *Bacillus thuringiensis* (*Bt*) has been developed. Two genes expected to enhance drought and cold tolerance of plants were introduced in chickpea and a number of putative transgenic lines became available at the end of the first phase. Already available insect resistant transgenic technology has been transferred to Industry. Bioremediation techniques have been developed for the

restoration of pesticide -hexachlorcyclohexane (HCH) and para-nitrophenol (PNP)- contaminated soils. Biofertiliser based on mycorrhizal fungi and Plant growth promoting bacteria developed and through large number of field trials demonstrated their use for improvement soil quality, crop productivity and nutrient uptake. With regard to the improvement of fungal disease resistance in wheat, new sources of resistance genes against different fungal diseases have been successfully identified in wild relatives of wheat and incorporated in commercial varieties through molecular breeding. During Phase II, 60 scientists were involved in scientific long-term exchanges in Switzerland (total 80 months) with 50 publications, 6 patents and 3 Technology transfers.

Indo-Japan: DBT and AIST, Japan has initiated 8 major projects in the area of bioinformatics, cell engineering, glycoscience and biomarkers.

Patents Filed

- Regioselective acylation of nucleosides (No. 1885/DEL/2009) - Indo-Denmark Project
- Isolated antigenic polypeptides useful for detection and immunotherapy of *Aspergillosis* - Indo-German Project
- A novel single step process for simultaneous enrichment of methane from bio-gas and treatment of effluents for reduction of BOD and COD using microalgae - Indo-German Project.

Technology Developed

- Dark fermentation followed by Bio methanation in two stages. Different organic materials like sewage sludge; cane molasses etc can be converted to hydrogen. The spent medium of this process is found suitable for the bio methanation process. Scale up studies of the process is in progress - Indo-Denmark Project.
- A PCR based diagnostic kit for detection of *Listeria monocytogenes* from food and clinical samples (human and animal) has been developed and is ready for commercialization. ICAR Research Complex for Goa - Indo-German Project**.** A database is also available in public domain online in subtypes and molecular types of *Listeria species. http://icargoa.res.in/ilcd.*

- Novel Simple Batch Phase Medium for high level expression of recombinant proteins in *Pichia pastoris* - Indo-German Project.
- Novel one-step method for purification of insulin precursor - Indo-German Project.

2.6.0 Biotechnology for Societal Development

The main objectives of the programme has been to promote the use of biotechnological processes and tools for the benefit of entrepreneurs and create platform for employment generation among the target population and diffusion of proven and field-tested technologies through demonstration, training and extension activities.

The main areas are biofertilizer production, vermicomposting, honey production, poultry, fish production, artificial insemination, mushroom cultivation, goat rearing, silk Worm rearing, fruit plant nurseries, ambulatory clinics, sericulture and women health care. Till now, ~45000 rural, SC/ST and women population is benefited through implementation of these programmes.

An example of innovative societal programme is "Network Project on Prasad Kit". A total of 8 ongoing projects are supported for creating employment opportunities for women residing around major shrines in states like Uttrakhand, Himachal Pradesh, Kerala, Karnataka, Uttar Pradesh, Assam and Arunachal Pradesh. For example, in Ajmer, 270 women were trained on preparation of rose water and scented commodities from the post offered rose flowers. As a result of their engagement in the project the earning of each woman is estimated to be ~2200 Rs. per month. Programme has benefited ~3000 women.

Another excellent example of contribution of rural societal programme is running of mobile ambulatory clinics for the farmers of Vidarbha region in Maharashtra. The programme was implemented by Post Graduate Institute of Veterinary and Animal Sciences, Akola to promote Animal Husbandry, Poultry, Dairy and Piggery in suicide prone area of Vidarbha. The programme is in collaboration with State Animal Husbandry Department and Maharashtra livestock development board for dissemination of advanced animal health cover technology for the social economic upliftment of poor dairy farmers.

Rural Bioresource Complex: In total, 5 rural bioresource complex have been setup in different States such as Maharashtra, Karnataka, Orissa, Haryana, Uttrakhand. The objective of bioresource complex is to train farmers either to maximize the agriculture production or to maintain the health of life stock and also to enhance the earnings of the local population. The programmes are implemented in association with Krishi Vigyan Kendras. The complexes help in sustainable agriculture development through dissemination of scientific knowledge.

Artificial Insemination: Artificial insemination training programme was carried out is superior germplasm at farm-gate level to enhance productivity of various livestocks e.g. the progamme got attention of 80% of tribal farmers in selected villages and helped in increase of their income by 3000-4000 rupees. The project received and overwhelming response in tribal population of North-Eastern Region.

Other Programmes

- Through pro-active role towards implementation of new programmes, the programme could extend the benefit to around 1,20,000 beneficiaries through the programmes on various income and employment generation activities.
- Low cost poly house construction for raising nursery-planting material has been developed for cultivation of medicinal and aromatic plants.
- Bio village project implemented could benefit the farmers in biofertiliser production
- Preparation of liquid seaweed fertilizer and in raising *Salvadora persica* plants in the wasteland.
- Special programme has been implemented for earthquake victims in Gujarat covering activities viz. vermin compost, organic farming, livestock improvement, tissue culture and *Spirulina* production.
- Awareness and training programmes on vermi-biotechnology implemented in ten states benefited more than 15000 farmers.
- These programmes could lead to entrepreneurship development in the village areas and job creation for the benefit of SC/ST target population.

2.7.0 Autonomous Institutions

2.7.1 National Institute of Immunology, New Delhi

National Institute of Immunology (NII) was established in with the mandate of coordinating research of high caliber in understanding the defense mechanisms of the body and to facilitate the development of innovative technology such vaccines, antibody based purification technology etc. During the plan period, a wide range of crucial issues in biological sciences have been addressed successfully by the scientists and several new lead molecules are in pipeline.

Technological leads: The Institute has continued with the concept of 'end-to-end' research in the biosciences, linking the outcome of cutting-edge biological science at the bench with pursuit of the leads of potential utility thrown up by this research.

Three international patents and three Indian patents based on institutional research have been granted. Here is the list of technologies with proof of concept:

- Composition and process for preparation of biodegradable polymer membrane/scaffold
- Ig gene specific oligonucleotides and uses thereof
- Immuno-contraceptive vaccine for controlling fertility in female dogs
- Process for solubilization of recombinant proteins expressed as inclusion body
- Compositions useful for the treatment of diabetes and other chronic disorder. Pharmaceutical composition for therapeutic or prophylactic treatment of bacterial infections and associated diseases
- Mechanism-based inhibitors of transthyretin amyloidosis studies with biphenyl ethers and new structural templates
- Detection of pathogen using antigenic prohibitin peptide
- Inhibition of human immunodeficiency virus infection by *lagerstroemia speciosa*
- RECQL4/REQL4 Variant – P-53 complex for altered mitochondrial function in Rothmund-Thomson syndrome
- Human Chorionic Gonadotropin (HCG) based vaccine for prevention and treatment of cancer

- Method for the therapeutic correction of hemophilia a by transplanting bone marrow cells
- A Novel cell surface antigen for protein based Pneumococcal vaccine
- Composition useful for the treatment of inflammatory disease or disorders
- Benzothiophene carboxamide compounds, composition and applications thereof
- Recombinant non-toxic protein vaccine against *Clostridium perfringens* infection and epsilon toxin intoxications
- A rapid method for generating gene knock down model

Technology Transfer

In 2010, NII developed technology related to the slow release of the Insulin. In the laboratory, the insulin aggregates were prepared, which has the natural tendency to release slowly therefore, it provide a technology for sustained release of the Insulin and provide protection to Diabetes patients for a longer duration with regard to the control of blood sugar level. The technology is transferred to the Industry.

- Immuno-contraceptive vaccine for controlling fertility in female dogs transferred to Indian Immunologicals Limited, Hyderabad, India.
- Process for solubilization of recombinant proteins expressed as inclusion body transferred to Therapuces Biotech India Private Limited, Chennai, India.
- Recombinant E-toxin and DNA based vaccine *Clostridum perfringens* transferred to Indian Immunologicals Limited, Hyderabad, India.
- Manufacturing Porous Gelatin Matrix transferred to ExCel Matrix Biological Devices Pvt. Ltd., Hyderabad, India.
- Composition useful for treatment of diabetes & chronic disorder transferred to Extended Delivery Pharmaceuticals, U.S.A.
- Production of bio-therapeutic buffalo growth hormone transferred to Indian Immunologicals Limited, Hyderabad, India.
- Production of bio-therapeutic human growth hormone transferred to Indian Immunologicals Limited, Hyderabad, India.

Patents granted (National and International): The Institute has a thrust to shift its academic endeavors towards translational side so that appropriate technology can be developed and commercialized.

- Process for the formulation of a single dose vaccine (Indian Patent 199589)
- Immunomodulatory compound for treating cancer (Indian Patent 210537)
- A Process for isolation of a compound 1-(3,4- methylenedioxy-phenyl)-1E-tetradecene exhibiting immunomodulatory activity (Indian Patent 197071)
- A process for developing immunological memory from single point immunization (Indian Patent 217115)
- A process for solubilization and recovery of bioactive proteins from mast cells (Indian Patent 217145)
- A method for producing an immuno-contraceptive vaccine (Indian Patent 217322)
- A Process for improving the immunogenicity of a weak antigen (Indian Patent No. 220690)
- A vaccine for the development of immunological memory (Indian Patent No. 231109)
- Inhibition of SPAG9 expression with SIRNAS. (EPO 1861496)
- Composition useful for the treatment of diabetes. (South Africa 2009/02374)
- 2-Thixothiazolidin-4-one compounds and composition as antimicrobial and antimalarial agents targeting enoyl-aco reductase of type ii fatty acid synthesis pathway and other cell growth pathway. (Australia 2007201027 and Singapore 136059*)*
- Inhibition of SPAG9 expression with SIRNAS. Patent granted (Singapore 135339)
- A process for the preparation of pharmaceutical grade plasmid DNA for therapeutic application (India 246388)
- A method for preparing a recombinant adenovirus vaccine against Japanese Encephalitis Virus (JEV) infection and a vaccine thereof. Patent granted (India 243547 and Singapore 123824)

Human Resource Development: NII conducts a residential research programme for undergraduates culminating in a doctoral degree. The Institute is academically affiliated to the Jawaharlal Nehru University, New Delhi. In 11th Plan, 120 Ph.D students and 142 Research Associates were trained in various disciplines of Immunology.

2.7.2 National Centre for Cell Science, Pune

National Centre for Cell Sciences (NCCS) has a major objective on R&D in the area of cell biology, signal transduction, cancer biology, diabetes, biodiversity, infection and immunity, chromatin architecture and gene regulation, stem cells, proteomics, bioinformatics and regenerative biology. In NCCS, number of novel anti-HIV compounds has been identified that have potential use as microbicide formulations against HIV/AIDS. The signal transduction molecules seems to be critical players in pathways involved in cancer is another major area of work. The institute has focus on diseases where either particular cell type is damaged or lost such as diabetes, osteoporosis and neurodegenerative disorders and their treatment by using regenerative or stem cell biology approaches.

The repository at the NCCS is the only repository that houses human and animal cells in India. The repository serves to receive, identify, maintain, store, cultivate and supply animal and human cell lines and hybridomas. Recently, the repository has recognized as an International Depository Authority under the Budapest treaty. During 11^{th} plan, the repository has procured more than 2000 cell lines. Currently, the depository possess 1,50,000 accessions, which are highest in the world.

Support Services: The Experimental Animal Facility (EAF) supplies standardized laboratory animals such as rabbits, inbred mice and rats of high quality. In addition, the EAF also imparts training on animal handling and ethics of usage of animals for experimental purposes.

During the 11^{th} Plan, NCCS established Proteomics and Bioinformatics sections as core facilities of the institute and are managed by the newly recruited scientists with appropriate expertise. NCCS proteomics facility has two high-throughput mass spectrometers. In addition, the institute also added equipments required to support the mass spectrometer facilities. The bioinformatics facility at NCCS provides access to high-performance computer resources and programming expertise. The computer infrastructure serves scientists at NCCS to master the informatics needs of their research in a proficient and cost-effective manner.

Human Resource: The institution trained 83 Ph.D. students, 190 JRF's, 258 SRF's, 152 summer trainees and published 295 scientific publications in total during 11^{th} plan and many of them published in high impact factor peer reviewed journals.

Research Leads: NCCS is very active in directing its research in welfare of the Indian society and number of lead compounds has been identified and some of the notable compounds are as follows:

- Anti-malarial (Zinc-di-L-prolinate from muscle hydrolysates)
- Anti-HIV activity (anti-HIV-1 molecule active against HIV and other viral strains)
- Hypoglycemic activity (Extract of Fenugreek seeds; Technology is transferred to Indus Biotech Pvt. Ltd, Pune)
- Hypolipidemic activity (heat stable preparation from Fenugreek seeds extract; Technology is transferred to Indus Biotech Pvt. Ltd, Pune)

Technologies developed/tranferred with proof of concept

- Creation of artificial bone marrow like environments to modulate stem cell fate *in- vitro*.
- Protocol for preparing aqueous extract of Fenugreek Seeds possesses hypoglycemic activities, comparable to Insulin at cellular and molecular level.
- Protocol for thermostable extract preparation from a protein rich fraction of Fenugreek Seeds (TEFS) decreases accumulation of fat in adipocytes and upregulates LDL receptor in Liver. The potential applications are in the management of Dyslipidemia and Obesity. The laboratory scale know-how has been transferred to Indus Biotech Pvt. Ltd, Pune.

Technology Commercialized

- Cryopreservation of Hematopoietic Stem Cells (AFMC, Pune)
- Use of phosphono-derivatives of selected aliphatic acids for anti-malarial activity and Use of selected amino acid-zinc complexes as anti-malarials (Shreya Life Sciences, Mumbai)
- Protocol for preparation aqueous extract of Fenugreek seeds which possesses hypoglycaemic activities comparable to that of Insulin and protocol for thermostable extract preparation from a Protein Rich Fraction of Fenugreek Seeds (TEFS), which has a potential application in the management of Dyslipidemia and Obesity (Indus Biotech Pvt. Ltd., Pune).

Patents Filed (National and International)

- Method and composition for treating osteoporosis (Indian patent no. 0497DELNP2004; Japanese patent no. 2005-509587; European Union (EU) patent no. 03782781.3; PCT/IN03/00431)
- Use of selected amino acid-zinc complexes as anti-malarials (Chinese, CN: 200480034426.3; Zambia, No ZA: 2006/03215; India, IN: 1328DEL2004; PCT/IB04/02320; USA, US: 10/893531; Turkey, TR: 2006/03675)
- Synthesis of new fluconazole analogues containing 1, 2, 3-triazole moiety and having better antifungal spectrum (India, IPO/ 054/NF/2008)
- Extract preparation from a protein rich fraction of fenugreek Seeds (TEFS) that decreases accumulation of fat in adipocytes and up regulates LDL Receptor in liver, which has a potential application in the management of Dyslipidemia and Obesity (India, IPO/1521/DEL/2008; PCT/IN08/00631)
- Preparation of dialyzed aqueous extract of Fenugreek seeds, which induces hypoglycemia, mediated in part, via stimulation of insulin signaling (PCT/IN2006/000217)
- A novel protein expression system (India, 105/MUM/2005; US patent no.7,604,980 B2)
- Anti-tumor activity of AECHL-1, a novel triterpenoid isolated from Ailanthus excelsa in vitro and in vivo (PCT/IN08/000795; India, 2262/DEL/2008)
- Bile acid derived steroidal dimers with amphiphilic topology (US patent no. 20060003974)
- Pharmaceutical composition having Virucidal and spermicidal activity (US patent no. 20080300197)
- Tumor suppressor activation polypeptide and uses thereof (India, IPR/4.19.20/06083/2006; PCT NO7/000402)
- Preservation of Human Hematoppietic Stem/Progenitor Cells using Mannose-Binding Lectins of Plant Origin (PCT, IPR/4.4.16.1/05037/2005)
- Composition for differentiation of cells (India, IP02660)
- A composition for creating artificial bone marrow-like environment and uses thereof (PCT/IB 2005/002249)
- Novel dimeric phloroglucinol compounds as anti-HIV and microbicidal agents (India, 1055/DEL/2009)
- Novel anti-HIV compounds (India, 1556/DEL/2009)
- Novel alkylated derivatives of quinoline 2, 4-diol with anti-HIV activity (India, 1557/DEL/2009)

- Zinc amino acid complexes for inhibiting the replication of HIV-1 in vitro (US patent filed)

Patents Granted (National and International)

- A composition for creating an artificial bone-marrow like environment and use thereof. Patent granted in New Zealand (No. 560813)
- Method and composition for treating osteoporosis (US Patent No. 7,335,686)

The centre has obtained 7 international projects from the international agencies such as the Wellcome Trust, UK and other collaborative programmes like British council, Indo-UK, Indo-French and NIH, USA AIDS International Training & Research programme.

2.7.3 Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad

CDFD has a dual mandate of providing services in the areas of DNA profiling and diagnostic testing for genetic disorders and conducting research in various discipline of molecular biology. The total number of scientific laboratories in CDFD is 14 at present and there is one service group each for DNA fingerprinting and diagnostics. The service group is taking the DNA studies for law enforcement agencies. Sun Centre of Excellence in Medical Informatics also established.

Services: Every year hundreds of disputed cases are forwarded either by the Hon'ble apex court or the regional courts for settlements of the biological disputes like finding the true parents or forensic cases like finding out the person committed the crime based on the biological samples collected from the victim e.g. in rape cases. Approximately 900 referred cases of DNA fingerprinting undertaken. Diagnostic and genetic counseling services provided to 12,800 patients and families. 18,300 newborn babies screened for inherited disorders of metabolism.

Diagnostics: A medical genetics unit is being operated jointly with the Nizam's Institute of Medical Sciences (NIMS), Hyderabad. During the year, thousands of patients were examined and tested for genetic evaluation and counseling. The patients with chromosomal and monogenic disorders, mental retardation, congenital malformations, multiple malformation syndromes, haemolytic anaemia,

short stature, skeletal dysplasias, myopathies, neurodegenerative disorders, ataxia, hypogonadism, inborn errors of metabolism and familial disorders.

APEDA-CDFD centre: The Agricultural Products Export Development Authority (APEDA), Govt. of India has entrusted CDFD with the task of certifying the quality and authenticity of basmati rice and about 600 export samples were examined for certification during the year.

Scientific Work: Research is being pursued in several frontier areas including infectious diseases of human such TB, cancer biology, silkmoth genetics, genomics, computational biology and bioinformatics, structural and molecular biology, fundamental studies on transcription and signal transduction, and plant biology Publications in international peer-reviewed journals are approximately 200, with an average impact factor of 3.79. Nine international patent applications filed, including those of development of basmati rice-specific DNA markers, process and strains for Arginine overproduction, process and strains for overproduction of plasmid DNA, Novel markers for diagnosis of tuberculosis.

2.7.4 National Brain Research Centre (NBRC), Manesar, Haryana

NBRC is established to pursue basic research to understand function of brain in human health and carrying out interdisciplinary research in neuroscience. The centre has networked 45 centres across the country and has initiated several multi-institutional, inter-disciplinary projects to further understanding of human brain. A digital library, which is made available to the scientists all over the country through electronic network, has been created. The centre has established close collaboration with several institutions abroad, which is shared with the scientists at its networked centers.

The centre has received research grants from international agencies such as Welcome Trust, UK, National Institutes of Health (NIH) and the Third World Academy of Science (TWAS).Trained manpower development in the field of neurosciences is fulfilled through initiation of M.Sc. programme in neurosciences and Ph. D. programme.

NBRC scientists have identified several anti-inflammatory compounds with therapeutic potential in Japanese encephalitis (JE). One of the compounds

"Minocycline", a derivative of tetracycline is now approved by drug controller general of India for a clinical trial in JE cases.

NBRC has initiated the development of new technology platforms for neuroscience research. One of the platforms is based upon the use of the state of art two-photon imaging technology for recording the neuronal activities in a living brain and neurons in culture. The second platform involves the cutting has technology of differentiation of human skin fibroblast into stem cells in order to understand the mechanism of brain diseases and their potential therapeutic application.

A translational clinical research unit has been setup with an objective to connect basic research to patient care. The unit has been setup in Gurgaon civil hospital. DBT made collaboration with NBRC through its glue grant scheme to pursue the clinical research and strengthening the clinical care of patient.

Patents Filed (National & International)

- Minocycline as a therapy in Japanese Encephalitis (211/DEL/2007)
- *In-vivo* labeling of Mammalian cone photoreceptors by injection of fluorescently tagged peanut agglutinin (2136/DEL/2007)
- *Withania Somnifera* plant extract and method of preparation there of [1775/DEL/2008 (Ref.No. IPA3922); PCT /IN2009/000430 (Ref. No.FPA2490 to FPA2496)]
- A technique to enhance the clinical efficiency of radio therapy and radio surgery specific radiobiology (2494/DEL/2008)
- A ready automated screening, diagnosis and classification technique for Alzhemeir's contour of brain (2532/DEL/2008)
- Bicyclic triterpenoid iripallidal as a novel anti-alioma and anti-neoplastic therapy *in- vitro* (PCT/IN09/000336, 2915/DEL/2008)
- A medical image enhancement technique based on image transform resonance [(PCT/IN09/000096 [(Claiming Priority #1216/DEL/2008 dt. 16-05-2008)(File #07093(PCT)], US patent application #12/992,470]
- A non-invasive technique to produce the stress image of fluid flow (Stress Tensor) within non uniform objects, with application to map inaccessible fluid flows and obstructions in medical and industrial (2986/DEL/2010)

Technologies Developed with Proof of Concept

- Thermal Conduction Tensor Imaging and Energy Flow Mapping for planning hypothermia or hypothermic treatment
- Stress tensor imaging of blood & CSF Flow to detect obstructive risk, stenosis or atherogenosis
- Tissue-adapted Image enhancement for MRI and CT using Stochastic Resonance Imaging.
- Rapid automated radiological method to detect Alzheimer's disease and Mild Cognitive Impairment.
- Perturbative radiotherapy for higher clinical efficacy using imaging-activated planning.
- Imaging-enabled methodology for optimizing therapy in Ischemic Stroke.
- Quantifiers to assess track speech motor milestones in children between 4-10 years using digital signal processing.
- Development of a novel *in vitro* model of Alzheimer's disease - Neurosphere cultures from transgenic positive and transgenic negative fetal brains have been developed. All transgenic positive cultures express huAPPswe and huPS1dE9 transgenes.

2.7.5 National Institute of Plant Genome Research (NIPGR), New Delhi

The institute has been setup with a mandate to strengthen of the plant biotechnology research and related activities. The research programme aims to contribute to the understanding of the structure, expression and function of genes along with arrangement of genes on plant genomes and manipulation of plant genes / genomes to breed improved varieties of food and industrial crops for high yields and better quality products.

The institute has initiated several challenging genomics programme such as chickpea genomics, International Solanaceae Genome Project. The institute also very active in understanding molecular mechanism of abiotic and biotic stress on mainly economic plants such as rice, wheat, tomato, potato etc. The institute is directing its research to find a way to increase the nutritional value of crops, fruits and vegetable. A major research programme at NIPGR is aimed to understand the structure expression and function of genes in plant genomes and using this understanding in genetic improvement of crops for high yields and better quality. During the year, the institute has contributed 34 publications in high impact journals and four national / international patents have been filed / granted.

Patents Filed (National and International)

- Extra-cellular matrix localized Ferritin 1 for iron uptake, storage and stress tolerance (PCT/IN2007/000231)
- Novel stress responsive transcription factor involved in plant growth and development ant methods thereof (452007/0266459A1)
- Chimeric Construct of Mungbean Yellow Mosaic India Virus (MYMIV) and its uses thereof (IPA- 2571/Del/2007 and PCT/IN/2008/000819)
- Process for production of anti-diabetic compound in root culture of *Catharanthus roseus* (IPA-1649/DEL/2008)
- Polynucleotide sequence of fruit softening associated α-Mannosidase and its uses for enhancing fruit shelf life (IPA-1647/DEL/2008)
- Polynucleotide sequence of fruit softening associated β-D-*N*-acetyhexosaminidase and its uses for enhancing fruit shelf life (IPA-1648 DEL/2008)
- A method for tandem cropping for increased production of food grain crops (applied: 0033NF2008)
- Novel stress responsive transcription factor involved in plant growth and development and methods thereof (US Patent-7,674,957 B2)
- Polyucleotide sequence of fruit softening associated α-Mannosidase and its uses for enhancing fruit shelf life (PCT/IN/2009/000387)
- Polynucleotide sequence of fruit softening associated *β-D-N-acetyhexosaminidase* and its uses for enhancing fruit shelf life (PCT/IN/2009/000388)
- Nucleic acid sequences encoding glutathione S-transferases associated with abiotic stress responses in plants (IPA-2302/DEL/2009)

Patents Granted (National and International)

- Plant vaieties of *Catharanthus roseus* named "lli" (USAUnited States Patent PP18315 granted in 2007)
- Novel stress responsive transcription factor involved in plant growth and development and mentods thereof (US Patent-7,674,957 B2)

Technologies with Proof of Concept

- Genetically modified protein-rich potato (new generation potato) with enhanced nutritive value by tuber-specific expression of seed storage protein AmA1 (amaranth albumin 1)
- Genetically modified tomato (GM-tomato) with enhanced shelf-life by silencing N-glycan processing enzymes mannosidase (α-Man) and ß-D-N-acetylhexosaminidase (ß -Hex)
- Transgenic mustard with low seed glucosinolate
- Transgenic rice with improved abiotic stress tolerance
- Resources to screen virus resistance in tomato and soybean

Technologies Transferred

- The complete chickpea transcriptome has been generated and information transferred to the industry for the development of "Chickpea Expression Micrroarray" to make it commercially available.
- The allele-specific marker developed for dehydration tolerance in foxtail millet is being used for allele mining and marker-aided breeding of foxtail millet by Tamil Nadu Agricultural University (TNAU), Coimbatore, Tamil Nadu, India.

Human Resource: The institute is training 86 Ph.D. students, 186 JRF/SRF and 77 Research Associate. The Institute has plans to expand the overall scientific strength of the institution and to get the International recognition through its advanced scientific research in plant biology

2.7.6 Institute of Bioresource and Sustainable Development (IBSD), Imphal

IBSD is setup to utilize the untapped bioresources in the north east region of the country. The main focus of the institute is on medicinal, aromatic and horticultural plants, microbial, aquatic and insect bioresources. The ultimate goal is to develop the processes and products based on bioresources.

Regional centre of IBSD is established at Sikkim. The interim facility has became operational from a rented building to carry out research on the rich biodiversity and bioresources in the Sikkim Himalayan Region.

*Medicinal and Horticulture Plant Bioresources Programme:*The main research focus continued to be on plant collection, taxonomical identification, *in vitro* propagation protocol development, prospecting of bioactive compounds for therapeutic uses and essential oils from the important medicinal and horticultural plant bioresources of Indo-Burma region.

From the studies of collection and evaluation of the plant wealth of the Indian region of Indo-Burma biodiversity Hotspot with special reference to Manipur, 100 indigenous medicinal and horticultural plant bioresources has been identified.
The institute has characterized 450 unialgal cynobacterial isolates and deposited to the fresh water cynobacterial repository at the institute. A plant cold *Oroxylum indicum* which is traditionally used as an anticancer plant in Manipur has been shown to have anticancer activity.

Aquatic and Insect Resources: Low cost induced breeding and mass seed production of a few important indigenous fresh water fish species namely climbing perch, cat fish, Pengva were undertaken and seeds distributed to farmers for polyculture trials.

Bioresources Database Development Programme: A digitized database has been developed from secondary sources and categorized based on kingdom, phylum and common names. Currently ~6000 records are available on the database including ~1600 floral, 500 ethano-botanical plants, ~3300 faunal, ~110 fungal and ~500 fresh water cynobacterial resources. Furthermore, a data base on Zingiberaceae and bamboo was developed. Efforts are made for analysis of microbial data using online and offline bioinformatics tools.

Separate bioresources database development of family Zingiberaceae from primary sources with special reference to Manipur giving emphasis on morphological picturization, molecular characterization, bioactive compounds, and traditional knowledge on economic and therapeutic uses is in progress. At present, 41 records have been added.

Microbial database of N.E. region with special reference to Manipur compatible to "Inventory of Microbial Resources of India (MTCC)" has been designed for microbial data collected and identified by the institute and database development is in progress. At present, 80 cyanobacterial records have been added.

Technologies to Rural Entrepreneurs

- Micropropagation protocol of medicinal Zingiberales viz., *Curcuma longa Cv. Lakadong*, Hedychium coronarium, Kaempferia galanga, K. rotunda, Zingiber *cassumunar, Z. officinale* and *Z. zerumbet*
- Protocols for micropropogation and *in vitro* flowering of *Dendrobium transparens*.
- Breeding and seed production technology of *Osteobrama belangeri* (local: *Pengba*)
- Formulation of low cost concentrate fish feed from locally available biowastes/materials for *Osteobrama belangeri* (local: *Pengba*)
- "Spirogel" – a cyanobacterial bioproduct of IBSD, Imphal for piles.

Rural Technologies in the Pipeline

- Value added compost/vermicompost production from "*Phumdi*" (biowaste mostly available from Loktak and other lakes of Manipur) utilizing low cost locally available bamboo bins.
- Standardized "*Hawaizar*" (fermented soyabean product) production with value addition.
- Micropropagation protocol for commercial production of disease free quality planting material of *Citrus* sp – *C.macroptera cv.Kwatha, C.aurantifolia cv. Kachai and C.reticulata cv. Khasi*
- Novel nitrogen fixing bacteria from *Neptunia* sp. for wetland rice culture
- Bacterial biofungicide for control of soil borne *Rhizoctonia solani* in tomato and *Macrophomina phaseolina* in french bean.

Bioresource Park: The IBSD bioresource park of 39.9 acres was developed at Haraorou for maintaining the rich germplasm of bioresources of the region along with multiplication of quality planting material for supplying to potential entrepreneurs and farmers.

Technology in production: Production technology of fermented soybean developed using activated starter culture of *Bacillus subtilis* is under viability trial for commercialization.

Production technique for quality vermicomposed from loktak "phumdi" was demonstrated in the farmer's field near loktak lake.

2.7.7 Institute of Life Sciences, Bhubaneswar, Orissa

The main areas of research concentrate are: Molecular Biology of Aging; Infectious Diseases (Cholera, Malaria and Filariasis), Molecular Aspects of Cancer; Environmental Biotechnology; Stress Biology; and Molecular Microbiology (Plant Microbe Interaction).

Scientific Achievements: Important scientific achievements includes identification of apoptosis inducing factors resulting in imparting anti-fecundity immunity, studies on identification and characterization of age associated genes, biochemical characterization of recombinant rice catalase a protein, biochemical characterization of thermostable superoxide dismutase of plant origin, in depth screening of biomolecules from diverse microbes collected from different ecological niches, development of novel promoters through signal and multiple shuffling of promoter DNA, molecular mining of genes potentially involved in diseases transformation of chronic myeloid leukemia, identification and characterization of salt and stress tolerance genes, development of nanoparticle bio-conjugates for breast cancer therapy.

It has been shown that non-toxigenic strains of *V. cholerae* O1 devoid of the core CTX genetic element and isolated from Brazil, Guam and Florida belong to multiple clones, and were clonally related to the non-toxigenic strains isolated from India.

- The Plant Biotechnology group has shown that the submerged leaves of *Potamogeton nodosus* are basically endowed with a major function to generate H_2O_2, transport it to the upper leaf to act as a component in signaling cassette of gene expression; a phenomenon comparable to the development of systemic resistance by expression of PR genes in plants under pathogen attack. A significant light dependent expression of CAT-C gene in rice discernible in full-grown plant was suggested to be associated with photo-respiratory activity of the plant. It was also reported that there is no relationship between intracellular water status and proline accumulation in metal stressed plants.
- It has been demonstrated in *Mesorhizobium ciceri* that the gene encoding for an enzyme 3-phosphoglycerate dehydrogenase is the first enzyme which converts 3-phosphoglycerate to 3-phosphohydroxy pyruvate in the pathways for the synthesis of serine.

- Several thermophilic bacteria isolated from the hot springs situated in Orissa and Uttaranchal were identified as the new species of the genus *Bacillus, Thiomonas, Comamonas, Brevibacillus, Aneurinibacillus*.
- Institute is initiating work on leukemia to study effect of post translational modification on the proto oncogene EVI1, novel drug delivery systems and nanobiotecnology with an emphasis on their therapeutic applications in the field of cancer, and finer deletion analysis of Mirabilis Mosaic Virus full length transcript (MMV-Flt) promoter and completion of MMV-Flt promoter DNA shuffled library construction in suitable expression vector.
- Expansion of research buildings, construction of a modern animal house, green house and student hostel has also been initiated.

Patents Filed

- A high throughput method for detecting apoptosis of embryonic stages of metazoan helminthic parasites (1145/KOL/2009)
- A genetically modified recombinant rice plant Catalase-B, expressed in E. coli host that avoids light and temperature impairment (1180/KOL/2007)
- A method for preparing a water dispersible Glyceryl Mono-oleate Magnetic Nanoparticle (MNP) formulation and use of the same (779/KOL/2009)
- A novel water soluble Curcumin loaded nanoparticulate system for cancer therapy (164/KOL/2010)
- A process for preparing Curcumin encapsulated Chitosan alginate sponge useful for wound healing (1189/KOL/2010)
- Drug delivery formulation of Rapamycin in the form of polymeric nanoparticles for cancer therapy (8/KOL/2011)
- A water soluble polymeric drug formulation and a process for preparing the same (77/KOL/2011)
- Novel sub-genomic transcript promotor DNA fragments and a method for obtaining sub-genomic promotor DNA fragments from Figwort Mosaic Virus (741/KOL/09)
- A novel pararetrovirus based hybrid promotor DNA fragment (742/KOL/09)
- A novel method for simultaneous detection and discrimination of bacterial, fungal parasitic and viral infections of Eye and Central Nervous System (International Application No. PCT/IN2008/000334).

The institute trained 83 JRFs, 78 SRFs, 8 RAs and 9 PhDs during 2007-11.

2.7.8 Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram, Kerala

The centre is established to understand the infectious and chronic diseases and development of drug, molecular medicine for the respective diseases. Some achievements are:

- The centre has developed a successful cell based protocol for identification of compounds that target rare tumor stem cell like cells and identified diaminothiazoles has a potential anticancer agent.
- The whole genome sequencing of dengue virus establishes the involvement of a new recombinant lineage for the virus. *In-silico* docking studies have identified three inhibitors for Chickunguniya Virus. In cell line studies one of the molecule found to be a strong inhibitor of viral infection.
- RCGB developed DNA barcode for 20 amphibian species of Western Ghats and identified nineteen peptides with antimicrobial activity from frog skin.
- As a part of plant molecular biology programme, RGCB fingerprinted 114 collections of medicinal rice 'Njavara' and 107 traditional rice cultivars of Kerala.
- RGCB is collaborated with WHO and International Atomic Research Commission for the development of vaccine efficacy centre. The centre is meant for carrying out clinical trials of the approved vaccine for HPV.

Patents Filed (National and International)

- Assay for detection of transient intracellular Ca^{2+} (India, 1276/CHE/2007 dated 06-06-2008)
- Assay for detection of transient intracellular Ca^{2+} (Europe, USA, PCT/IN08/000370)
- Anti TB activity in the fruit extracts of *Aegle marmelos* (India, 2735/CHE/2010)
- Novel Anti-Microbial Peptides (Patent Application No. 2639/CHE/2011)
- Synthesis and anticancer activity of a novel Cu (II) coordination complex (India, 2007, No. IP05525/RB/SGM/sm)
- Primers for the microsatellite region of *Piper nigrum* (No. 3377/DEL/2005)
- Chalcone synthase (CHS) gene from Ginger (No:167/CHE/2007)

- A method of detection and quantification of nucleic acid and kit thereof (Patent application No.: 1489/CHE/2011)
- Novel porphyrin derivatives for Photo Dynamic Therapy (PDT): A process for the preparation and thereof and their use as PDT agents and fluorescence probes for biological applications (India, No. 0147NF2009)
- Extracts from a plant, processes for obtaining the extracts and fractions and applications thereof (No. 2743/CHE/2010)

Patents Granted (National and International)

- Primers for the microsatellite region of *Piper nigrum* (No. : 3377/DEL/2005)
- HDPA-PS resin - A novel, flexible, mechanically stable polymer support for Solid Phase Peptide Synthesis (India, 919/DEL/2003; USA, 10/625894)
- A new solid phase method for the preparation of diaminoketothiazoles [India, 239492 (2004) - Granted in 2010]
- A chemotherapeutic composition used in the treatment of cancer (No: 241416 Dated-28-07-2010 CBR No: 6405)
- A process for the preparation of herbal extract from the fern *Chelianthes farinose* (No.269/DEL/2006)
- A process to prepare a phytomedicine for Cancer with an extract of *Janakia arayalapatra* (No.: 949/DEL/2000)

Technologies with Proof of Concept

- A simple and novel assay method for detecting the activity of calcium channel
- Produced stable clones producing monoclonal antibody against human IgM
- Efficient method for identifying NUMTs
- Novel porphyrin derivatives for photodynamic therapy (PDT): A process for the preparation thereof and their uses as PDT agents and fluorescence probes for biological applications
- MCF-7 Bid Ds Red stable cell line for anticancer drug screening. The cell line has been deposited with ATCC for patent purpose. Can be transferred to industry, after patent procedures
- A technique for sensing intracellular calcium transients has been developed. This has been adapted to detect the activities of neuronal NMDA-type glutamate receptor and Capsiacin receptor. Not yet transferred to industry as patent application is pending.

- Resins developed for Solid Phase Peptide Synthesis. HDPA-PS – A new flexible, mechanically stable polymer support for solid phase peptide synthesis. (DBT) US Patent Granted [US 7,135,534 B2]
- A new class of 'solvent-like' dendrimer resins, Divinylbenzene crosslinked Polystyrene Gel for Combinatorial Solid Phase Organic Synthesis [DBT], Indian Patent [3343/DEL/2005]
- PS-A-PEG and DMA-A-PEG Gel dendrimer resins for Solid Phase Organic Synthesis [DBT], Indian Patent (3344/DEL/2005]
- Isolated and identified an anti-TB molecule (Ethyl *p*-methoxycinnamic acid) from *Kaempferia galanga*, a native medicinal plant. Patent procedures pending.

Technologies Transferred

- Developed a platform for simultaneous diagnosis of Dengue and Chikungunya. This has been transferred to HLL Life Care Limited (a Govt. of India PSU) and is now being further developed at a joint technology development incubator facility into a "point of care" diagnostic system
- A web resource, (available at www.tarmir.rgcb.res.in) has been developed for the integrated analysis of microRNA- mRNA expression profiling. This server allows users to input their list of differentially expressed miRNAs alongside mRNA expression levels to extract meaningful miRNA-target analysis results. Placed in public domain
- Characterized the Interferon-γ of an Asian Elephant (*Elephas maximus*) for the first time. The clones have been transferred to industry for production of an early diagnostic assay for Tuberculosis detection in captive elephants.

Training and Teaching

The Institute provided training to 135 Ph.D students, 55 JRF/SRF, 8 RAs. During 11th plan, 8 PhDs were awarded by the institute.
Further details may be seen in the website http://rgcb.res.in

2.7.9 Institute of Stem Cell Biology and Regenerative Medicine (InStem), Bangaluru, Karnataka

InStem has initiated its activities from an interim facility created at NCBS, Bangalore. The mandate of the institute is to develop tools and technologies

through stem cell and regenerative medicine research. The infrastructure facilities developed at InStem will be available to the investigators of both the institutions i.e. NCBS and InStem. NCBS and InStem also established a not for profit company called as Centre for Cellular and Molecular Platforms (C-CAMP). The centre is established with an objective to professionally manage the available advanced technology platforms, to trained scientist and to provide services.

Research Programme: InStem have signed a memorandum of understanding which allows close interaction of InStem with the Centre for Stem Cell Research (CSCR) at the Christian medical college, Vellore. A full GMP facility has been created for generation of Stem Cell for clinical trials. Mouse iPS stem cells have been generated for the first time in India in the centre. The centre is also involved in clinical trials using autologous adult stem cells to treat diseases like acute myocardial infraction etc. InStem initiated the research programme include:

(i) Development of new human stem cell models
(ii) Development of iPS cell lines from mouse and human
(iii) Creation of knockout mouse models in collaboration with RIKEN-CDB Japan
(iv) Development of two model organism for stem cell research
(v) Initiation of structure biology programme
(vi) Human mesenchymal stem cell research
(vii) Continued muscle stem cell research

The centre has a programme to support young scientist for long training in stem cell research under DBT overseas schemes.

Training Programme: InStem is organizing several workshops, seminars and symposiums for the exchange of scientific knowledge. The Ph.D. programme of the institute is intended to provide high level training in interdisciplinary interactive science.
Further details may be seen on the website http://inStem.res.in

2.7.10 Translational Health Science and Technology Institute (THSTI), Gurgaon, Haryana

THSTI is a new autonomous institution of DBT, which is established as a part of the health biotech science cluster situated in Faridabad, Haryana. THSTI is

designed to conduct innovative translational research and develop research collaborations across disciplines and professions to accelerate the development of products for the improvement of human health. Highlights of the present activities of THSTI are as follows:

Training and Education: THSTI is providing short term as well as long term training to the students, young investigators through DBT, ICMR, CSIR and UGC fellowships. 'Vaccine Research Innovation (VRI) Award' has been created for young investigators below the age of 35 years with an aim to identify and mentor young scientists with innovative ideas and desirous of pursuing research on vaccines and infectious diseases.

Scientific Meetings/Workshops: The THSTI organized an 'International Symposium on Protective Nutrients 2010' to review the current understanding of mechanisms of protective nutrients, the non-classical beneficial actions of traditional minerals available and the clinical evidence for their use. An another meeting on 'Understanding the Genomic Basis of Disease' was organized with an idea to initiate interaction between clinicians and biologists to discuss broad principles and designs of studies to understand the genomic basis of disease and responses to vaccines.

Research Programs: The research activities are currently focused in three broad areas, viz vaccine and infectious diseases, pediatric biology, biodesign and diagnostics development which is pursued by its three centres namely Vaccine & Infectious Disease Research Centre (VIDRC), Pediatric Biology centre (PBC) and Clinical Development Services Agency (CDSA).

Faculty Development Programme: A Faculty development agreement has been signed between DBT and Massachusetts Institute of Technology (MIT) to provide financial support at MIT for faculty development of Health Science Technology (HST) unit of THSTI. Two scientists have been selected so far as faculty of HST with a mission to establish and nurture educational and research programs that integrate engineering, science, medicine and business to advance human health and develop manpower to provide leadership in the area. The manpower development is on the model of the MIT- Harvard Health Science Technology institute which has provided exemplary scientists, innovators and entrepreneurs. The centre is interdisciplinary and integrating the engineering, biology, biomedicine, bioinformatics, chemistry and physics fields to run a Ph.D. and post-

doctoral programme for physicians and engineering graduates concurrently and develop technologies for heath care. Currently THSTI laboratories are functioning from an interim facility located in Gurgaon. The permanent campus is coming up in the Biotech Science Cluster at Faridabad (Haryana).

Patents Filed: A method and device for detection of anti-transglutaminase antibodies (No. 1133/DEL/2011)

2.7.11 National Institute of Biomedical Genomics (NIBMG), Kalyani, West Bengal

The Institute is a new autonomous institute, aiming to use genetics and genomics as tools to understand human health and disease. Emphasis is to translate the scientific knowledge acquired from these two domains especially to transform human health care. Currently, the institute is functioning from an interim facility at the Netaji Subhash TB Hospital, Kalyani. Recently the institute has taken possession of 30 acres of land at Kalyani, West Bengal.

International Cancer Genome Consortium (ICGC)-India Project: The ICGC which is under operation at NIBMG aims to generate comprehensive catalogues of genomic abnormalities in tumors from 50 different cancer types and subtypes across the globe and make the data available to the entire research community. The ICGC consortium comprises ten countries with focus on oral cancer. NIBMG and ACTREC, Tata Memorial Hospital, Mumbai are the research sites of the ICGC-India project. The project has a non-exclusive partnership with Roche, who have provided hardware worth over Rs. 20 crores.

Kalyani Cohort Study: Work has been initiated on a cohort of about 20,000 individuals drawn from villages in and around Kalyani, which will serve as a platform for prospective studies on genomics of health and disease under the aegis of the DBT, Govt. of West Bengal.

Malaria Evolution in South Asia: The primary objective of this project is to study the evolution of malaria in India. This project is funded by the U.S. National Institutes of Health (NIH) in collaboration with University of Washington, Seattle, USA; NIBMG, NIMR and Sphaera Pharma. NIBMG's role is to study the genomics of susceptibility to Malaria and also to serve as the data and statistical analysis centre for the entire project. In addition, a project has been undertaken to

study the genomics of myocardial infarction, in collaboration with Apollo Hospitals Group and IGIB, New Delhi.

2.7.12 Regional Centre for Biotechnology (RCB), Gurgaon, Haryana

RCB is a newly established institution of DBT under the auspices of UNESCO (Category II institute). Presently, it is functioning from an interim facility at Gurgaon, Haryana. The centre is proposed to cater to all countries in the region including India in carrying out biotechnology research of highest caliber and developing knowledge-rich highly skilled human resource. Association with UNESCO expands the opportunities to create world class education and research programmes and seeds of global cooperation.

Training & Education Programmes: Young Investigator Awards (RCB-YI) have been instituted with a career oriented scheme to identify and mentor outstanding young scientists (below the age of 35 years) with innovative ideas and desirous of pursuing research at the interface of disciplines in biotechnology. Research fellowships have been instituted for the students who have completed MSc/MBBS/B Tech/MVSc or equivalent in any discipline that is relevant for innovative multi-disciplinary biotechnology research for registration for the award of Ph D.

Research Programmes: The studies are aimed at understanding the specificity of antigen recognition using structural, immunological and thermodynamic approaches that may lead towards designing and development of new generation of vaccines. Structural issues pertaining food allergies are also being addressed. Other research interest focuses on the elucidation of molecular mechanisms of mitotic regulation to understand the basis of asymmetric stem cell division leading to differentiation and cancer. RCB has strong interests to develop targeted drug/gene delivery vehicles and to explore the cellular and molecular barriers for *in-vivo* delivery applications. Various other research projects relate to the synthesis of biologically active organic/inorganic nanomaterials especially polymers, nanoparticles, carbon nanotubes, liposomes for bio-sensing, cellular imaging, drug delivery, and gene therapy applications to target different signaling pathways responsible for cancer and other diseases.

The executive director has assumed the charge of the centre and selection process for faculty & administrative staff is being pursued. While interim facility has been

set up at Gurgaon, the permanent campus of the centre is coming up in the Biotech Science Cluster being set up at Faridabad, Haryana.

2.7.13 National Agri-Food Biotechnology Institute (NABI), Mohali, Punjab

The institute is a part of Agri-Food Biotechnology cluster being set up at the Knowledge City in Mohali. NABI will be a centre of excellence in translational science and product development, working towards development of innovative food processes and products keeping in view the current and future markets. It will also be involved in training human resource in food science & technology as well as nutritional science. NABI became functional since February, 2010 and is presently working from an interim facility at Mohali, where few facilities have been developed and initiated programmes in the thematic areas like Gene discovery in wheat for improvement of nutritional and processing quality, Molecular studies on seed development for designing seedless fruits, Identification of long distance mobile factors responsible for plant growth and development, using *Arabidopsis thaliana* as a model, and Genome-wide association related data mining in *Arabidopsis*.

NABI has signed three MoUs with (i) National Research Council-Plant Biotechnology Institute, Saskatoon, (ii) University of Saskatchewan and (iii) Genome Prairie, Saskatoon for developing collaborative programmes in genomics, bioinformatics and food processing, involving the exchange of faculty and scholars.

Research and Development

- Functional genomics for nutritional and processing quality in food grains
- Accelerated breeding for processing quality in Wheat
- Genetic transformation of Banana for quality improvement
- Quality and post-harvest stability of farm produce
- Developmental biology (seed development & signal transduction) for crop Improvement
- Development of genomic resources for grains and horticulture crops

Currently NABI has 10 JRFs/Ph.D., 1 SRF and 1 Research Associate as trainees. To upgrade their knowledge, the NABI scientists visited many parts of the world and attended seminars, workshops and conferences.

2.7.14 National Institute of Animal Biotechnology (NIAB), Hyderabad, Andhra Pradesh

DBT established NIAB with the approval of the Government of India. A temporary office of the institute has been established in the campus of the University of Hyderabad, Hyderabad and an officer on special duty has been appointed. The institute will focus on translational science and capacity building in the area of Animal Biotechnology. The vision is to enhance knowledge on livestock production and health and translate the knowledge for developing a globally competitive livestock industry through innovative science and technology development.

2.8.0 Bio-clusters

2.8.1 Biotech Science Cluster, Faridabad, Haryana

The Biotech Science Cluster at Faridabad was envisioned in the Biotechnology Strategy document released by DBT in November 2007. Since then wide-ranging consultations have been held with Indian and overseas experts on the concept, design and operation of the cluster. The signing of the Memorandum of Understanding (MoU) is the culmination of these consultations and represents an important milestone for India as this is the first time such a major cluster is being established in the country. Few partner institutions of the cluster i.e. Regional Centre for Biotechnology (RCB) and Translational Health Science and Technology Institute (THSTI) are already functioning from their interim labs facilities commissioned earlier this year at Gurgaon. Other off campus partners includes Stanford University, USA; AIIMS and IIT, Delhi.

The Biotech Science Cluster at Faridabad promoted by DBT took a major step forward when the heads of four founding institutions namely NII, RCB, THSTI and NIPGR came together to sign a MoU to create a new legal entity called the Cluster Board. The Cluster Board is an enabling mechanism by which these institutions, while maintaining their own autonomy of governance, can address not only common infrastructural and cluster-related administrative issues but also synergize their complementary intellectual strengths and facilities to create a seamless campus. It is hoped that such a campus will promote collegiality and encourage researchers from different backgrounds and disciplines to work

together. Inter-institutional cooperation and collaboration will be the norm rather than an exception within the cluster. The Cluster Board will also be the means for the member institutions to pool their resources to develop common facilities in strategic directions for the benefit of the community. One of the first tasks of the Cluster Board will be to coordinate the development of this new campus, build facilities of the respective founding members and ensure that a functional campus management is in place.

2.8.2 Bangalore Bio-cluster

The Central and the State Governments have joined hands to set up the Bangalore Bio-cluster at 20 acre site on the GKVK campus of the University of Agricultural Sciences, Bangalore. The cluster is comprised of the National Centre for Biological Sciences (NCBS), the Institute for Stem Cell Science and Regenerative Medicine (InStem) and the Centre for Cellular and Molecular Platforms (C-CAMP). The three institutions are interacting and sharing knowledge and resources on a regular basis to enrich their research programmes. The focus of InStem is on translational and clinical stem cell research by building on the existing links with the CMC-DBT Centre for Stem Cell Research at Christian Medical College, Vellore. On the other hand, C-CAMP is acting as the provider and developer of technology and enabler of scientific activity and entrepreneurship. This is an institutional model for cutting edge scientific research aimed at utilizing various Centres of Excellence for developing a new hub.

2.8.3 Agri-Food Biotechnology Cluster, Mohali, Punjab

Agri food biotechnology cluster is being set up at the Knowledge City of Mohali, which would promote translational research in the area of Agri-Food processing and to foster entrepreneurship. The cluster comprise of National Agri-Food Biotechnology Institute (NABI), Bio-Processing Unit (BPU) and a Biotech Park. The Agri-Food Biotechnology Cluster is a unique facility with an inter-disciplinary approach reinforced by the synergy and location of various institutions and forward linkages with prospective entrepreneurship. It will link biotechnology of crops with that of food and nutrition, while facilitating bench to market progression of products and services and act as a catalyst of innovation in state of Punjab and adjoining region.

NABI will be a centre of excellence in translational science and product development, working towards development of innovative food processes and products keeping in view the current and future markets. It will also be involved in training human resource in food science & technology as well as nutritional science. NABI became functional since February, 2010 and is presently working from interim facility at Mohali Biotech Park.

The Bio-Processing Unit (BPU) shall link the R&D systems with a production facility to serve as an incubator for start-ups. It will facilitate scale-up and process optimization of new technologies developed by NABI (or acquired through licensing from other sources) as well as provide industry linked services including quality testing & certification. Currently the matter pertaining to setting up of BPU is being looked after by NABI. The Biotech Park is being designed to house a number of start-up companies along with common amenities in various thematic areas of biotechnology including Agri-Food biotechnology. This has been registered as a Section 25 Company. DBT along with Government of Punjab has already appointed a promoter for the Mohali Biotech Park.

2.9.0 I&M Sector – Assistance for Technology Incubators, Pilot Projects and Biotechnology Parks

2.9.1 Biotechnology parks

Department has supported Biotechnology Park, Lucknow including five Biotechnology Incubation Centres one each at Hyderabad, Bangalore, Kochi, Chandigarh and Solan.

Hyderabad: Incubator provides common instrumentation facilities and bio-reactors, bio-processing instrumentation, down-stream processing & analytical instruments.

Bangalore: Provide common instrumentation facilities and is under construction.

Trivandrum: Provides bio-processing & scale up facility, micro-propagation facility, plant extraction facility, analytical laboratory facility and utility support & design engineering and project supervision.

Chandigarh centre would provide extraction facility for medicinal and aromatic plants and agro/food testing and certification facility.

Solan centre would provide tissue culture hardening facilities, cultivation of temperate aromatic plants using biotechnological interventions, pilot cultivation of selected high value medicinal plants and post-harvest management of bio-fresh project and technology aided food processing.

Biotechnology Park, Lucknow: The Park is set up on 8 acres of land provided by the Department of Science & Technology, Government of Uttar Pradesh. The thrust areas identified in the initial stage are Health Care, Agriculture, Environment, Industrial Application and Energy.

Industrial units like M/s. Shantha Biotechnics Ltd, Hyderabad; M/s. Green Park Bioherbs Industries, Delhi; STPI, Lucknow and M/s. M.S. Biological Pvt. Ltd., Lucknow has been allotted space and plots on lease agreement. Letter of Intent for plots on lease is received from M/s. Magna Marketing, Kanpur; M/s. Press India, Lucknow; M/s. Kanha Biotech, Lucknow; M/s. Rako Biotech, Lucknow and M/s. Kanjaria Associate, Lucknow.

2.9.2 Public Private Partnerships

A. Small Business Innovation Research Initiative (SBIRI)

Department has launched "Small Business Innovation Research Initiative (SBIRI)" to boost public-private-partnership effort in the country. The SBIRI aims to strengthen those existing private industrial units, whose product development is based on in-house innovative R&D; create opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs; stimulate technological innovation; use private industries as a source of innovation and enhancing greater public-private partnerships and increase product commercialization in public-private sector derived from Government funded R&D. The SBIRI scheme operates in two phases viz. SBIRI Phase – I: The funding in this stage is being provided for highly innovative, early stage, pre-proof-of-concept research. Preference is given to proposals that address important national needs and SBIRI Phase – II: The funding in this stage is being provided for late development and commercialization of innovative research leads. Projects wherein proof-of-concept is already established and available with R&D institution or R&D unit of the industry are also eligible for direct phase-II support. The key objectives of the scheme are to provide support for early stage, pre-proof-of-concept research in biotechnology by industry, to support late stage

development and commercialization of new indigenous technologies particularly those related to societal needs in the healthcare, food and nutrition, agriculture and other sectors, to nurture and mentor innovative and emerging technologies/entrepreneurs, to assist new enterprises, to forge appropriate linkages with academia and government.

A new scheme on 'Encouraging development and commercialization of inventions and innovations: A new impetus' is recently approved by the Cabinet. Efforts are underway for formulating a network programme and guidelines for strengthening the public-private partnership. Road shows have been organized throughout the country to popularize the SBIRI scheme.

The agreement has been executed by the department with Biotech Consortia India Ltd., New Delhi who is acting as the Special Purpose Vehicle (SPV) / Fund Managers for smooth running of the scheme.

Technical Screening committee (TSC) and the Apex Committee evaluates the SBIRI proposals. Site visits are conducted to industries to assess their suitability for funding. A list of projects funded so far is available on the website www.sbiri.nic.in/

Achievements

- Microelectromechanical System (MEMS) based sensors are developed for the diagnosis of Acute Kidney Injury (AKI) using a biomarker 'Neutrophil Gelatinase Associated Lipocalin'.
- Diagnostic kits for the differential detection of malarial parasites and screening of pulmonary and extra-pulmonary TB have been developed.
- Recombinant Uricase for the prevention and treatment of tumor lysis syndrome developed.
- Nanocarbon porous matrix Drug Eluting Stent (DES) was developed and is under clinical evaluation.
- Nanotechnology based peptide inhibitors for the treatment of osteoporosis has been developed.
- A novel cell-interactive ECM analogue biomaterial platform for cell biology research and regenerative medicine applications has been developed.
- Biochemicals form crustacean exoskeleton has been isolated and utilized in the manufacture of products such as 'Pelrich Plus' (organic fertilizer) and 'Soil Next' (organic planting media).

- A new product 'Palkofeed Aqua SSF' with phytase as one of the major component is being commercialized as feed for poultry, pig and aquaculture.
- A recombinant 'Follicle Stimulating Hormone (r-FSH) has been developed and commercialized under the brand name 'FOLIGRAF'.
- A silk protein blend film was developed for burn wound management.
- A technology to replace polyclonal anti-snake venom serum with monoclonal cocktail has been developed.
- Development of nitrifying bioreactor technology for organic recirculation of Prawn seed production
- An auto dispenser developed indigenously for generic bench top uses and for specific diagnostic applications

B. Biotechnology Industry Partnership Program (BIPP)

In order to support discovery and innovation in Biotech industry covering all sectors of agriculture, human, health and environment, Biotechnology Industry Partnership Programme (BIPP) was approved in 2008 as advanced technology scheme. It is a government partnership programme with the industries on a cost sharing basis for path-breaking research in frontier futuristic technology areas, which provides a government contribution of 30-50% to the industry. The scheme is only for high risk futuristic transformational technology/process development, mainly for viability gap funding with a focus on technologies having economic potential and those which can make Indian industry globally competitive. The uniqueness of this scheme is that it is for "Break through research" which enables product and process/technology development leading to commercialization with IP ownership rights resting with the company.

Processes have been standardized for submission of project proposal, evaluation and release of funds. The complete BIPP programme is online and can be accessed on the website www.birapdbt.nic.in. A web based application has been developed which helps in maintaining confidentiality as well as transparency and efficiency.

BIPP achievements

- Production of a cost effective VLP-1 HPV vaccine using *Pichia pastories* and/or *E.coli* is underway.
- A formulation for H1N1 pandemic influenza vaccine is being developed to conduct preclinical toxicology and Phase I/IIa clinical trial.
- Development of "Mucosal Vaccine for HPV is under process

- Identification and development of promiscuous Anticancer Compounds from Microorganisms having anticancer activities against cervical, bladder, colon, breast and other cancers, as well as HIV/AIDS.
- A new molecule, TRC4186 is under clinical trial for the alternative treatments of Heart Failure Complicated with Diabetes Mellitus
- Development of a process for enhanced Ethanol yield from Molasses is under active research studies
- Development of "Herbicide & Stress tolerant" transgenic onion. Validation for its efficacy to sustain the high concentration of herbicide is in progress in tobacco.

C. Biotechnology Industry Research & Development Assistance Programme (BIRAP)

In order to promote innovation, pre-proof-of-concept research, accelerated technology and product development in biotechnology related to agriculture, human health, and environment, etc., it was proposed to establish Biotechnology Industry Research Assistance Council (BIRAC**)** as an autonomous, dynamic, flexible and futuristic organization. BIRAC will provide technical, financial and other required innovation services to promote the growth of biotech industry, particularly, start-ups and Small and Medium Enterprises to meet wider social needs with special emphasis on BIPP. In order to kick start activities of BIRAC, a pilot BIRAP has been established in partnership with Association of Biotechnology Lead Enterprises (ABLE) and under pilot BIRAP the following activities have been launched or conceptualized and finalized for launch under BIRAC (Figure 6.2). The BIRAC has already got the Cabinet node.

BIRAP has been organizing and facilitating series of discussions on possibilities of technology transfer and acquisition e.g. In affordable healthcare sector, BIRAP is engaged in technology transfer discussions for implants and devices useful for neonatal care and biofortification of banana with University of Queensland, Australia.

- Technology transfer and acquisition
- *Stanford-India Biodesign (SIB) Programme:* BIRAP is a strategic partner of the Bio-design Programme of DBT-Stanford University, USA; in providing necessary facilitation for the validation and commercialization activities for low cost new medical technologies for the Indian consumers.

- *Secondary Agriculture:* A pilot study on secondary agriculture for Punjab has been started. Industry proposals have been invited and this activity is being driven by BIRAP.
- *IP facilitation and management*: BIRAP is currently doing a detailed IP analysis for all its Industry related R&D programmes. BIRAP-BCIL IP Cell has been created and is being strengthened to provide facilities to the academia groups and industry on FTO searches for industry projects, Landscape analysis and technology mapping advisory services on issues like criteria for patentability and IP strategy.
- *Policy & Analysis Cell:* It facilitates evaluation of proposals and decision making for support to the biotech industry. The Cell has acquired relevant reports and detailed reviews on some priority areas for analysis. Skilled personnel prepare detailed search and analytical reports for specific industry areas. A database of resource persons and experts has also been developed.
- *Legal and Contracts Cell*: BIRAP concerned with Industry related research, technology transfer and licensing, therefore, legal, IP and technology transfer contracts and agreements are of special importance. The cell provides the necessary services to the industries as per their needs.
- BIRAP is preparing a contract research scheme for agri biotech academia-industry interface to take the academic research leads forward for validation by the industry. BIRAP is also in consultation with ICMR, DST, CSIR, ICAR and other Institutes and Universities for preparing the 'Guidelines for Safe and effective handling of nanomaterials.
- *Capacity Building Programmes*: BIRAP is organizing workshops and seminars on biotech licensing, how to write an effective grant proposal and training of trainers and I P management.

2.10 Programme for North Eastern states

Special efforts have been made through several visits and meetings with universities/ governments and institutions to fund programmes that have potential to impact on life science education, agriculture, animal health and bioresource utilization through biotechnologies and bioindustrial development. These include setting up Bioresources Development Centre, Shillong; Biotechnology Incubator at IIT, Gauhati; Programme Support to Clinical Research Network; Network on Management of Classical Swine Fever in Piggeries and star colleges for

strengthening life science and biotechnology education and training at undergraduate level.

2.11.0 Summary of Assessment of 11th Plan

- During the 11th plan (2007-2011) it appears that the total number of projects would exceed about 3000. Thus, a detailed assessment of the first four years of the plan i.e. 2007-2011 was considered for some trends and thrust assessment. So far, about 2410 projects out of 5750 projects received have been implemented under competitive grant in various schemes with success rate varying year to year in range of 25-30 per cent. Most of the projects (1715) were below Rs.50 lakhs with 3 year project duration followed by projects with cost upto one crore (538). More than 160 projects are multi-institutional network projects or large centers/ facilities with investment up to Rs 5 crores and above (**Figure-1**).

- Among the areas 26% (535) of the projects were in the area medical biotechnology covering vaccines, diagnostics, human genetics and host pathogen interaction followed by 22% in agriculture and allied areas of biotechnology; basic research (20%); bioresources and bioprospecting (19%) and 12% in capacity building (facilities / international collaboration/bioinformatics and HRD). In terms of expenditure, trends were similar. Translational R&D in sectoral areas was evident as priority in 11th plan while adequate importance was given to basic and emerging areas research **(Figure-1)**.
- Estimates of 2007-2011 also revealed that Universities received 50% of projects/funds followed by research institutions and public private partnerships **(Figure-2).**
- In order to assess the performance of extramural research projects, revelent information was collected across projects and institutions. It was recorded that a total of 1104 publications having impact factor 5 and above; 312 patents (national/international) have been filed and 110 patents have been granted; 105 technologies developed, 21 technologies transferred to industry and 5 were commercialized. Health care technologies dominated in technology developed compared to agriculture.

2.12.0 Major unfinished agenda for 11th Five Year Plan for 12th plan directions

Since majority of the programme proposed during the 11th Plan have taken off and necessary approval have been obtained, the Department in its analysis internally found few major areas of unfinished agenda:

- There is a need for technological leap forward in improving agriculture productivity particularly under unfavourable climatic situations like drought and climate change. A major effort would not be launched due to lack of collaborative efforts among agencies dealing with agriculture research. Globally, agriculture and climate change research is also emerging area and several developments and investments have to be carefully watched for initiating major programmes.
- Promotion of private sector R&D in agriculture biotechnology has been a challenging task. The existing PPP programmes across departments also registered very low number of applications for availing the schemes compared to other areas like medical biotechnology. Special efforts are needed to address the issues in a long term sustainable basis than the current approach.
- In case of healthcare research and technology development, there is slow birth of start-up companies. The experience gained in PPP programmes of DBT reflect the need for specialized more innovative schemes and modalities of the support for at least for another five year plan period in future, although DBT has proposed to add to its programmes the Ignition Grants Scheme for scientists entrepreneurs and fellowships for industry scientists.
- A technology development and diffusion policy of DBT along with strengthening of technology management capacity in terms of manpower and infrastructure needs to be created.

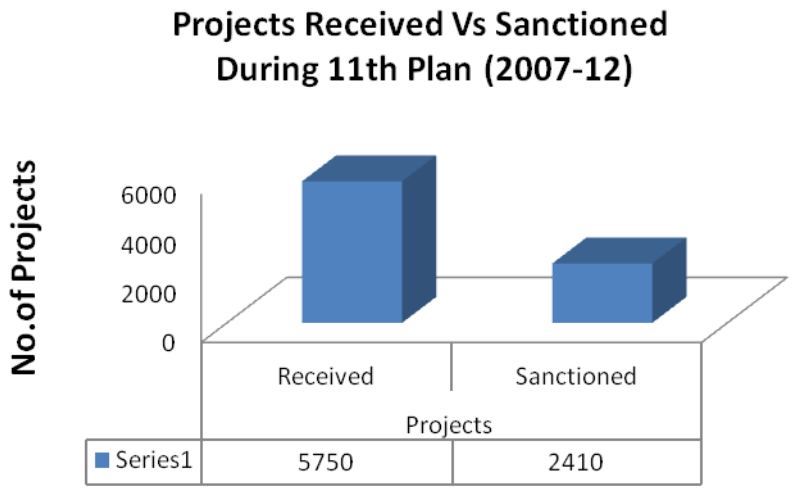
Path ahead

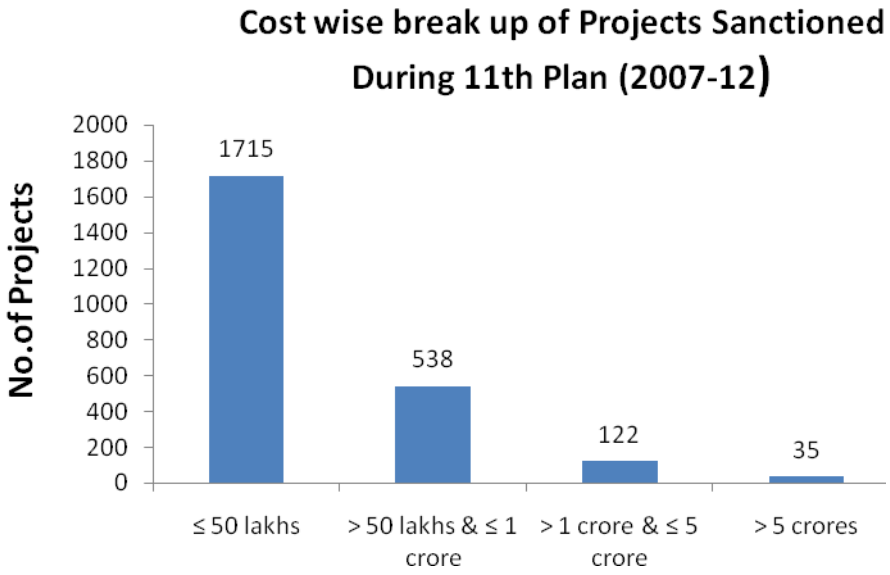
The approach towards the 11th plan was to create tools and technologies that address the problems of the largest section of the society, provide products and services at affordable prices and make India globally competitive in the emerging bio-economy. Developing a strong biotechnology industry and technology diffusion capacity is critical to fulfill this vision. The success of this vision over

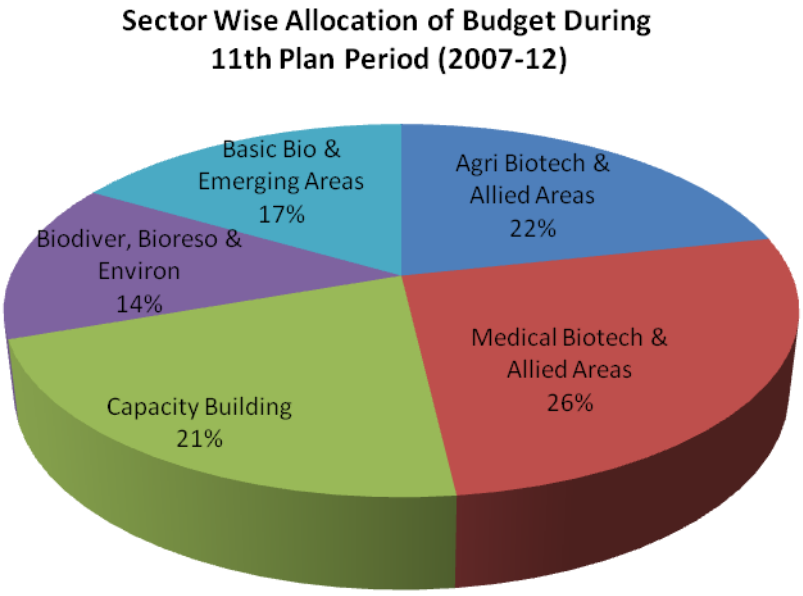
the next decade will be reflected through (i) greater enrolment of students in life sciences; (ii) increase in the number of persons with higher levels of education and skill in life sciences and biotechnology; (iii) greater contribution of research to economic and social development (iv) increased contribution of university system to basic life science as well as translational biotechnology research (v) strong international partnerships linked to national goals (vi) increased number of new companies and increase in SME's engaged in R&D, and finally (vii) the Indian biotech industry generating revenue to the tune of at least US $ 10 billion annually and creating substantially more jobs by 2020.

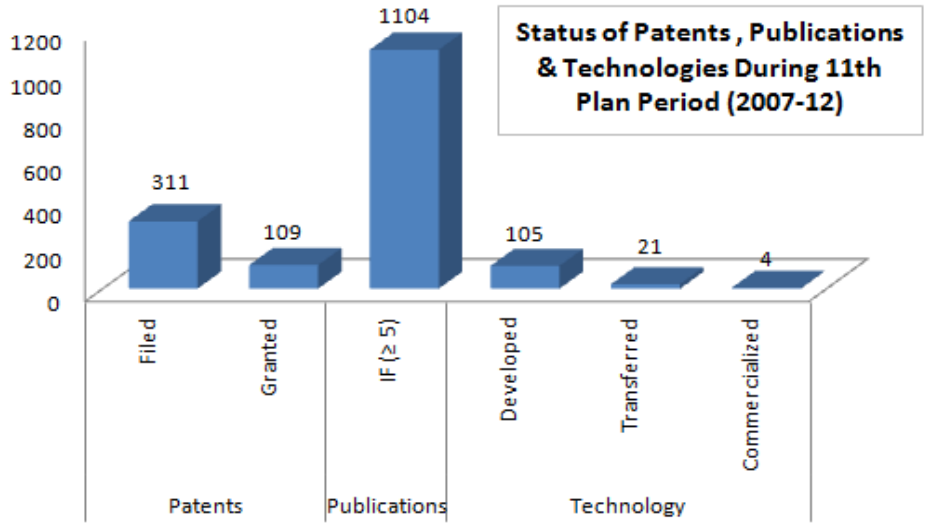
The success of 11th plan /National Biotech Strategy has been so far, in terms of implementation of all the major programmes or their necessary approvals. Results are already coming up in several programmes in terms of technology development, technology transfer, enrolment of students, industrial training and absorption, promotion of excellence and innovation through establishment of centres of excellence, industry-academia technology platform, and establishment of BIRAC and implementation of BIPP and SBIRI programmes. Some other programmes which are being implemented in final year of the 11th plan in addition to those proposed originally would augment the efforts. However, for a long-term effect, the foundation prepared in the 11th plan should be strengthened with innovative schemes, research resources and smart governance and management mechanisms for future mission.

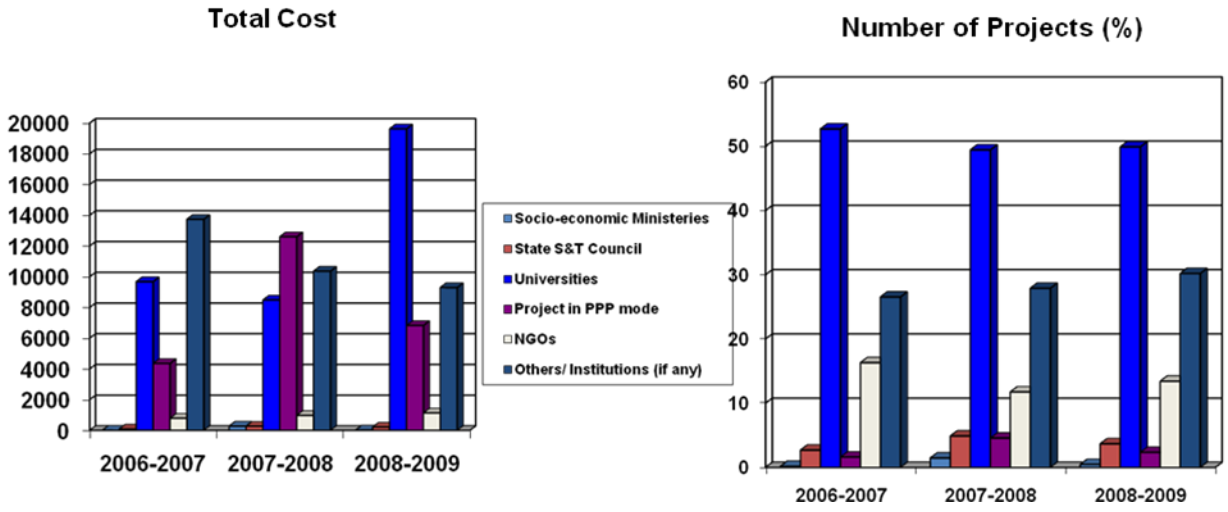
Future of biotechnology depends on how the investments and schemes will be implemented to create a large scale life science entrepreneurship. Loans, grants, human resource generation with skill from discovery to markets, contract research, incubation, start up support, hand holding of SMEs, filling the gaps in entrepreneurship capacities of universities/institutions, involvement of IITs, engineering and medical colleges are all important.


Projects Received Vs Sanctioned
During 11th Plan (2007-12)
No.of Projects
6000
4000
2000
0
Received
Sanctioned
Projects
Series1
5750
2410


Cost wise break up of Projects Sanctioned
During 11th Plan (2007-12)
No.of Projects
2000
1800
1600
1400
1200
1000
800
600
400
200
0
1715
538
122
35
≤ 50 lakhs
> 50 lakhs & ≤ 1 crore
> 1 crore & ≤ 5 crore
> 5 crores


Sector Wise Allocation of Budget During 11th Plan Period (2007-12)
Basic Bio & Emerging Areas 17%
Agri Biotech & Allied Areas 22%
Biodiver, Bioreso & Environ 14%
Medical Biotech & Allied Areas 26%
Capacity Building 21%


Status of Patents , Publications & Technologies During 11th Plan Period (2007-12)
1200
1000
800
600
400
200
0
311
109
1104
105
21
4
Filed
Granted
IF (≥ 5)
Developed
Transferred
Commercialized
Patents
Publications
Technology



Extramural Funding-distribution pattern across agencies (in Lakhs)

3.0 RECOMMENDATIONS OF THE WORKING GROUP ON BIOTECHNOLOGY

The Working Group on Biotechnology constituted by the Planning Commission deliberated on the following important priority areas for 12th Plan programmes and projects:

- Human Resources from discovery to market: Gaps and emerging needs
- Research resources and facilities for academia and industry
- Basic sciences and emerging areas for global competency
- Biotech industry development and future trends
- Technology acquisition, transfer and licensing for product development
- Innovation and Governance: New Models, Mechanism and Alliances

Besides identifying priorities of the Department for the Twelfth Five Year Plan, the Planning Commission mandated the working group to:

- Suggest measures including policy initiatives for enabling India to emerge as a major global technological power by 2025
- Suggest plan programmes for the Department adopting a ZBB approach and keeping in view the priorities and goals for the Twelfth Five Year Plan as well as the agenda for the Decade of Innovations during 2010-20
- Define deliverables as well as goals for the Department for the Twelfth Five Year Plan period as well as Annual Plans, both in terms of tangible and non-tangible outputs and formulate guidelines for deployment of resources for relating inputs to the specified goals

A Five Year Plan has to be embedded in a medium and long term strategy for development of a sector. We additionally held a national concentration on "Vision and Strategy for Biotechnology by 2025". This Biotechnology Strategy II is a continuum of the Biotechnology Strategy I. This consultation examined possible barriers in each sector to achieving set goals and how to overcome these including needs for new mechanisms and institutional framework for action. Within this analytical framework, an effort is made to carve out the implementable programmes and projects for 12th Plan. The DBT constituted expert committees in the following 12 niche areas:

- Basic, Disciplinary and Inter-disciplinary Sciences
- Biotechnology for Agriculture & Food Productivity
- Biotechnology for Human health and Wellbeing
- Biotechnology for Animal health and Productivity

- Value- added Biomass & Products from Natural Resources
- Technologies for Clean Energy and Environment
- Food and Nutritional Security
- Education and Training
- Biotechnology for Social Development
- Industrial Biotechnology
- Intellectual Property Landscaping, Technology transfer, Incubators, Entrepreneurship, SME support systems
- Bioinformatics, Computational and Systems Biology

The above exercise involved 176 experts in 12 different niche areas and the inputs collected from these experts groups shall be utilized to finalize **"Biotechnology Development Strategy II"** addressing both medium and long term policy initiatives and programmes & projects in the niche areas to make India globally competitive during the period 2012-25.

In addition to above inputs, the Directors of the DBT autonomous institutions were requested to conduct regional meetings at their institutions for the purpose of involving all the known experts in and around their State/City from Industry, National Institutions and Universities. The mandate given was to review the current status and collect various ideas and proposals for 12th Plan regionally and nationally. The areas of interest included development of Life science and Biotechnology in terms of current and emerging area of research and how to steadily move to higher frontiers in the world; reforms and redesign of education, bio-industrial development, regulation, infrastructure and human resource development, technology management including acquisition, technology transfer, licensing and product development, innovative models of partnerships and alliances with private sector, universities/institutions etc. The autonomous institutes were also asked to examine how they would contribute additionally to the 3-4 fold increase in the pool of researchers and scholars in the biotechnology sector recommended by the vision groups to achieve 2020-2025 goals. The inputs received from these institutions were also considered for formulating this report.

The 11th Plan of the Department was based on 'National Biotech Development Strategy-I' formulated through wide ranging consultations involving various stakeholders. The first four years of the 11th Plan ending on March 2011 has been highly challenging, eventful and almost every year major programmes, new institutions & centres have been approved, implemented and established. Programmes/Schemes started in the first two years have already given rich dividend in terms of publications with high impact factor, national and international patents and

transfer of more than 50 technologies towards product development and commercialization. The existing DBT institutions excelled both in discovery led innovation and technology development, while the new institutions have all started the research activities in the interim facility with working plans for construction of main buildings of the institutions.

3.1 Vision and Strategy

Keeping in view the above inputs, success and lessons learnt in implementation of the first "Biotechnology Development Strategy-2007" which formed the backbone of 11th Plan (2002-2007) working group report, the wide range of programmes and projects implemented during the last 3 years of 11th Plan and their spillover effects in order to continue the ongoing programmes, objectives and investments as well as the support new ideas of innovation and their supporting resources the recommendations for 12th Plan have been made in this report.

The overall vision of the Department envisaged during 11th Plan was "to take bioscience to new heights, promote interdisciplinary research, create biotechnology tools and technologies that address the problems of agriculture productivity, food production, nutrition security, health care and environmental sustainability by providing new and emerging technology, products and services at affordable prices, generate employment opportunities and make India globally competitive in the emerging bio-economy". Capacity development for translational research received strong emphasis. With this overall vision, the strategy of 12th Plan has been formulated with major goals around which programmes and projects shall be taken up.

The main mantra of 12th Plan proposals is around the overall strategy of **"accelerating the pace of research, innovation, development and technology transfer to advance biotechnology as strategic area by taking India's strengths in foundational sciences to globally competitive levels and expanding the application of biotechnologies for overall growth of bio-economy within the framework of inclusive development".**

This requires visualizing the biotechnology sector as a national enterprise with functional connectivity and a common goal rather than focus on individual components in the public, not for profit or for profit space, a system that functions effectively as a whole.

3.2 Major Strategic Goals

(i) Expand available pool of research scholars and scientist at all levels (Ph.D, PDFs, young faculty) in biological and interdisciplinary space by 3-5 folds:

- Expanding biological/life science Departments in universities, IITs, medical, veterinary and agriculture and pharmaceutical universities/Departments, centres of excellence, existing and new DBT/DST/CSIR biology institutions.
- Expand disciplinary, more important interdisciplinary bio-based science linking to quantatives sciences (chemistry, engineering, physics).
- Expanding biological and interdisciplinary sciences in human, animal and plant science systems to achieve greater translatability of knowledge with feasible model system Setup 'Graduate Schools' for inter disciplinary science, and translational research; Ph.D programs involving about 6-8 mentors belonging to different disciplines through a network of inter Departmental or inter institutional arrangements linking disciplines at fundamental level and domain level.
- Support "Glue Grant research" programme linking education research and translational research programs between Departments in General Universities with professional Universities and domain institutions. For example: physical & biological sciences; clinical and biological sciences; biological and chemical science; medical science and engineering; biological, computational and pharmaceutical sciences, biological, computational science and agriculture; biological, chemical and veterinary sciences. The purpose is to foster sustainable connectivity in education and research and sharing of infrastructures.
- Establish 'Centres of Excellence' around current basic science concepts and emerging areas such as RNAi biology, metabolomics, systems biology, synthetic biology, chemical biology etc., and develop strategy for mapping translatable knowledge and facilitating translation.

(ii) Connecting and augmenting existing competences across institutions and universities for bio-economy and social impact:

- Biosciences-chemical sciences: Synthetic biology for next generation biofuels.
- Nanoscience, chemical sciences-pharmaceutical sciences and clinical research for drug delivery, novel diagnostic, medical image.
- Biodesign concept with biology-engineering-clinical/translational research for cell therapy implants, devices and new regenerative medicine.

- Bio-informatics, genomics and plant breeding for molecularly designed crops;
- Food and nutrition science in public health for nutrient bio-fortification;
- Infection science, molecular biology and immunology for vaccine development;
- Biological, computational and chemical science for bio drug development.

Some mechanisms for implementing the goal include:

- Inter institutional centres may be grant-in-aid based or time bound programme support based. Independent coordination secretariat will be an essential feature
- DBT autonomous institutions extra mural centres with a career path for faculty.
- International collaborative projects and networks for connecting national competences with global competitive.
- Projects connecting public sector competences with that of private

(iii) Expanding, diversifying career paths with a linkage to high-end interdisciplinary sciences, innovation, translation and entrepreneurship:

- Expanding existing strength: by 3 folds through increase in current areas of relative strength such as molecular and cell biology, structural biology, immunology, neurobiology, bioengineering.
- Diversification linked in new areas related to biotechnology for enhancing impact: nanobiology, chemical biology, biophysics, synthetic biology, system biology, bioengineering, bioprocess engineering and manufacturing technology.
- Science talent fellowships for physicians for Graduate, MD/DNB, and Ph. D levels with early career assured support for 5 years post training. The people created may be clinical investigators, clinical research scholars, translational researchers, bio pharmaceutical researchers, and integrated bio science-bio engineering scholars;
- Career development awards for skills in validation, regulatory testing, equipment repair and maintenance, product formulation and development etc.;
- Academic-industry joint fellowship programme;
- Career path in clinical and translational research: Clinical research scholars, translational science scholars, clinical bioinformatics, biostatistician.
- Career path in regulatory sciences: toxicologist, field trial agronomist, ecologist.

- IP technology transfer and knowledge management expert. A home based career system for women scientist in this area is feasible if early career support is given.
- Entrepreneurship and education: setting up of learning by doing centres or fellowships.
- Industrial R&D and product development career path.
- Career development awards for biology teachers
- International partnered Ph.D and Post Doctoral Programmes and Fellowships in gap areas where local training capacity is weak;

Some mechanisms for implementing the goal include:

- New curriculum in designated universities and institutes will be required for many of these areas. To be implemented through the proposed National Education Council for Biotechnology (NECB).
- Setting-up of finishing school in PPP mode.
- Center/State sponsored units and centres for training and skill development with fellowships
- PPP in joint education opportunities at Ph.D and PDF level.
- Dedicated incubators in academic institutions/universities.
- Supporting teaching skill and research enhancement programme.
- New centres or units in existing institutions.

(iv) Strengthening regulatory science and infrastructure:

- Establishment of Biotechnology Regulatory Authority of India: pending the clearance of bill, BRAI development unit could be setup to coordinate regulation related activities like HRD, setting-up of facilities etc.
- Promotion of regulatory science research units.
- Setting of regulatory testing facilities in critical areas.
- Devising mechanism for accreditation and notification of laboratories.
- Human resource development in regulatory science, testing and documentation through career development awards and fellowship awards.

(v) Expanding existing autonomous R&D institutions:

- Expansion of current strengths of researchers and scientist by 3 folds at all levels - Ph.D, PDF and scientists through on-site expansion for establishment of second research campus

- Setting-up of extra mural research centres on or off site to promote translational science, launch mission programmes or to advance interdisciplinary science areas related to new basic science such as system biology, synthetic biology, or bio science – bio engineering or to mission programmes on bio energy, health technologies, agriculture technologies, nutrition fortification or nationally relevant research resource creation;
- Starting of number of disease specific network programmes as alliance based centres.
- Expanding physical infrastructure-hostels, laboratories, equipment, guest house and technology platforms.

(vi) Expansion and commissioning of bioclusters at Faridabad, Mohali, Kalyani and Hyderabad and setting new clusters:

- Setting-up of research related hospital facilities, contract labs for SMEs, GMP facilities, common technology platforms, entrepreneurship education and training centres;
- Strengthening and completing initiated clusters; New clusters were initiated in the later part of the 11th Plan at Faridabad, Mohali and Bangluru. In the first phase, lead institutions have been initiated. In the next phase, cluster boards will be established as Societies or Section 25 Companies and through these incubators, bio parks, business and entrepreneurship centres, need and opportunity analysis units, connectivity governance units and business centres will be established. Inter-institutional centres are ideally located in these clusters to minimize cost as some of the relevant infrastructure and services would already be available. These centres may be related to areas such as bone and cartilage problems, bio-design, and implants and devices, biopharmaceuticals /biosimilars and nano science based drug delivery, cancer biomarkers and therapeutics; Bio food processing and agriculture technology. Standard governance models would be used everywhere.
- **Establishment of new clusters**: Opportunity analysis would be carried out to identify sites for at least two more clusters where some existing institutions already exist close by. Possible sites include Kalyani at Kolkata, University of Hyderabad, Gujarat and Maharashtra. A scientific approach would be adopted for transparent decision making. State governments and local industry will be effectively engaged for this purpose.
- **Regional technology incubators and parks for innovation, product development and training:** Incubation facilities are required to be expanded as we promote innovation in entrepreneurship. Incubators will be strategically located in universities and institutions in bio-clusters, knowledge parks and a

new incubator and park society will be created to provide necessary connectivity.

- Offices for technology transfer and management and to provide connectivity for innovation

(vii) Establish DBT grants-in-aid or partnership research and translational centres through long term (EFC) support in 5 best universities/institutions. Some areas of interest include:

- Bio -Veterinary science and technology for animal productivity and health.
- Bio -Agriculture sciences and innovation for pre-breeding, GM technology and molecular breeding.
- Cell and tissue engineering and regenerative medicine.
- Biopharmaceutical sciences and health technology.
- Infectious disease sciences and health technology.
- Metagenomics and health and disease.
- Chemical biology and synthetic biology.
- Bioengineering and interdisciplinary sciences.
- Nutrition and food science technology for fortification.

The final choices and selection will be through a competitive process.

(viii) Reorient "Grand Challenge Programme" Scheme of 11th Plan to address national priorities in various developmental sectors through bottom-up approach and also encourage discovery led innovative ideas. Some examples include transforming science and innovation in the following areas:

- Science and technology for safe pregnancy and child birth
- Metabolic disease – prediction, diagnosis, cure;
- Nutrition for public health and wellness.
- Molecular breeding for food security.
- Climate change and agriculture productivity
- Better animal health and nutrition
- Water use efficiency in agriculture for addressing drought and rainfed areas
- Bio-prospecting of bio-resources
- Emerging areas of nano-biotechnology for medicine;
- New generation Bio-energy;
- Application arising out of chemical biology, synthetic biology and system biology

- Grand challenges in new basic sciences - new drug targets, new lead compounds of nano-biotechnology, personalized medicine, drug discovery, bio-fuels, system biology etc.

Some mechanisms for implementing the goal include:

- Mission projects with separate governance, management, milestones with inter Departmental participation and global partnerships.
- Bottom-up idea based competitive grands for R&D and innovation.
- Network projects with several partners along the value chain from translational research to product development and commercialization.

(ix) Rejuvenate and establish new research resources, facilities and services:

- **Established National Life science Resource Centre (NLSRC)** with specialized research staff, informatics support and data bases to network all research resources, training for skill development activities and organize a systematic information access management facilitating biology research community.
- Setting up of more GLP certified protein purification/characterization assemble units, drug screening facilities, GMP pilot lot facilities;
- Setup national centres for facilitating resources for low and virtual suppliers for small organizations example micro array, knockout mice possibly in collaboration with private sector.
- Setup to new technology platforms/centre for implants, devices, cell therapies including (i) validation and prototyping, (ii) animal physiology and (iii) large animal safety testing on the model of Sri Chitra Medical Institute.
- Novel antibody development facility for human use.
- Animal testing and breeding facilities – **knockout** and large animals Tool development centre for synthetic biology.
- Centre for storage and retrieval of biological resources.
- Setting-up of viral testing facilities.
- Clinical trial support GLP compliant validation labs;
- Setting-up of bio-banks around mission mode and translational programme.
- Technology platform for SMEs and small businesses to meet research needs.
- Genomic and proteomic facilities
- New generation sequencing service units
- Toxicology units.

(x) Leverage international collaboration for partnerships in cutting edge areas research, education and technology development, access, acquisition:

- Establishing joint centres of excellence
- Linking DBT autonomous institutions with international institutions and universities
- Joint collaborative innovation involving industry with global organizations
- Partnerships programme for linking Indian academia/industry programmes with international counter parts
- Joint human resource development programmes involving training Ph.D student, faculty engaged in teaching and education etc., in science and in dominance area.
- International 2 X 2 and 1 X 1 public private partnership projects.
- Industry- Academia international institutional consortia in Mission Mode.
- PPP on neglected diseases and crops.

(xi) Continued and Sustained support to public private partnerships with new innovative funding schemes:

- Ignition grants to the most nascent innovation, entrepreneurs working in incubators or protected but non compliance environment
- Creating, nurturing and sustained support to startup for early stage technologies
- Provision of "bridge funding" firms to function between successive private equity funding or planning for IPOs.
- Innovative industry partnership funding programmes such as therapeutic drug discovery projects, secondary agriculture
- Facilitating, patenting activities of SMEs
- Special investment incentives to industry for building more biotechnology/pharma SEZs
- Focused funding an affordable technology of social relevance, neglected disease.
- Contractual research support to public sector labs to avail of company facilities for pilot lot production / phototype development
- Clinical/ field testing support for indigenously developed products.

(xii) Promoting discovery led innovation and strategic investments in priority sectors:

- Vaccines and diagnostics development
- Bio-energy and next generation bio-fuels

- Bio-design – implants and devices
- Molecular crop breeding by design
- Biopharmaceuticals and drug delivery
- Bio instrumentation.

(xiii) Promoting new generation biotech industries:

- Bulk/specialty chemicals/biochemicals
- Diagnostics and multi analyte units as a part of multi analysis system.
- Food and nutrition
- Biotech led/enable services – engineering, components and equipment manufacture
- Bioremediation technologies
- Implants and devices

(xiv) Technology acquisition, transfer and licensing for product development:

- Establishment of III (Intelligence and Innovation Idea) units to serve as "think tanks" in life science and biotechnology to imagine the future and prepare for the future
- Setting up of technology acquisition fund with legal process and mechanism
- Setting up of technology and IP management centres

(xv) Communication platform/system for creating awareness and public understanding of biotechnology with special reference to agriculture biotechnology:

- Centre for biotechnology communication for content and coordination
- Communication units in universities and institutions
- Regular programmes and publications in electronic and print media
- Authorized communication expert groups for crisis management and response

(xvi) Expediting legal framework and legislations:

- Biotechnology Regulatory Authority of India Bill
- Public sector funded IP Management Bill
- DNA Profiling Bill
- Regional Centre for Biotechnology Bill

(xvii) Strengthening and consolidation of major 11th Plan initiatives:

- Schemes for promotion of innovation and excellence
- DBT partnered centres in existing institutions
- Schemes of public private partnerships
- Research resources specialized centres, translation platforms and service facilities
- Innovative human resources development programmes
- New institutions established and in pipeline
- Major R&D programmes and networks for technology development
- Operationalization of 3 biotech clusters at Faridabad, Mohali and Bangalore.

(xviii) Promote policy research and analysis in biotechnology:

- Establish centres/units for health and agriculture biotechnology policy research and technology analysis and forecasting;
- Capacity building through workshops, training and research;
- Support policy dialogue among stakeholder through special meetings and seminars.

(xix) Reengineering the economic model for biotechnology product/industry development:

- Extending the weighted tax deduction for manufacturing activities
- Broadening definition of R&D expenditure to include regulation and patent activities
- Deduction in import duties of high-end and bio-analytical equipment/facilities
- Operationalisation of Biotechnology Industry Research Assistance Council (BIRAC)
- Special incentive for affordable technology and product development
- Expand infrastructure support for commercialization of indigenous innovation.

(xx) Reforms in funding and project management:

- New competitive grant system based on expert committee report
- Online submission of projects, review and registration (e-promise)
- Flexibility and standardization of project cost components
- Distinct project management for product innovation projects.

3.3 Human Resource Development

During the previous plan period, emphasis was given to M.Sc./M.Tech, Ph.D and post doctoral programmes to address the needs of the research and development. In the 11th Plan, the following innovative programmes have been taken up from undergraduate levels.

Based on a review of all the schemes, the following recommendations for ongoing initiatives were made:

- Expand with intensive monitoring the "Star College Programme" strengthening undergraduate education in life science to include one such college for every city/district head quarters over a period of next 12 years. During the 12th plan, setting-up of 100 colleges may be aimed. The process of selection could be based on independent assessment and accreditation in consultation with existing agencies and UGC. It has also been recommended to open a dialogue with UGC/AICTE to phase out UG degree in biotechnology. The Star College Progrmame should have a provision for strengthening science education in those colleges that are below the benchmark for selection as a Star College. This will fulfill the agenda of inclusive development, focusing on less developed states and districts. It is recognized now to scale up these efforts, an institutional mechanism for guiding these efforts and for teachers training needs to be put in place. This will be through the proposed Biotechnology Education Council to be set up.
- The ongoing PG teaching programme, M.Sc./M.Tech programmes may be ranked based on their past performance for continuation of support. At the same time incentives and faculty positions may be extended for universities with high performance.
- A beginning has been made in Master, Ph. D level programme for physician scientist and now need to use initial experience, to start a major scheme in the country. This will require engagement with Ministry of Health, Department of Higher Education and UGC. We have recently concluded an agreement with National Board of Examinations for academic DNB programmes in accredited medical centres in the country linked to one of our autonomous institutions.

- The fellowship schemes for reentry into India have been very successful and about 200 scientists were brought back in the last 2-3 years. The DBT-Welcome partnership programme is doing well based on external review and

will be continued. The Ramalingaswami fellowships and other reentry programmes need to be expanded to achieve greater coverage of Europe and Scandinavian. It is heartening that vast majority of Ramalingaswami fellows are readily finding faculty placements. We propose now to hold young investigator meetings in all the continents of young Indian scholars working overseas on the model of the YIM meeting held at Boston every year. This meeting connects Directors of all new institutes and universities with young research scholars. The intake of 50 scholars per year for Ramalingaswami fellowships needs to be doubled. We will initiate Distinguished International Professorships for overseas scientists willing to establish a Lab in India, run a Ph.D programme in partnership and spend at least 8-12 weeks every year in India. This scheme is currently restricted to DBT's own institutes and will now be extended to others.

New Proposals

Human resource development in life science and biotechnology needs to be revamped. Some of the challenges include:

- Convergence or inter-disciplinary sciences requires research personnel trained at the interface of different disciplines.
- Many students with science background at graduate and post graduate level and even with Ph.D are not gainfully employed either due to lack of opportunity for higher studies or due to the quality of Ph.D training (with required skill sets) Vs high bench marks set of selection criteria for research and faculty positions in public and private sectors. This will be addressed through creation of 3-4 finishing schools in different regions.
- Increased automation, highly sophisticated instruments/equipment, Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) in R&D and industrial production require human resource with specialized technical training and skill sets customized for the purpose. New programmes will be started to address this.
- Many industries in India often complain of non-availability of readymade talent that fits into a job profile. While some companies do conduct training programs, there is a need to provide graduates and post graduates with technical skills as well as communication/IT and problem solving or analytical skills. Such training programs would provide job opportunities to students besides saving time efforts & investment of the companies. Finishing schools located in key biotechnology development states, in the country can address this issue.

New role for Science Ministries in education requires providing creative & minimal intervention for value addition by providing faculty in gap areas, emphasis on faculty improvement programmes, recognition of teachers, opportunities for teachers and students for visits to leading National and overseas laboratories, research exposure for students by research projects during vacations, industrial training, framing of modal curricula and study material.

In order to meet the above requirements, the following proposals/initiatives have been made:

Establishing of '**Life science and Biotechnology Education Council'** to coordinate, network and implement education, training and skill development activities from school to post-doctoral level. The council shall also be involved for assessment of human resource requirements across disciplines and skill sets, formulating innovating training programmes, fellowships, curriculum development, teachers training, education tool development, accreditation, education policy research and facilitating the monitoring of ongoing schemes of DBT. The council will conceptualize and create new programme for physician scientist, interdisciplinary Ph. D's, training for innovation, professional and entrepreneurship training and training places.

Dual degree M.Sc./M.Phil, M.Sc/Ph.D, M.Sc./M.B.A., M.Sc./M.Tech, MD/Ph.D.

- Master level training in interdisciplinary biopharma and translational science.
- M.Sc. with 1st year specialized training in industry/research labs
- Instrumentation specialized training (proteomic, gene sequencing)
- Master in clinical bioinformatics, clinical investigatorship, clinical research scholars and translational science scholars. MD, DNB-Ph.D or DM-Ph.D programs.
- Training programme for IT and Technology transfer professionals, Laboratory quality assurance managers.
- M. Tech. in biodesign - bioengineering.
- Dual degree 3 years M.Sc./MBA in bioenterprise management, agribusiness management, pharma-business management
- Specialized master level courses in biotechnology related to forestry, veterinary, food & nutrition, forensic biotech, bio-economy, infection science, statistics and genomics.
- Develop dual degree sandwich programmes for collaboration of Indian universities with overseas universities and Ph. D and Post Doctoral levels.

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 in gap areas relevant for new science area and translational area
- Structured workshop for Training of UG & PG teachers in star colleges/PG teaching programmes of DBT
- 4 regional institutes for training in translational science on the pattern of THSTI
- Life time achievement award for superannuated teachers based on performance
- Career development awards for teachers
- Provision for training as an integral part of programmes with huge equipment grant such as FIST by DST
- 5 technician training programmes

Specialized Short Term Training Programmes for skill improvement in the Biology / Biotech / Bioengineering interface in the areas of:

- Recombinant human monoclonal antibodies and production
- Drug discovery
- Stem cell technologies
- Transgenic plant related technologies
- Transgenic animal development
- IPR & regulation

This will require establishing technology platform with added training responsibility in different region of the country. A new contract carrier path for such short term training centre is to be developed.

Setting up of **'Finishing Schools'** to make available readymade talent to various S&T based industries. These finishing schools could be biotechnology domain specific and could be established preferably through public private partnerships or consortium of industries with Government support or in partnerships with Industry associations (CII, FICCI).

Institute wide array of **'Career Development Awards'** with lucrative pay packages to working professionals/faculty (physician, engineers and pharmaceuticals scientist) to pursue Ph.D and participate in innovation and technology development activities. (Some examples include DBT-Tata innovation fellowship given to R&D scientists).

This would accelerate innovation and product development/design activities which quite often do not result into scientific publications (a measure of performance of science).

Fund **Career Development Programs** that attract talented medical students, physicians and dentists to the challenge of clinical research careers to recognize and motivate them to contribute in medical innovations and technology development.

A Special Grant for Mentorship should be made available for graduate science colleges to invite faculty or established scientists from National Institutions or Universities to mentor in various science subjects for teaching, guiding research activities and designing laboratories and experiments.

Introduction of special course/summer training opportunities for graduate students to appreciate and inspire life science: Each National institute/DBT funded universities may be supported to have summer school programs for promoting life science. On pilot basis a scheme should be started to identify bright students in science at school level in rural areas. Summer training concepts should be promoted for empowering knowledge to students in subjects of their choice. Institutions can select students based on certain set criteria and also can support for their travel and accommodation. The concept of sustained engagement during all vacations should be promoted among students. Institutions should set aside certain amount of budget for facilitating summer training for students.

Employing New Tools and Technologies for Life science Education: Three different levels where interventions through new tools and technologies are required such as: teaching & learning methods and knowledge landscape. These methods need financial support, educational tools creation, tools adoption, tool literacy etc. Creation, distribution, utilization and tracking of tools and technologies in education is to be done. Similarly, knowledge databases are required to provide knowledge collection, knowledge compilation etc. Knowledge creation needs a primary survey, user defined knowledge customization. Knowledge customization should be aiming of more attractive, effective and interesting learning as well as teaching.

Creating Service Centers and fellowships for Training personnel which include:

- Distinguish teacher training professorships and schools for teachers training
- Centers for practical training (associated with educational institutions but independent of their administration
- Centers of advanced practical training and services

- Polytechnic schools for training in using and maintaining in biotechnology based tools

Sector specific recommendations on Human Resource Development

A. Bioinformatics

It was recognized that there is a need for highly specialized and trained manpower requirements with know-how of new computational machines; expertise in Systems Biology and Association mapping ; analyzing huge volume of data now being generated due to advent of deep sequencing technologies and emerging needs industry. The recommendations made for the purpose include:

Training of current generation students and scientists

Changes recommended in existing Bioinformatics courses; while no more new Bioinformatics courses need to be started, the existing courses must be reoriented to include a major component of biotechnology and wet lab; the computer science programming component in the course work may be increased, by employing hardcore computer science faculty for training; every course should have a specialization; and Choice based Credit System for Bioinformatics, Computational and Systems Biology course in M.Sc. Biotechnology may be introduced.

Some recommendations for Training of Biotechnology students/ scientists included:

- One year diploma course for biology students
- Hands-on-training for experimental biologists
- Short-term overseas / national fellowships for Ph.D students and scientists
- One year Industry training for students
- Training of college teachers
- After BSc, Bioinformatics Technician training program
- Start Interdisciplinary 5-year MSc, M Tech and Ph.D programs with strong Agricultural and Medical Science component.
- Partnered centers where MSc and MTech training / projects can be done in a multi-disciplinary area
- International collaborations for projects and Dual Ph.D programs

- Visiting Professorship to bring world class faculty to India for
- teaching in the emerging areas on assignment basis
- Attracting NRI scientists working in the field of Bioinformatics-Ramalingaswamy and IYBA like fellowships of DBT
- Book writing grant to retired teachers and scientists

B. Genomics and Health

- 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 generate clinical, laboratory, genetic, statistical, bioinformatics, experts to conduct clinical research studies.
- Educational Fellowships for interdisciplinary translational research (e.g. infection biology, immunology, evolutionary biology, ecology, epidemiology and mathematical modeling) to create new research paradigms
- Initiation of graduate school courses in clinical and translational research in medical schools relevant to vaccines.
- Supporting Ph.D. and post-doctoral programmes in medical schools vaccinology.

C. Infectious Disease

- M. Sc. and Ph. D level training or an academic DNB will be initiating in an interdisciplinary infectious science programme n medical schools and universities.
- A graduate school, one each around each major pathogen would be initiated.
- Biodesign type fellowship would be initiated in diagnostic and biomarker development through national biodesign alliance.
- Overseas fellowships in infectious disease research would be initiated.
- Short term training centers would be established in existing institutions.

D. Chronic Diseases

- Three-way networking of medical, engineering and basic science for issues such as those related to prosthesis, devices and imaging.
- Special grants and career development awards to support Ph.D., M.D. and M. Tech.

E. Stem Cell Research and Regenerative Medicine

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.
- Create opportunities for overseas scientists to work in India Post docs/Senior Scientists; Collaborative Science Chair (CSC) for 5 years (at least spend 2/12 yearly);
- Capacity building for research and generating ideas to facilitate the conceptualization and designing of medical devices and implants:
- Research interfaces with medical/clinical environment; technical environments; public and community health.
- Increase the number of fellows and interns for training in clinical immersion process.
- To establish/promote graduate school concept at the biodesign inter-institutional Centre.
- To produce a large number of medical technology innovators.
- To expand multi-disciplinary, team-based program across the country to train engineers and physicians for clinical immersion through biodesign process in India.

- Introduce healthcare technologies including biodesign in the curriculum of medical and engineering schools for undergraduate and post graduate programmes.
- To create quality manpower in engineering school in partnership with medical schools for multidisciplinary research, skilled technicians, manufacturing engineers and regulatory staffs.
- To establish collaboration with various international institutes/universities.

F. Food and Nutrition Security

- Generation of a critical mass of well-trained food biotechnologists and nutrition biologists for nutrition and translational research relevant to agriculture and human health through post graduate courses and specialized training programmes.

G. Societal Development

- Need to produce skilled and unskilled manpower required for farm and non-farm trade related activities and creation of self-employment with social Innovations as a theme and social and behavioral sciences embedded in HR development.

H. Energy bioscience -Training and Capacity Building

- Energy Biosciences fellowship and chairs will continue to be supported
- 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.

I. Bioprospecting - 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.
- Training programmes in specialized areas such as molecular pharmacology, phytochemistry, advanced and robust screening protocols.

J. Secondary Agriculture - Training and capacity Building

- Rural Bio-resource Complex in North-East India at North-Eastern Hill University, Shillong will continue on 12th plan.
- DNA clubs programmes have very good response and will be carry forwarded to next plan.

3.4 Promotion of Excellence and Innovation

The overall aim of this programme during 11th Plan was to establish centres of excellence, specialized centres, support multi-institutional network projects and institutional / Departmental programme support. The specific goal is to enhance the innovative ability of the institutions and investigators with well-developed research programme in specific areas of biotechnology.

The scheme provided funding to augment and strengthen institutional research capacity for promotion of excellence in interdisciplinary science and innovation in specific areas of biotechnology. The programme is intended for institutions with a substantial investment in, and commitment to biotechnology research. The programme will provide flexible long-term support for highly innovative research (both basic and translational) in biotechnology, which creates not only high-quality publications and intellectual property but also translational outputs through mid and high end innovation.

The following six categories of grants will be provided under this programme:

Category I: Centres of Excellence (COE) in Biotechnology with a specific thematic focus
Category II: Centre of Excellence (COE) in Biotechnology with academia-industry partnership
Category III: Outstanding Scientist Research Programme in Biotechnology
Category IV: Specialized Centres in Biotechnology Innovation
Category V: Institutional Programme Support to an identified institution/ Department with multiple investigators in various disciplines
Category VI: Multi-institutional Network Programme involving a number of independent investigators who share knowledge and common resources

Under this scheme, Department during the 11th plan promoted establishment of centres of excellence and programme support projects. The performance indicators included are publication with high impact factor, national and international patents, early translational leads for technology development, number of Ph.Ds trained and facilities established.

However, two major shortcomings of these schemes are:

- The scheme was based on advertisement requesting for proposals under the five categories. Therefore, the subject area was left to the choice of investigators rather than addressing research, education and industry requirements at the national level through a top-down approach. There is need to do more to attract translational centre requests.
- Most of the proposals received were around outstanding scientist research programme and multi institutional network programme categories rather than other categories. It is important that the concept of coE's be extended to include other modalities.

Recommendations

- Recognizing the excellent outputs from this programme, it is recommended to continue the scheme for 12th plan with an objective to establish 50 more such centres covering all categories by design rather than choice of investigators.
- While the bottom-up approach of soliciting research proposals may continue, the trend needs to be balanced with a new approach in establishing centres around, national priorities in life science and biotechnology.

The following suggestions have been made:

- Setup networks centres '**Graduate Schools'** for inter disciplinary higher level and translational Ph.D programs involving 4-6 mentors belonging to different disciplines through a network of inter Departmental or inter institutional arrangements linking disciplines at fundamental level and domain level. Under this programme, the graduates will be trained through a network of participating laboratories/universities/institutions to provide a comprehensive experience and skills in handling both basic and applied research. The network participants could share teaching and research resource to the programme and the graduate scholars could spend few months of time as a mandatory requirement in other laboratories. This would result in generation of graduates with translational research abilities narrowing down of the existing large number of Ph.D programme into elite Ph.D course. A separate governance mechanisms and institutions of high quality could be involved.

- **Support centres for networking through a "Glue Grant Research"** linking education and research programs between Universities and Colleges, Universities and National Institutions, General Universities with professional Universities at the interfaces of for example: biological sciences including engineering, medical, agriculture, veterinary sciences; some examples of research interfaces include: Nano-science and biology; engineering and medicine, genomics and breeding; biology and chemistry; biodesign; breeding crops /livestock, energy solutions etc.

- Establish inter-institutional and institute/university centres with shared objectives, complementing/supplementing each others strengths and weakness in basic and translational research capacity for addressing major national problem of social economic relevance. An example is collaboration of basic research institution in life science with medical hospital. These centres will be grants-in-aid based. It is critical to develop a contractual carrier path for them and other extramural centres to ensure success.

- In order to rejuvenate core basic research in foundational sciences, 10 centres of excellence for use-inspired discovery in plant sciences, animal sciences, human biology systems and industrial research are proposed. The largest of 3-fold increase in current level of scholars proposed by overseas group can't be achieved without expansion of existing excellent centres. IIT's represent a

major opportunity to add bioscience, and interdisciplinary science and translational research that is bio based.

- It is proposed to support inter Departmental clusters of bioscience interdisciplinary science and engineering for education, research and technology innovation in Indian Institutes of Technology. Several IITs have already started biology programmes, by strengthening these activities through a programme support ensuring key human resource, infrastructure and equipment regulatory and translational facility, clinical and agricultural connectivity with existing 40-60 faculty members engaged in biology and engineering science, an additional 500 Ph.Ds annually can be generated under this programme. Proposals have already been generated from six IIT's and a strategic think tank is working with the IIT's for a long term strategy for novel educations as well as R&D and product innovation.

- New centres for translational science education and innovative research will be established in 5 medical schools linked to other neighbouring institutes. The areas may relate to Molecular Medicine, Cancer Nanoscience, bone and cartilage biology, metagenomics for health and disease, infection science & technology. The centres can be of three types (i) Grants-in-aid in existing institutions (ii) Programme based with for five years extendable for good performance by additional 4 years, followed by closure or absorption by host institute. (iii) virtual inter-institutional networks around anchor, coordination institution with DBT partnered governance.

- **Support to DBT partnerships grand challenge** research centres for translational research of excellence in the areas of highest national priorities for technology development in health care and agriculture are proposed in 10 institutions/universities through a long term support by EFC process of approval through providing core grants, governance system and project grants. The potential institutions for such support would include agriculture/veterinary/medical universities and institutions. This would fill the gap for linking discovery based innovations and translational research providing access to biological and technical resources, specialized expertise and infrastructure available with the partner institutions/universities.

3.5 Research Resources, Facilities and Services

The Department during the last plan established more than 60 facilities for services to academia, industry and research scholars; providing access to reagents, experimental animals, sophisticated equipment for experimentation and data collection, micro organisms etc. These facilities have been supported in the following modes:

- Support to individual investigators or institutions including autonomous institutions of DBT based on requirement and the potential users.
- Establishment of large facilities for National requirements, advanced research areas and legal requirements. For example, establishment of International Depository Authority (IDA) for deposit of patentable microorganisms at IMTECH, Chandigarh and NCCS, Pune.
- Programme based infrastructure support to universities and institutions to facilitate advanced research and educational needs.

In all these modalities, it has been noticed that users at large are not properly aware of the resources and norms for their access and utilization. Further, many of these facilities cater to the needs of institutes hosting them with little time for outside users. With the growth of small and medium enterprises, emerging areas and legal framework of accessing and utilizing biological material, expensive nature of high-end equipment and lack of adequate expertise for operation and maintenance requires a new approach for development of research infrastructure including governance, institutional framework and recognition for personnel employed executively for providing services in these facilities.

Recognizing the lessons and the emerging requirements, the following proposals have been made:

Recommendations

- A **National Life science Resource Centre (NLSRC)** to be established with specialized research staff, informatics support and data bases to network all research resources, training for skill development and organize a systematic information access, manage and coordinate all these activities to facilitate better services to the research community.

The following facilities need to be established for emerging technological needs

- Facilities for development and providing access to **Critical Animal Models,** which offer essential clues to a broad range of human diseases and disorders. The purpose is to provide high-quality, disease-free animal models and specialized animal research facilities for biomedical investigators and supports the development of a wide range of research models, particularly marine invertebrates and lower vertebrates.

- Support **Animal Facilities Up gradation Program** to upgrade animal facilities that support biomedical and behavioral research. In addition to upgrading the facilities, these grants could assist institutions in complying with the emerging trends of Animal Welfare Act and policies related to the care and use of laboratory animals.

- Establish four primate research centres for facilitating research and regulatory requirements.

- Support **Research Infrastructure Strengthening Programme** to provide funding to **expand, remodel, and renovate** or alter existing research facilities or construct new research facilities to meet the requirements of emerging sciences at various centres and institutions.

- Support research, development and access to sophisticated technologies for acquisition of new state-of-the-art shared instrumentation; high performance computing, molecular and cellular structural biology technologies, biomedical engineering, noninvasive imaging and spectroscopy, mathematical modeling and computer simulations through grants, contracts, and cooperative agreements.

- Establish new repositories, bio-banks and strengthen the existing ones for providing access to life science researchers to an array of important biological materials such as microbial strains, cell lines and genetic material.

- **During the 11th Plan the Department has set up Centre for Cellular and Molecular Platforms (C-CAMP) with GLP** certified protein characterization laboratory at NCBS, Bengaluru. India has only one GLP certified protein characterization laboratory at NCBS, Bengaluru. These laboratories are essential in providing necessary support during two crucial stages of biopharmaceutical product development cycle. To meet the growing needs of

Biopharmaceutical industry it is proposed to setup at least **four more such GLP certified protein purification and characterization** laboratories spread across the country.

- Establishment of protein production facilities preferably in public private partnership for the production of biopharmaceuticals in the interest of India Society.

- Establishment of Unit for production and distribution of biotechnology based bio-chemicals, reagents and supporting consumables etc.

- **Expansion of Viral Testing Facilities:** Presently there are only few facilities for viral safety testing and assessment in Mumbai, Pune and Bangaluru. Therefore, there is a need to support 3 more such facilities including the needs of veterinary and fisheries.

- **Regulatory Testing Laboratories and Facilities:** There is a growing concern about the lack of adequate GLP certified testing facilities for regulatory purposes dealing with agriculture and health care including veterinary biological. It is proposed to establish **"a society or central agency for regulatory testing and certification laboratories"** with some core activities and facilities with a network of public sector laboratories. DBT may strengthen the existing public sector laboratories, along with agreed reforms in governance and management of services desirable for GLP certification and necessary accreditation. The priority areas include toxicology, environmental risk assessment, compositional analysis etc. to meet the protocols and guidelines of existing and emerging regulatory requirements.

- **National network of field trial and phenotype analysis centres** in different agro-climatic zones involving State Agriculture Universities and ICAR institutions for evaluation of genetically modified crops in terms of their performance and environmental risk assessment will be established following standard operational practices of re-productivity isolation security arrangements, notification and monitoring.

- Establish seven referral laboratories with data storage and retrieval system in collaboration with ICAR for development of molecular tools, DNA fingerprinting and genotyping of annual/perennial crop germplasm, fish and animal resources and epidemiological monitoring of diagnosis of pests and

diseases, genes and molecules and to resolve legal disputes in plant variety ownership claims, IPR and implementation of biodiversity act.

- Validation and clinical trial services facility for veterinary vaccine and diagnostics in collaboration with ICAR with a network of participating institutions and veterinary universities/hospital is essential for meeting the needs of emerging animal diseases particularly of zoonotic in nature.

Other facilities to meet the advances in life science and industrial requirements:

- Transgenic knock-out facilities
- GMP training facilities
- BSL2 and BSL3 facilities
- Facilities for genomic and proteomic analyses strictly on the efficient service basis
- Establishing facilities in collaboration with Biotech industries to produce simple, easy to use diagnostic assays/reagents.
- Toxicology

- **Boosting University Interdisciplinary Life Science Departments Education and Research (BUILDER):** During the 11th Plan, DBT supported up-gradation of interdisciplinary linking of life science Departments in two Central and seven State universities with the vision that an availability of high quality and effectively educated postgraduate students as doctoral and postdoctoral scholars in an appropriate number; is central to India's competitiveness in emerging global bio-economy. The grant is intended to address the gaps identified through a thorough internal assessment of strengths and weaknesses and scientific connectedness of life science Departments and their research infrastructure. The areas of strengthening may relate to infrastructure and teaching and training, laboratories needed for new faculty, fellowship, short term training programmes, exposure to innovation experience for scholars, academic-industry interphase: all directed to sound and effective education linkages to research.

- In view of the successful results in term of increasing number of Ph.Ds, quality of publications and capacity to generate extra mural funded projects in the supported universities, it is proposed to extend the scheme to cover 25 more universities.

- A similar scheme tailored to the needs of agriculture, veterinary and fisheries universities/colleges in collaboration with ICAR would be extended during the 12th plan to strengthen human resource, infrastructure, modern biotechnological inputs in research and product development programmes. About 20 universities/colleges are recommended for such support based on past performance with reforms and redesign in governance and management of the programme through an agreement.

- In the strategy, we proposed a 2 category approach one process is based on merit i.e, the other is for assisting universities in least developed states, keeping a ration of 65% to 35%. This is to promote inclusive development.

3.6 Bioinformatics, Computational and Systems Biology

During the 11th Plan, Department has covered 165 institutions under the BTISnet program and illustrated three important major consortia projects on development of TB, Rice and Mango databases. Human resource development programs like post graduate courses, short term training programs, industry training and BINC examination were also implemented well and could be continued during next plan. However, the following key observations and recommendations were made:

- A **National Level Bioinformatics Institute** for depositing the data generated by Indian researchers is a pre requisite and this Institute would address issues in validating and consolidating the now fragmented and unreliable databases being produced in the country and above all International databases like EMBL are reaching their limit for accepting more data, especially due to huge datasets being generated with deep sequencing platforms which would essentially address the needs of Indian researchers.

- The bioinformatics support is still in nascent phase and hence becoming a major bottleneck for biologists for undertaking active research in the field of bioinformatics and computational biology. The biologists are not geared to handle the massive datasets now being generated by the new generation high-throughput technologies. DBT need to address these needs by **setting up permanent service centers in the existing institutes** that are involved in generating this huge data and financial grants may be provided for strengthening this activity. These centres would be wetlabs around computational biology linked to the main institutions.

- Institutes have adequate users of the existing software, but lack people who could develop better tools and expertise in writing codes for ever increasing needs and to strengthen this, collaboration to be established between DBT and Department of IT through a common platform where students with IT and Biotech skills would be trained and a connectivity could be established to breed a newer generation of scientists who are well trained in both fields catering to a wide array of applications in agriculture, healthcare and environmental sectors to fields like translational bioinformatics in drug discovery and systems pharmacology.

- **New Twinning or Glue Grant Research** schemes could be launched during the 12th Plan period to support projects which are interdisciplinary in nature and which require collaborations of experimental biologists in the agriculture and medical areas with cross sectoral Departments/industries in IT sector in public private partnership mode to promote and encourage the Bioinformatics Industry in the country for developing solutions in national priority areas. DBT can initiate a dialogue with DSIR for exempting DSIR requirements for bioinformatics companies/ institutes and should be made eligible for weighted tax deduction and other fiscal incentives applicable to certified labs/ institutes/ organizations.

- Very few software tools & databases are developed in India to cater to the needs of life science domain and most of those that exist are not validated and are highly fragmented. This is primarily due to lack of state-of-art computing facilities to analyze the voluminous data being generated and to carry out research at par with the world. A **National Data Policy** is proposed to be established, 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.

- **Development of Data Repositories for Promoting Translational Bioinformatics :** The volume of data now being generated due to advent of deep sequencing technologies requires not only skilled manpower to analyze huge data generated by researchers but also there is a need to develop more e-resource platforms to pool the bulk datas generated which can be eventually shared among various institutions/ industries etc.

Some of these platforms may include:

- 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.

- **Developing world class Computing Facilities:** Number of **supercomputing facilities** may be increased to address the growing demand from various Institutions/ Universities / Industries and one strategy could be introduction of **Cloud / parallel computing** in the country. Financial support may be provided by DBT for setting up of such facilities and initially 3 such facilities could be established in three regions of the country and based on its performance and monitoring, based on need and those performing well maybe upgraded.

- **Promoting discovery led innovation and strategic investments in priority sectors:** The Department has been addressing the application of biotechnology across areas of agriculture, health care, environment, animal husbandry since beginning of 9th Plan period. To start with modest investments through open ended R&D programmes driven by individual investigators till the end of 10th Plan (2002-2007). These efforts resulted in capacity building in terms of human resource and laboratory infrastructure, good quality publications, patents and prototype products. Based on these foundations, during the 11th Plan, the sectoral road map was formulated to implement the projects based on sectoral national priorities through top-down approach by soliciting proposals through "request for proposals" widely advertised and multi institutional network projects sharing objectives from basic research to technology development. This approach further was complemented with establishment of centres of excellence, technology platforms/incubators and public private partnership to translate laboratory prototype technologies into products of commercial value through validation, formulation, regulatory due diligence and technology transfer.

The experience and evidence from the sectoral strategy during the 11th Plan provided a strong base for reshaping the approach for 12th Plan in various sectors for formulating programmes, projects and product development activities. In every sector therefore more than one mechanism or modality, linkages, partnerships, alliances and platforms are required for successful development of Science & Technology. Accordingly, the following approaches shall be used for implementing sectoral priorities:

- Capacity building in terms of sector specific human resource and infrastructure.
- Supporting open ended discovery led innovation R&D projects
- Developing network of projects around sectoral priorities from discovery to markets involving multiple institutions, disciplines, skill sets and expertise
- Establishment of sector specific small and medium facilities/platforms/incubators
- Strengthening legal and administrative framework for technology assessment, transfer and licensing processes.
- Providing emerging policy research support for technology choice, development, deployment and commercialization.

While the overall requirements of life science education and research are generally addressed in the schemes on human resource development, infrastructure and bioinformatics support the sectors specific requirements shall be met out of sectors specific schemes due to the above sequel of requirements.

Therefore, for the 12th plan even within the sectoral areas basic research R&D and strategic research and technology development have been bifurcated. The strategic research involves all the above (a-f) elements combined with effective project management and monitoring mechanism for achieving the targets in time bound manner.

3.7 Agriculture and Allied Areas

3.7.1 Crop Biotechnology

Agriculture biotechnology remains to be important priority sector to provide needed technology push and application of emerging sciences to supplement efforts of National Agriculture Research System (NARS). The overall goal of agriculture biotechnology is to achieve higher productivity and better quality food while reducing resource wastage. Accordingly following priorities have been identified:

a. Policy support

For rational and responsible use of GM technology, requiring high investments with uncertainty and public concerns, it is recommended to revisit 'Swaminathan Report on Agricultural biotechnology (2005)' to develop a policy framework of crops and traits against available technology options and alternatives. Such a policy framework would streamline current research in public and private sectors, guide the regulatory and trade policy.

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.

b. Basic and use Inspired Research

In plant science needs to be rejuvenated with relevance for sustainable agriculture addressing critical research gaps in nutrient uptake, transport and utilization, plant-microbe/insect/parasite interactions, mechanisms underlying growth and metabolism under stress and apomixes. Other areas of research include:

- Pre-breeding research utilizing genomics information and interfaces with wide hybridization, molecular mapping new centre will be created
- Improved photosynthetic, nitrogen fixation and nutrient utilization potential
- Improved reproductive efficiency with regard to yield convertibility
- Protection of yield loss due to stress/climate change
- Mitigation of post-harvest loss
- Enhancement of nutritional value
- Introgression and pyramiding useful genetic loci in diverse germplasm

c. Translational Science and Strategic Research

- 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. This would be operated through BIRAC.

- A few 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.

- In crop biotechnology, the key to developing more productive, robust and climate resilient crops, utilization of natural variation both for qualitative and quantitative traits and molecular mapping of these traits is important. This could be achieved by strengthening pre-breeding and heterosis for production of varieties and hybrids in rice, wheat, cotton, coarse cereal grains, mustard, safflower, sunflower, pigeon pea through network programmes around coordinated centres.

    - Pre-breeding refers to all activities designed to identify desirable characteristics and/or genes from un-adapted materials that cannot be used directly in breeding populations and to transfer these traits to an intermediate set of materials that breeders can use further in producing new varieties for farmers Pre-breeding programs can generate new base populations for breeding programs and also assist in identifying heterotic patterns for hybrid programs. During 12th Plan, a network of 10 prebreeding units would be established in collaboration with SAUs and ICAR. These centres should provide comprehensive, stable and reliable platform of resources and information for the exploitation of genetic diversity, to underpin pre-breeding activities. The key deliverables will take the form of a breeders and pre-breeding 'toolkit' which includes i) genetic markers in the context of reference linkage maps; ii) a defined range of germplasm representing significant, useful allelic variation; and iii) information to place these resources in context of trait variation amenable to breeding selection and iv) maintaining and developing digital data bases of seed and pathogen genetic resources, and enable resolution and introgression of useful variation.

- Research and technology for biofortification to improve the nutrient content of crops

- Newer techniques of post harvest technologies should researched for mycotoxin management, shelf life and bioengineered innovative

products and formulations should be developed for storage and packaging

- Development of Transgenic crops for resistance against biotic & abiotic stresses. High throughput transgenic platforms need to be established

- **Changed management of Agriculture Technology Programme:** A new scheme of governance of translational programmes needs to be put in place totally separate from our competitive science funding system. For this purpose, technology management units fully empowered to monitor and to arrange problem solving consultancy and assistance will be put in place to create an industry level efficiency in management.

3.7.2 Biotechnology for Animal health

(i) Policy Support

- Long term policy for mass immunization against endemic diseases, deworming, supplementing micro/macro nutrients to livestock and poultry.
- Development of supportive and harmonized regulatory environment for authorization of vaccines, diagnostics and therapeutic technologies

(ii) Basic Research Priorities in Host-Parasite/Pathogen Interactions

- Creation of facilities for "Centre of Experimental Parasitology (CEP)" in view of Global Climate Change. Built multi disciplinary strategic research capacity in response to climate change to anticipate and respond to emerging and re-emerging animal diseases including zooneses
- Gut immunity to enteric infection; target delivery of gut immunogen through 'M-cell' to induce mucosal immunity
- Pulmonary immune response to pneumonic agents
- Understanding evasion of host immune response by pathogens and the contribution of host immune genes
- Deciphering the pathogen–driven immune bias for eliciting protective immunity

(iii) Current and emerging areas of research in veterinary science

- Enhancing animal production and traits improvement through genetic interventions
- Newer adjuvants, vaccine delivery systems; development of indigenous viral vectors and use them as vaccine delivery systems
- Genomic medicine-Gene therapy – For relevant conditions
- Development of nano particle or micro-particle based DNA or other vaccines; if receptor mediated delivery is not possible
- Development of DISC (disabled infectious single cycle) viruses as vaccine (alternative to attenuated viruses)
- Establishment of complete molecular epidemiology of endemic infectious/parasitic diseases of livestock, companion animals, birds and wild fauna
- Emerging areas of research in veterinary science
- West Nile Fever in equine and migratory birds
- CCHF and Rift Valley fever in sheep
- Urgent need to continue research and development of new efficient pharmaceuticals to overcome multidrug resistance to bacteria and parasites.
- Integrated management for sustainable worm control in livestock

(iv) Translational Science and Strategic Research in Veterinary Vaccine and Diagnostics

In terms of disease burden and economic loss, major problems on priority for development of new generation vaccines and diagnostics identified.

(a) Vaccines (Table 1)

- Pulmonary immune response to pneumonic agents
- Development of new generation vaccines for cattle, buffaloes, goat, sheep, swine, poultry against brucellosis, haemorrhagic septicaemia, FMD, bovine TB PPR, ORF, ET, Swine fever, ETEC, RV, RD, IBD, FP, duck plague and duck cholera
- Tick vaccines effective against small and large animals; development of cross-protective tick vaccine suitable to Indian condition

(b) Diagnostics (Table 2)

- Development of DIVA and molecular diagnostics for cattle, buffaloes, goat, sheep, swine, poultry against brucellosis, haemorrhagic septicaemia, FMD, bovine TB, PPR, ORF, ET, Swine fever, ETEC, RV, RD, IBD, FP, duck plague and duck cholera.
- Pen side diagnostic tests for leptospira, swine fever, mycoplasma, listeria, Bovine mastitis, viral/bacterial diseases of poultry
- Development of cheap, field level, rapid, single test diagnostic kits (PCR based etc.) for trypanosomiasis, theileriasis, ehrlicosis (dogs-on payment), babesisosis (dogs), subclinical and clinical mastitis

Table-1

	Cattle	**Buffaloes**	**Goats**	**Pigs**	**Mithun**	**Yak**	**Chicken**	**Duck**
Development of new generation vaccine	Brucella, Haemorrhagic septicaemia, FMD,	Brucella, Haemorrhagic septicaemia, FMD	PPR, ORF, ET, FMD	Swine fever, HS, FMD, RV, ETEC	FMD, Brucella, HS	Brucella, FMD	RD, IBD, FP,	Duck plague, Duck cholera
Development of new generation diagnostics	DIVA diagnostics for FMD, Brucella, User friendly tests for FMD, Brucella, Molecular diagnostics.	DIVA diagnostics for FMD, Brucella, User friendly tests for FMD, Brucella, HS Molecular diagnostics.	DIVA diagnostics for FMD, Brucella, PPR User friendly tests for FMD, Brucella, HS, PPR, ORF Molecular diagnostics.	DIVA diagnostics for FMD, CSF User friendly tests for CSF,FMD, RV, ETEC, Molecular diagnostics.	Diagnostics for FMD, Brucella, HS Molecular diagnostics.	Diagnostics for FMD, Brucella, HS Molecular diagnostics.	Diagnostics for RD, IBD, FP Molecular diagnostics	Diagnostics for DP, Molecular diagnostics

Table 2

Priority area	Present status	Status envisaged in future	Road map for achieving this goal	Strategy for implementation of the road map	Performance indicator and outcome
Vaccines and delivery systems and alternate therapeutics	• Use of conventional vaccines • Only one new animal vaccine (PPR) introduced in the last 10 years • Vaccine delivery through parenteral routes • Alternate therapeutics such as siRNA	• Use of new generation vaccines • New vaccines for emerging and re emerging diseases • Mass delivery of ND vaccines through aerosol /oral routes • Alternate therapeutics available for certain diseases such as mastitis	Initiation of work in areas such as • Development of recombinant /DNA vaccines for existing diseases • Marker vaccines • Development of new vaccines • Easy delivery of vaccines through oral, aerosol, transcutaneous routes • Combination vaccines • Work on siRNA targeting cytokines etc in mastitis • Genotype matching of vaccine and field viruses	• Industry-academia collaborative project • Technology transfer from other poultry companies abroad • Large scale field trials in comparison to existing vaccines • Use of adjuvants including genetic adjuvants • No. of vaccines combined and given as a single shot • Research on siRNA for cytokines	• Number of new generation vaccines approved for trial/experimental use • Reduction in 'vaccine shots' • Mass application of vaccines ensuring better vaccine compliance • Availability of siRNA therapeutics in market
New generation Diagnostics	• Laboratory confirmation of clinical diagnosis rare	• Field based diagnostic kits should be used for confirmatory	• Identification and expression of immunogenic proteins for	• Industry– academia collaborative projects for generation of newer diagnostic reagents	• Number of laboratory confirmation techniques used to supplement clinical diagnosis

	• Only conventional reagents used in diagnostic methods • Research being undertaken on generation of recombinant antigens or monoclonal antibodies (mAbs) for diagnosis	diagnosis • All diagnostic kits available should be based on recombinant proteins / mAbs/recombinant antibodies • Alternate diagnostic methods such as aptamer based biosensors, fluorescence polarization assays etc should be available	application in diagnosis • Mass production strategies for such proteins • Development of mAbs, recombinant antibodies using phage display technology, peptide antibodies, aptamers etc.	• Internal and External validation of the reagents / kits developed using these developed reagents • Technology transfer for mass production and field use	• Early and specific diagnosis leading better control
Centre of Excellence in wildlife disease diagnosis	• Laboratory diagnosis rarely being done due to late reporting and unsuitable material submitted for laboratory examination	• Develop expertise in wild life disease diagnosis taking in to consideration these problems unique to wild life	• Use molecular tools in disease diagnosis with non-invasive samples	• Develop expertise and kits for diagnosis of specific diseases such as tuberculosis in elephants, sexing of birds, meat speciation etc	• Better health status of wild animals and more accurate disease prevalence estimates

(v) Facilities/infrastructure requirements relevant to Vaccines/Diagnostics development

- Establish a center of excellence for penside diagnosis in animal diseases; to evaluate and use existing diagnostic reagents to develop them in kit/test for field use and possible commercialization
- Biological resource generation; in-bred chicken lines, certified SPF chickens/eggs, standardized and validated reagents such as hyperimmune serum, antigen etc, antibodies for Veterinary species such as cytokines, TLRs of bovine, chickens etc, resource populations for genetic studies, transected cell line models with animal immune genes e.g. Bovine TLR 7 expressing cell line
- To establish more BSL III/IV laboratories to handle infectious agents/ to study pathogenicity tests
- To establish **National Wild Life Disease Diagnostic Centre** having pathology, microbiology, medicine, and surgery personals

3.7.3 Animal Productivity and Quality

To improve the livestock including poultry for enhancing food production and productivity, a multi pronged approach is required which involves breeding, reproduction technologies, nutrition and health care.

(i) Basic and use inspired Discovery Research

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.

(a) 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 form 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.

The programme on characterization of the rumen microbial environment through metagenomics and next generation sequencing technologies will be launched to understand the process of methanogenesis and develop strategies for suppression of methanogens.

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.

(ii) Translational Science and Strategic Research

High density SNP arrays have been developed in cattle, chicken, dog, pig, sheep and horse etc. Such arrays have been developed on exotic stocks. 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.

(a) 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.

Embryo transfer technology has been standardized in cattle, buffalo, sheep, goat, camel etc. However, due to high cost of hormones/biologicals, the benefit of the technology has not reached the farmers. Therefore, 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.

A major multicentric programme on generating transgenic animals will be launched for enhancing livestock productivity, diseases resistance and production of biopharmaceuticals.

Development of technologies for degradation of lignin and enrichment of animal feeds based on agro-by product residues

(b) Nutrition

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 generating about 500 million metric tonnes of agro-residues every year.

(c) 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.

(d) 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.

3.7.4 Aquaculture and Marine Biotechnology

DBT supported 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.

The non food sector of marine biotechnology offers phenomenal opportunities for process and product development. These resources may be explored for newer applications and identification of novel compounds for a wide variety of applications. Marine environment remains a critical source of products that would include food, bioactive compounds, and biomaterials having medical and industrial applications.

(i) Goals and targets

- Biofuels from marine algae
- Extremophiles
- Novel microbial enzymes
- Metagenomic approaches to bioactive molecules

(ii) 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 up a **National Institute on Marine Biotechnology**

3.8 Value-added Biomass & Products from Natural Resources

The overall objective is to enable sustainable production and enhance the intrinsic value of natural resources for new products developed through synergistic interaction between industry, academia and Government.

Biodiversity characterization studies held at spatial and non-spatial level have provided the most detailed documentation of the rich biodiversity in the country. This should now be strongly exploited for product development. There is acute shortage of trained manpower to efficiently utilize natural resources; whatever expertise available is scattered at different places across the country, there is no central place where all expertise for complete drug discovery exists. Therefore there is a need to:

- 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

The following proposals are made:

During the 12th Plan the activities under National Bioresource Development Board would continue. The thrust would be on value added products from Biomass and Bioresource. With the rich Biomass and Bioresource reserve, the main emphasis is to move towards a Biobased economy to achieve this programmes need to be supported for both basic and translational research. This could be in four major categories:-

- Biofuel-Energy Biosciences
- Bioindustrial products
- Bioprospecting for bioproducts
- Secondary Agriculture

The Characterization and Inventorization of Resources and Capacity Building from school level are important components which would strengthen and add value to the development of technologies for a sustainable Bioeconomy.

(i) Bioprospecting for Bioproducts

The **Vision** is to enable sustainable utilization and enhance the intrinsic value of natural resources for new products developed through synergistic interaction between industry, academia and Government.

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

Strategic Research Programmes

Launch a National Mission on Bioprospecting and Product Development from Natural Resources

- Microbial prospecting for industrially important compounds
- Prospecting of other natural resources – Fungi, Lichens etc.
- Chemoprospecting for high value phytochemicals from Seabuckthorn which is a rich source of antioxidants and finds immense use in nutaceutical and cosmaceuticals.
- Prospecting and product development of non-timber forest product- Gums, resins, tannins, mucilages
- Commissioning study to find out the global markets and priorities for various natural products, market intelligence on natural products to be an integral component

Setting up of a National Centre for Drug Discovery and Product Development from Natural Resources

Focus:

- Early discovery: automated rediscovery, automated chemistry;
- Development: preclinicals, DMPK, animal studies all under GLP practices accredited to FDA standards;

Strategy:

- Careful identification of priorities on natural products based on market potential and commercial aspects
- To make available multi-disciplinary facilities
- Carry out translational programmes for conversion of available leads into drugs from natural resources

Setting up of Repository for Extracts, Phytochemicals & Botanical Reference Standards for Quality Assurance of Plant-based Drugs

- Facility to act as natural product libraries
- Accessible to researchers across academic institutions and industries
- Maintaining comprehensive information system for all research leads generated from natural resources

(ii) Biochemicals and Biomaterials

The bio-refinery concept of bio-based economy aims to make optimal use of plant components. It should be capable of using all kinds of sustainable produced biomass, including wood and dedicated agricultural crops, plant and animal derived waste, municipal waste and aquatic biomass (algae, seaweeds), having an ability to replace the fossil-energy based products in an economically viable manner . In bio-refinery concept, feedstock selection, logistics, and bio-refining techniques are used to optimize valorisation of available functionalities and biomass utilization. Though, currently, in niche chemical industries, biomass is hardly used as a chemical feedstock but it is being envisaged that the biomass can contribute to a significant reduction in fossil fuel feedstock components for bio-chemicals production. Biomass is based upon a carbon backbone and contains much other interesting chemical functionality in contrast to all other alternative energy sources. Applications should be focused on best employing the unique properties of biomass. Efficient and sustainable use of the unique properties of biomass, which is of paramount importance, can be enhanced by the use of bio-refinery processes and their products, which will form the foundation of a future bio-based economy.

Presently there are, **Nine Value Added** (below mentioned Figure) chemicals/bio-chemicals and bio-fuels namely, acetic acid, methanol, ethanol, butanol, ethylene, mono ethylene glycol, lactic acid, green diesel/ gasoline and acetone, which are primarily prevalent in the market, either produced through bio or petro routes.

However, amongst them the **Most Prominent Value Added** bio-chemicals/ bio-fuels in India perspective include **Acetic acid, Lactic acid, Ethanol and Green Diesel** programme will be supported. In addition the programme will also focus on developing a large numbers of Biomaterials from biomass including Bioplastics.

(iii) Secondary Agriculture

Priority areas which will be supported for both Basic and Applied research and product development include both (a) Food and Feed related Agriculture Industries (b) Non-food Agriculture Product Industries. Since the by-products or 'wastes' of food processing industry are all "natural resources", they have a huge potential waiting to be tapped in the form of nutraceuticals, mucilages and food colours, or as substrates for potential fermentative production of biomolecules which are currently being practiced. Development of analytical facilities and trained manpower would be a pre-requisite, the main requirement is the willingness of the industries to seriously look into these issues.

Some of the major Industries and Byproducts to be supported and specific interventions in gap area to be addressed are:

- Food and Feed grains and their Byproducts
  a) Soybean
  b) Other Grain Products and Byproducts

- Horticulture and Food processing industries
  a) Fruit and vegetable processing
  b) High-Value Secondary Food Products
  c) Byproducts from fruits and Vegetables
  d) Bioactive Molecules from Biomass

- Medicinal and Aromatic Plants Industries
  a) Pure Herbs and Herbal Extracts
  b) R&D-Based Phytoceuticals and Novel Medicinal Compounds
  c) Functional Foods
  d) Aromatic Plants Industries in India

- Animal Products and Byproducts
  a) Poultry and Fish Feed
  b) Other Animal Byproducts

- Alternate crops (Bioresource) and Technologies
    a) Enzymes and Chemicals
    b) Marine Products
    c) Other Bioresources
    d) Biorefinaries

Characterization, Inventorization and Repositories

- Programmes on spatial and non spatial inventorization and the Indian Bioresources Information Network (IBIN) will continue to be supported this is the largest Biodiversity database.
- To create a network of gene banks for conservation and supply of germplasm of natural resources to academia and industry
- A list of target species to be conserved in gene banks to be carefully drawn based on availability and commercial importance
- Characterization of germplasm using chemical and molecular methods
- Develop linkages with global gene banks

3.9 Energy Biosciences - Biofuel and Green Chemistry

The **vision** is to create a Biotechnology enterprise equipped with viable green and clean technologies. The Vision outlines what our long-term goals should be if we are to truly achieve cost-effective clean energy development with recent refinements to the technology. The Vision now provides a complete framework for achieving the set Goals and Targets.

Goals and Targets:

- 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 Bio oil.

Strategy for next five years:

- Strengthening existing centres of excellence.
- Create new centres of excellence in gap areas

- 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 important to encourage the existing one as well as to create new research centres for focusing research in relevant field
- Private sector involvement would be encouraged 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.
- Collaborations and strategy alliance building with pockets of excellence-National and Global
- Address regulatory gaps

Implementation Modalities

- Launch a Strategic Research Programme towards achieving the Goal of 20% blending by 2025.
- Set up atleast 5 Joint centres on the similar pattern as DBT-ICT and DBT-IOCL.
- Create a Team India of at least 100 scientists in interdisciplinary Research Areas.
- 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.
- Train atleast 100 Post Doctoral Overseas in specialized areas such as Synthetic Biology, Enzyme and Protein Engineering, Metabolic Engineering, Systems Biology etc.
- Attract atleast 25 overseas scientists to the centre through Energy Bioscience Fellowship and Institute atleast 5 chairs, one in each centre.

Science Programme Strategy

- Strategic Research Program : Commercial production of Biofuel from different feedstocks for 20% Blending development of cutting edge technology for conversion to Biofuel interventions to address gap areas: Biodiesel, Bioethanol, Green Diesel, Algal Biofuel, Biobutanol, Biohydrogen, Biochemicals and Fuel Cells
- Basic Research Science Project

(a) Feedstock improvement
(b) Algal Biofuels: Microalgae, Macroalgae

3.10 Medical Biotechnology and Allied Areas

3.10.1 Genomics and Health

The 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.

Genomics driven biology and product innovation will drive the future world of customised medicine. This approach requires genomic/proteomics based biomarkers for diagnosis of sub groups on customised biologicals as drugs are focussed. We need to prepare our research enterprise, through an effective institutional network to promote this model of drug development linked to PPP.

Specifics and Tasks that are required to achieve this Vision include

(a) **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, and by genomics driven biology and new drug design. Biomarkers are an essential component of any customized therapy.

(b) **More Widespread Genetic Testing Services** should be provided for diseases with chromosomal aberrations or disorders where underlying culprits are highly penetrant genes.

(c) **Focussed Research in understanding of mechanisms of predisposition, initiation and progression of diseases** that have multiple low-penetrant genes as underlying causes is required.

(d) **Epidemiology and Genomics which requires** maintenance of electronic medical records in hospitals, including relevant genomic information.

(e) **Genomics Education** A well-trained workforce is required for better implementation of genetic principles in clinical studies and enhancing Genomics research.

(f) Institutional Mechanisms for Human Genome Research

(g) **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.

(h) **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

(i) **Basic and Translational Research**

A. Continuation of programmes (Number of projects including infrastructure, construction activities and financial implications)
B. New programmes proposed

- Major projects, Networks, Centres and facilities
- New initiatives in emerging and evolving areas
- Continue implementation of the ongoing activities in the area of human genetics and genome analysis
- Implementation of India specific International Cancer Genome Project - oral cancer
- Novel gene identification for monogenic and complex disorders
- Validation of known SNPs, identification of population-specific novel SNPs, generation of population-specific SNP databases and subsequent use of these in whole genome scanning approaches for linkage and association studies
- Large scale mutation screening in genetic disorders with high geneotype-phenotype correlation and generation of pathogeneic mutation databases for Indian populations
- Detailed genotype–phenotype correlation studies for the mutations, SNPs, haplotypes etc.

- Functional genomics including biochemical, cell biological and other relevant assays for gene polymorphisms
- Animal models of human genetic diseases for detailed functional genomic investigations including
- Research in Mouse Molecular genetics: Animal models for human disease gene conditions, to answer specific questions relating to human disease using mouse models, Ability to create, Knock out, Knock in, Site directed mutations, transgenic animals etc.
- Translational Genomics
- Epidemiology and Genomics

C. Genomics Education

- 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

i. Creating Genomics Awareness in General Public and Healthcare providers

3.10.2 Vaccines

Our long term vision is to upgrade quality and breadth of the basic and use inspired research relevant to pathogen host interaction, innate, acquired, compartmentalized immune response, factors effecting host responses and in general move from mouse to human research as it is more widely generalizable. A centre for human immunology will be established at the National Institute of Immunology partnered with Translational Health Science Technology Institute.

In the 11^{th} plan many vaccine candidates have advanced into late clinical trials and it is critical to maintain the momentum, using collaborative innovation networks and public-private partnership as our tools.

Our approach can be summarized as follows:

- identify all infectious and non infectious candidates where preventive or therapeutic vaccination would help.

- Develop detailed molecular epidemiology knowledge in the country, strain variability, immunity of natural infection, environmental factors modifying immune response.
- Identifying potential approaches to candidate design, **empirical** and traditional, genomics and computational science guided immunogen design and using novel platform technologies and adjuvants for delivery.
- Preclinical and clinical development through clinical translational centres.
- Continuous work on basic biology of infection disease, discovery work on immune system and protective immunity, structural biology and computation science to improve immunogen design.

During the Plan, we will continue the preclinical and clinical development of existing vaccines candidates through our collaborative innovation, PPP based approach.

Specific programme for 12th Plan

- Vaccine science immunity at **extremes of** ages, mucosal system and mucosal immunity, antigen presentation and processing, microbiotome and immunity, immunology of the reproductive tract, immune memory, molecular basis of acquired immunity following natural infection or vaccination.
- Specific biology of each major pathogen in *in-vivo*
- Vaccine related technologies.
- Novel platform for immune design and delivery through multiple sites.
- High throughput systems for assessing protective immunity in humans, adjuvants, stabilizers, computational science guided immunogen design, reverse vaccinology for vaccine development.
- Research resources – Animal model of disease and large animals for assessing safety, immunogenicity, high throughput systems for human immunology, pathogen repositories of major pathogens, toxicology facilities, clinical trial centres, infections science centres with population based ID programmes, GMP pilot lot production and biosafety II and III.

Translational Science and Strategic Research

- Continue implementation of vaccine development projects which were initiated during 11th plan under Vaccine Grand Challenge Programme such as rotavirus, cholera, malaria, TB, JEV, DNA based rabies (animal, human), Vi-polysaccharide typhoid, HPV, HIV/AIDS, to bring them to a logical conclusion.

Short-term: To develop and commercialize vaccines against Rotavirus, Cholera, Typhoid and Rabies human (DNA based)

Mid-Term: To take into pre-clinical and clinical development new vaccine candidates : Malaria, Dengue, Tuberculosis and Japanese Encephalitis, Human Papilloma Vaccines, Chikungunya, HIV, Non oral Polio

Long-Term: To investigate new approaches for development of affordable vaccines against Cancer (HPV), Polio (normal) and Pneumococcus protein based, hepatic C, cancer.

Grand Challenges Projects in vaccines

- Improved Vaccines - Create effective single-dose vaccines
- Prepare vaccines that do not require refrigeration
- Develop needle-free delivery systems for vaccines
- Create New Vaccines-Devise reliable testing systems for new vaccines
- Solve how to design antigens for effective, protective immunity
- Learn which immunological responses provide immunity.
- Ways to overcome limited immunogenicity of oral vaccines in India.

Infrastructure

- To set up clinical academic centres in medical schools and universities and (i) infection molecular epidemiology (ii) human immunology (iii) In vivo testing in animals and humans model.
- National epidemiological diagnostic management consortia and centre for epidemiological data storage and management for rapid response to infectious diseases. (electronic based).
- 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 establish internationally partnered infection science – vaccine partnership "Centers of excellence for vaccine research" to rope overseas talent to facilitate research on difficult to develop vaccines.

3.10.3 Infectious Diseases

Infectious diseases continue to be a serious burden on national economy despite advances in science, technology and medicine. The vision of the Department 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

(i) Basic Research

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 diagnosis and treatment. The following broad areas have been identified:

- 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

(ii) Translational Science and Strategic 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, which are 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

infectious diseases 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.

(iii) Infrastructure and new institutional mechanism

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 **'Infection Science Research & Training Centres'** in strategic locations across the Country, in medical schools and universities as grant in aid (3) and programmed based (3).

A twining institute between North-East Region and Faridabad Cluster (THSTI and RCB) for Collaborative research and training of scientific personnel would be a good starting point. The education, training and research provided by this centre would be a much-needed resource for the North Eastern region and the entire Country.

3.10.4 Chronic Disease Research

Biology under lying chronic diseases and development of tools for prediction, early diagnosis, detection for prognostication of complications and response to therapy of number of chronic diseases is a major priority. The lack of capacity in this area is a deep concern, given the huge burden of chronic disease in India. This is a challenge

that needs to be addressed in this Plan. It is critical to develop capacity, as existing demand for funds in the area is suboptimal. The major diseases for focus in India are cancer, diabetes, bone and cartilage disease, chronic liver and kidney disease, cardiovascular disease and CNS disorder – depression, Parkinson, dementia, epilepsy.

Our programme for 12th Plan will be as follows:

- Promote basic research in immunity, inflammation, aging using traditional and systems biology approach.
- Disease biology research
- Genomics and epigenatics as basis of disease biology targeted to identified sub groups where gene-disease association is high
- Characterizing signaling pathways within defined patient sub groups.
- Develop biomarkers and novel therapeutic approaches and evaluates them in PPP model. This can be achieved only by creating dedicated centres with translational capacity both in identified public institutions and capacity in private sector.
- Promote development of Cell based therapy and regenerative medicine for key chronic diseases.
- Build research resources – next generation sequence, proteomics, hybridoma and human and antibodies, toxicology, protein characterization and others.

Specific disease based programmes for focus

- Genomics, Biology, diagnostic and biomarkers, biodrugs, rehabilitation engineering and clinical trials.

    - Cancer
    - Bone and Cartilage
    - Diabetes
    - Chronic Lung Disease
    - Chronic Liver Disease
    - Major neurological disease

- **Mechanism to be used**

    - Adhoc projects through RFP's .
    - Establishment of new centres in existing institutions as per 3 categories outlined already.

- Glue Grants between basic science institutions, university Departments and medical schools.
- Graduate school in each of above areas.
- Overseas training of medical scientists and in medical orientation for basic researches.
- Resources for drug development, biomarker discovery, biobanks.
- **A major centre of chronic disease biology at Faridabad cluster as an autonomous institute with strong translational resources.**

➢ **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 cancer 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 similar biologics

- **Mental Illness & Neurological Disorders**

  - Multidisciplinary research the areas of Neuroscience and Multi-scale modelling of the brain; Major brain disorders relevant for our country, Malnutrition and brain, Neuroinfection, Brain tumors and hypoxia, Neuroethology, Stem cell research, Neuroprostheses, Epilepsy and Injury, Neurodegenerative diseases
  - Development of animal models
  - Developing new pharmacological & non-pharmacological therapies, including cognitive retraining paradigms
  - Affordable and non-invasive diagnostic approaches including structural, functional and molecular imaging

- **Infrastructure**

  - Establishing new centers, one each for 2-3 Chronic Diseases of national relevance
  - Setting up informatics centres for reliable data on disease burden and formulating prospective cohorts for chronic diseases with bio-banking
  - Repositories of biological material for example CSF, serum, DNA, imaging data as well as standardized clinical information for targeted disease

3.10.5 Stem Cell Research and Regenerative Medicine

The vision programme is to achieve a leadership position in the areas of developmental biology, disease models/drug development and regenerative medicine.

- **Critical areas which need attention**

  (a) Developmental biology
  (b) Disease models and drug development
  (c) Regenerative medicine

(i) Policy

  - To revise regulatory guidelines for research and therapeutic applications of stem cells
  - Encourage public-private partnership in these ventures

(ii) Basic and translational Research

- Basic biology of all types of stem cells (embryonic, adult, induced piluripotent stem cells etc.)
- Translational and clinical research using adult stem cells such as haematopoeitic stem cells, mesenchymal stem cells, peripheral progenitor cells etc.
- Use of stem cell in drug discovery for screening candidate and toxicology
- Application of adult stem cells for tissue engineering and repair
- Developmental Biology: Innovative models for studying developmental biology in models such as Drosophila – lower animals/higher animals, cell based models (ESC/iPS)
- Disease models and drug development: Research to develop Innovative disease models in higher animals (farm animals/non-human primates) and disease specific cell based models for cancers/hereditary genetic diseases (ESC/iPS)
- Tissue engineering: To explore the potential of adult stem cells for tissue regeneration and repair and cell therapy. Clinical trials of adult stem cell based therapies (early and advanced)

(iii) Infrastructure

- Establish two centers for regenerative medicine/cell based therapy/bioengineering in the country
- To generate patient specific cell lines and establish Cell and tissue banking/repository
- To set up five Centres for regenerative medicine/cell based therapy/bioengineering in existing or new medical schools, engineering schools and institutions

3.10.6 Medical Devices and Implants

The long term vision is to boost high order of innovation entrepreneurship for developing affordable implants and devices for the large and poor population of the country.

Critical areas which need attention

Medical devices and implants

In-vitro diagnostics

(i) Policy

- Reforms regulatory and policy framework for enhancing innovation including development. Standards and protocol testing for biodesign products
- Reducing the import of medical devices by indigenous innovation and fast market implementation

(ii) Translational Science and Strategic Research

- 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
- Expansion of biodesign concept in other IITs, medical schools and institutes across the country
- To create an effective 'National Biodesign Alliance' with the partnering institutions (virtual) with a secretariat at THSTI, Faridabad as a virtual National Institute. The alliance will have strong linkage to industry and Global partners
- 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.
- To develop simple, rapid, indigenous, low cost medical devices and implants by applying four AAAAs i.e. affordability, accessibility, availability and appropriateness.

(iii) Infrastructure

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

3.11 Food and Nutritional Security

Vision is to employ food fortification and biofortification to address micronutrient deficiencies, nutrigenomics of metabolic syndrome, food safety and development of functional feeds.

Critical areas

- Food fortification and biofortification of food crops for addressal of micronutrient deficiencies with a special focus on iron deficiency anemia
- Child malnutrition with a focus on severe acute malnutrition (SAM)
- Strategies for treatment and prevention of diet related chronic diseases eg. Obesity and Diabetes
- Functional foods and nutraceuticals for health promotion
- Beneficial role of probiotics and prebiotics in human health
- Shelf life extension of foods
- Food safety for prevention of food borne diseases and health hazards
- Human resource development in the area of Food and Nutrition Sciences

The main thrust areas of food and nutrition were during 11^{th} plan were food fortification, food safety, molecular detection of GM foods, probiotics for human health, addressing micronutrient deficiencies, development of low cost foods supplements and utilization of agricultural residues for value added products. In addition four institutions supported for capacity building in the area of food science and technology. Continuing on these foundations the following programmes are proposed for 12^{th} plan:

(i) Policy

Alliance among DBT and other 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"

- Develop technology assessment capacity and standard practices for acquisition of critical food fortification and biofortification technologies

(ii) Basic and Translational Research

- 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 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 high bioavailability
- 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 malnutrition conditions
- Development of nutraceuticals and functional foods for the prevention of diabetes, obesity, cardiovascular disease etc.
- Identification of probiotics and validation of their 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
- 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
- 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

(iii) Infrastructure

- 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
- Establishment of validation centres for nutrition claims with a focus to collect valid data on the phytochemical components of different Indian foods
- 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

3.12 Biotechnology for Social Development

The vision of Department of Biotechnology in the social sector is to develop and adopt simple technologies for improving family incomes, nutrition, health and to reduce inequalities through use of precision tool and techniques for future creation of wealth ensuring social justice especially for the welfare of the poor.

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 diffuse solutions and technologies available in the country that are not reaching to people
- Vulnerability
- Vocational training
- Knowledge resources and information technology
- Green energy and bio-fuel
- Creation of on-farm/non-farm employment
- Integrated livestock based farming

During 11^{th} plan, biotechnology based programme has been implemented with a mission to address social development goals to benefit target population viz. Women, SC/ST and Rural farmers through skill development with agro-based, horticulture, animal husbandry, secondary agriculture, value based product and process development through training and demonstration programmes undertaken in various income and employment generation activities. The emphasis was given on diffusion of proven and field tested technical know-how to the end users with an approach reaching the unreached through outreach programme. Keeping in view of the lessons learnt in the implementation of the programme so far some innovative schemes are proposed for the 12^{th} plan:

- Continue projects/ programme mode support to some extent with certain modification/ revisions of funding guidelines for the social sector
- Focus on projects in the areas
    - Farm-based technologies

- Health-based technologies
- Waste disposal and water sanitation
- Translation of mass use technologies (scaling at population level)
  - Farm and non-farm innovations
  - Instituting management perspective
- Social mobilizing and Marketing

(i) Establishing Institutional Framework

- Establishment of 'Rural Technological Innovation & Application Centre' on a sustainable basis in each region including north east
- Establishing Centres of Excellence for social innovation and invention
- Supporting prominent NGOs for diffusion and evaluation of technologies
- Establish centers of Rural Entrepreneurship Development
- Establish incubator facilities for entrepreneurs to prosper in rural industrialization in biotechnology.
- Linkage with other host for profit agencies for implementation of projects in joint collaborations in livelihood sector.
- Giving equal sharing benefits to farmers in patenting/ innovations and traditional knowledge.
- Leadership development
  - Identifying elite core
  - Repackaging training programs to match private sector
- Assessing determinants of technology acceptance by communities / businesses
  - Penetration and coverage
  - Cost-effectiveness/economic evaluation
  - Cultural and social appropriateness
  - Social entrepreneurship
  - Other factors
- Technology evaluation, Standardization and accreditation

3.13 Bio-Processing and Industrial Biotechnology

Vision is to produce 20% of India's bulk chemicals by biocatalysis/bioprocessing technologies; facilitate creation of manufacturing companies with substantially indigenous IP.

Strategies for 12th Plan

- **Setting-up of 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. A contract carrier path is critical to rapid creation of such extramural entities linked to institutions.

- **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.

- **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.

- **Setting-up 'Technology Development Centres' within existing academic Institutes**
  - 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
  - Centres will also work closely with industries and pilot test the technologies developed by the centres or elsewhere, at a reasonable scale and engage industry to assist them to take the developed technologies to commercialization

3.14 Bio-clusters, Incubators, Entrepreneurship, Innovation Support to Industry, Intellectual Property and Technology Management

During the 11th Plan, several initiatives have been taken such as Small Business Industry Research Initiatives (SBIRI), Biotech Industry Partnership Programme (BIPP) for public-private partnerships. In order to provide technical, financial and

other required innovation services to promote the growth of biotech industry, particularly, start-ups and Small and Medium Enterprises to meet wider social needs eastablishment of Biotechnology Industry Research Assistance Council (BIRAC) has also been approved as Section 25 Company for the following activities:

- Innovation funding
- Capacity building and mentoring programme
- Technology development programme
- Initiating technology acquisition
- Landscape analysis and technology mapping
- Support services for policy and analysis etc

In addition, Biotech Parks/Incubators in collaboration with State Governments will also be established.

While all the above activities continue with reforms based on experience, the activity will be scaled up during 12th Plan **with a vision is to create Indian enterprises with sustainable competitive advantage to deliver affordable products through synergistic interaction of public and private sector.** The various initiatives include:

(i) **Expanding the Industry Innovation Funding Schemes:** beyond SBIRI and BIPP schemes.

- Ignition Grant Scheme is being launched by the end of 11th plan. The grant will be available to individuals or a team of individuals (and not institutions) - in partnership with private investment agencies as a co-investment - that will help mature nascent ideas into to a stage where a startup company can be envisioned. This will be for all the potential entrepreneurs and Biotechnology industry focused researchers who have an exciting idea which may be in the nascent and planning stage and have an unmet need for mentorship and funding from Angel Investors in India. BIRAC would enter this space as a facilitator along with an able partner to support and nurture these high risk early starters and their concepts.

- Funding for Technology Access, Acquisition and Licensing: Technology acquisition scheme will be initiated to acquire important technologies or licenses in the area of Biotechnology for highest national interest. This will include licensing of Genes, Microbial expression system etc. and would help accelerate cost effective product

development. This scheme would help industry in developing product or range of products or services in the priority social sector areas of agriculture, control of major diseases, green manufacturing, bio energy etc. **Technology data warehouse will be maintained for** 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
- Nurturing collaborative research in translational validation
- Product commercialization funding
- Provision for "**Bridge Funding**" for firms to function while they are between successive private equity funding or when they are planning for their IPOs. Funds also should be made available for start-ups**,** to file for patents across different geographies as the cost for filing such patents could be prohibitive

(ii) Support bio-clusters with Business Incubation Infrastructure, Technology Validation and Scale-Up Infrastructure

It is proposed to set up 3-5 more bio-clusters in addition to 3 bio-clusters (Faridabad, Bangaluru and Mohali) in 3-5 zones of the country (North, South, West, East and Central)**.** The clusters may require creation of technology incubators, bio parks, innovation centres, business and entrepreneurship development units under a cluster board as a Section 25 Company or society. These clusters will be located close to existing institutions that can be strengthened with additional programme based niche centres. The selection will be through a competitive process.

(iii) Institutional Level Capacity for Technology Management

Over 20 Technology Transfer Organizations (TTO) spread across the country:

- with 10 professionals per institution, the need for minimum of 200 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

(iv) Policy support

A new bill on 'Protection and Utilization of Public Funded Intellectual Property' will be expedited through parliamentary process.

(v) 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.

Two centres for entrepreneurship learning and education will be established.

3.15 New Institutions Proposed During 12th Plan Period

3.15.1 National Institute of Marine and Microbial Biotechnology

EFC of this institute has been pending in inter-ministerial consultations. The location for the institute and techno-economic feasibility has already been worked out. The major objective of the institute is focus on the non food sector resources in the country. The key areas of research would be marine extremophiles; marine pharmaceuticals and bioactive compounds; marine biomaterials; marine enzymes; bioremediation; marine genomics; marine nanotech; marine algae as a source of biodiesel; and very selected upstream areas of mariculture technologies. The NIMB will house a number of marine biotech start up companies and provide a strong leadership in the country for translational research and process/product development. A continuous and dynamic linkage with the marine biotech industry will be maintained to foster its development.

3.15.2 Biotechnology Regulatory Authority of India (BRAI)

The Authority will be an independent, autonomous, statutory agency established through the act of parliament by the Government of India to safeguard the health and safety of the people of India and to protect the environment by identifying risks posed by, or as a result of, modern biotechnology and managing those risks through regulating the safe development and deployment of biotechnology products and processes. The Authority will be responsible for regulating the research, transport, import, manufacture and use of organisms and products in health care, agriculture,

veterinary and environment. The BRAI bill after cabinet approval has been tabled in Lok Sabha for introduction. A detailed establishment plan has been prepared with requirements of human resource, infrastructure and managerial aspects.

3.15.3 Institute of Bioinformatics and Computational Biology

The proposal made in 11th plan was discussed in detail with several stakeholders and new proposal is made. The proposed Institute's main goal is to empower scientists and researchers to develop new powerful tools for large scale analysis of the data, developing models and hypothesis regarding different biological processes. These tools can be used to develop new applications related Omics and system biology. The Institute will also make the required tools and databases accessible to the Indian scientific community. The Institute shall operate on a collaborative mode involving faculty, professional staff and students from Universities, IITs, medical Schools at one hand and Industry on the other hand.

3.15.4 Institute of Biodesign, Bioscience and Bioengineering

The main objective of the institute is basic and translational research, education and training blending academic, industry, and government partnerships to develop and commercialize innovative, life sciences-based technologies. The research groups will be led by multidisciplinary scientists belong to disciplines of cellular and molecular biology, computational biology, Physics and Physical chemistry, medicine, chemical and mechanical engineering, virology, or materials science and engineering. he Institute addresses questions in basic life sciences as well as their implications in human biology in health, disease, diagnostics and therapeutics. The facilities include:biomedical image analysis; biomedical instrumentation; biomedical signal processing & e-health; biomedical ultrasonics & biotherapy laboratory; drug and vaccine delivery, fluidics and biocomplexity; robotics ;intelligent patient monitoring; orthopaedic biomedical engineering; physiological understanding through modelling, monitoring & analysis; tissue engineering & bioprocessing. The research shall be focussed on biomaterials, molecular sensors, neuro-prosthetics, biomems, regenerative biosciences and engineering, medical devises and implants. The institute shall supported by medical centre and global partnerships.

3.15.5 Institute of Chronic Disease Science and Biotechnology

The mandate is to undertake, aid, promote, guide and coordinate use inspired basic and translational research of a high caliber in basic and applied on the causes, prevention and treatment of a broad range of diseases such as stroke, heart disease, hypertension, kidney disease, and diabetes. Some focused areas research include: advanced cell based therapies; bioengineering, imaging technology and informatics ; cardiovascular; bone and joint research; clinical engineering research; clinical research; clinical studies in health and disease; molecular biology and mechanisms of disease; obesity biology; skeletal muscle pathophysiology research; veterinary clinical research etc. Education and training leading to Ph.D. degree; organizing workshops, seminars, symposia, training, programmes of specialized nature and to serve as a national reference centre and provide consultancy services are other activities.

3.15.6 Infectious Science and Biotechnology Institute in North East (Linking to THSTI as partner for Training and Education)

The Institute will be established in collaboration with Translational Health Science and Technology Institute (THSTI) in North Eastern Region. The objective is to pursue an integrated strategy involving research from the gene to population and including basic to applied to clinical research addressing specific needs of infectious diseases of the region. The focus shall be on infection research, covering a range of human and animal pathogens and using an array of approaches. These include looking at the impact diseases have on populations (epidemiology); the evolution of the pathogen; the immune response that develop to fight the pathogens and prevent disease; the molecular basis of pathogen virulence, all of which contribute to better diagnosis and treatment of disease, e.g. through vaccine and drug development.

3.16 Expanding Existing Autonomous R&D Institutions for setting up of Innovation and Translation Centres and up gradation of Infrastructure

The achievements of 14 autonomous R&D institutions established before and during the 11^{th} Plan were reviewed by the working group in terms of scientific performance and fulfilling the objectives of EFC of new institutions. The following observations were made:

- The institutions established before 11^{th} plan are facing problems of obsolesce in terms of equipment and infrastructure
- Some of the institutions do not have guest houses, conference rooms and residential facility for faculty

- The excellent basic research is not supported by adequate innovation and translation services
- The EFC approved 11th plan institutions have been provided with sub-critical budgets and require additional budget beyond EFC value to fulfill the committed objectives

Recognizing the above issues and the pace of progress at international level in life science and allied technologies and to enhance the capacity of the institutions for advanced research, infrastructure, human resource to be competitive globally it was recommended to expand existing autonomous R&D institutions for setting up of innovation and translation centres and upgrade the infrastructure and equipment. Along with these, it was also suggested to invest in cutting edge areas of science such as system biology, synthetic biology, nanobiology etc.

The detailed requirements and specific proposals recommended for each institution is given below:

3.16.1 National Institute of Immunology, New Delhi

The Institute will continue its efforts in twelfth plan in advancing our knowledge in immunological sciences through high quality research in Immunology. These programmes will extend the unique blend of expertise at the Institute for actual use by the health care sector. They involve extensive collaborations, both nationally with other sister institutions and internationally with academic centres across the world. The current emphasis is to develop technologies and innovative solutions for healthcare problems relevant to India. The present plan aims at developing innovative and affordable solutions for a whole range of diseases that afflict the various sections of the society to advance the health and wellbeing of the developing world, particularly the Indian population. The four primary areas of broad significance are - immunity and infection, molecular design, gene regulation, reproduction and development.

Basic Research in Immunology

The institute has strong strength in Immunology and continues to do basic research to find out the intervention strategies for the infectious and immunity related diseases. Specifically, the broad objectives of our research programme and ancillary activities will be:

(i) **Infectious Diseases:** Institute extensively studies the basic biology of the infectious diseases such as TB, Malaria, AIDS/HIV and their impact on the immunity system. Now, the institute plans to further elucidate the mechanisms used by the immune system in responding to infectious pathogens so as to provide guiding principles for preventive, diagnostic and curative strategies. Molecular characterization of the strategies used by a variety of pathogens in causing infection and disease and their ways of intervention for the development of drugs against infectious diseases.

(ii) **Reproductive Biology:** Analysis of the developmental and genetic mechanism related to the process of reproduction and development of vaccines for the animals. Also to understand how these processes are correlated with various other factors such as environmental influence and creation of transgenic or knock outs to understand the basic reproductive processes and their correlation with the immune system.

(iii) **Basic Molecular Biology:** Delineation and understanding the fundamental process of DNA replication and channels of flow of genetic information and possible pathways involved in these processes especially with regard to immune system and understanding the genetic repertoire of antibodies formation. Special emphasis will be on genomics-based approaches.

Development of understanding the role of carbohydrate based molecules in delineating the mechanism of fundamental biological and immunological processes.

Dissection of the fundamental rules of molecular design and recognition, especially for protein molecules by cutting-edge research in the post-genomic field of proteomics so as to provide the framework for rational optimization of lead molecule activity in drug design programmes

(iv) **Biomarkers:** Genomic studies of human and animal genomes and to undertake the germline genetics in both the systems to understand the origin of human genetic diseases and identification of suitable biomarkers with the possible targets of their interference.

(v) **Aging:** Identification of signaling pathways leads to aging and also identification of modulators which might intervene with the process of aging.

(vi) **Infection and Immunity:** Understanding the basic mechanism involved in the differentiation of various immune cell types such as B & T cells and analyzing their role through metabolic glycan engineering at genomic level and applies the knowledge in pathophysiological conditions.

(vii) **Product Development:** Delivery of industrial products either through modification of the existing systems or development of novel techniques through cellular or tissue engineering.

(viii) **Knowledge Enhancement:** Dissemination and upgradation of scientific information both through professional journals to the worldwide community of scholars, and through symposia, conference and public lectures to the community at large around

Vertical Translational Research Programme

Three distinct directions are planned in this area:

Design of novel inhibitors for decimating pathogens

A programme dedicated to research on novel approaches for development of potent agents against the major infectious diseases, tuberculosis and malaria may be established jointly by the National Institute of Immunology and Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR).

Identification of new lead molecules of potential therapeutic interest through a combination of approaches integrating traditional sources of knowledge, current advances in combinatorial chemistry as well as the futuristic genomics-based predictions.

Anti-viral microbicides and vaccines development

Institute has earlier developed a method of for one-pot synthesis of aminoglycoside antibiotics–peptide conjugates. The pure form of the bio-conjugates is under bio-efficacy testing by profiling the HIV replication inhibition *in-vitro* using Indian isolates of HIV.

The technology for the Rota-virus vaccine has been transferred to M/s Bharat Biotech, Hyderabad. This vaccine aims to reduce the incidence of diarrhea or its severity in neonatal children. The vaccine entered into Clinical trial Phase-III trial. These trails

are supported by DBT together with PATH. The institute also making sustained efforts to design a better vaccine candidate for JEV and HPV virus.

Cancer diagnostics and therapeutics

Dissecting the specific molecular anatomy of a tumor is likely to be critical for the development of more specific, efficacious and safer cancer treatments that can be based on an individual tumor's oncogenic mechanisms. Towards this end, a cancer research programme involving a network of international as well as national collaborations is being initiated in cooperation with Centre for Cancer Research & Cell Biology at Queen's University, Belfast and India Institute of Medical Sciences (AIIMS), Safdarjung and Moolchand hospitals to develop future research in the bench to bedside direction, to determine the cellular and molecular mechanisms involved.

Establishment of Innovation foundation

The experience with technology transfer agreements has brought NII to the opinion that well-developed products of great potential are not reaching the marketplace as consequences of two problems. One is a lack of a critical mass of professional biotechnological expertise in the industrial sector and de novo translational capabilities for such novel technologies. NII therefore feels that there is a need to broaden the focus of technology-oriented research by academia beyond product-specific efforts to include these more basic issues through establishment of an Innovation foundation with core facilities in the 40-acre area that NII in the progress would be give space as per activity.

As a venture takes off, the laboratory unit will be further equipped and manned jointly, resulting in optimal utilization of resources for specific purposes. Such a modular design, with the facilities envisaged, also allows NII to propose the use of this system for establishing an innovation center for public-good projects. In order to make this design of innovation laboratories work, a substantial degree of flexibility is essential in the administrative structures of such a center.

Center for genetically defined Macaque strains

Essential requirement in the course of translating world-class Indian science to the technological marketplace is the requirement for testing and related experimentation on whole animal systems, with a species that is closest to humans. A primate facility of Macaque strains of monkeys shall be established with facilities to ensure clean,

genetically well-defined primate strains translates into a requirement for genetically inbred, as well as genetically manipulated strains of primates.

New programmes

NII-2 Campus

National Institute of Immunology has realized to evolve as a leading facility for solving the problems through cohesive approach so that modern biology problems can be resolved with a model permits open interaction, infusion of new ideas and close local operational collaboration and creating the world class research teams. The NII-2 campus will be built in a 40 acre land in Faridabad and facilitate interaction with the translational perspectives at THSTI and RCB.

The NII-2 will be built in 2 phases, with 1 unit being built in each phase. One unit will consist of a building of 5 floors (G+4) with each floor consisting of 8 laboratories of approximately 2200 sq. ft. of space. It is envisioned that each Centre will consist of 8 senior faculties and 8 junior faculties, who will supervise approximately 40-50 Ph.D students and 20 research associates, 4 technical personnel and 2 administrative staff. Therefore, in the 8 Centres, the total number of people will be about 500 researchers with about 250 researchers being inducted over a period of time in the first phase. The infrastructural requirements will be supported by DBT.

Dwarka Campus

NII procured a 2 acre plot of land in Dwarka sector-V several years back. NII proposes to initiate the building of this campus and start new programmes like an international fellowship programme, a visiting scientist programme and a workshop in a structured fashion to increase NIIs strength in multiple ways while promoting collaborative science.

Systems Biology and Alzheimers Disease

The long-term goal is to provide a system level understanding of immune regulatory signaling network in the context of pathogenesis which may involve knockout or transgenic mice. Another objective is to identify the novel transcription factors relevant to Dendritic cell biology to understand the role of Dendritic cells in diseases like tuberculosis and HIV-AIDS.

Alzheimer's affecting 30 million people worldwide. Protein aggregation and accumulation plays a crucial role in many neurodegenerative diseases including Alzheimer's. NII will try to identify non-peptidic small molecule inhibitors of Aβ aggregation and accumulation.

Interdisciplinary Programme

1. Development of future diagnostic platform technologies
2. Identification of cancer biomarkers and means of intervention
3. Identification and exploitation of the relationship between cell death and diseases
4. Understanding the underlying mechanism of autoimmune disorders

International post-doctoral fellowship programme

NII proposes to initiate a post-doctoral fellowship programme to vitalize exchange between SAARC, other Asian and African countries. The post-doctoral programme will be of 2 years duration with the possibility of a 3rd year extension. The total intake of post-doctoral students each year will be 20. The post-doctoral students will be selected from diverse fields of biomedical sciences relevant to the area of the programmes and will be required to devote full time in research.

International visiting faculty programme

The institute would like to invite scientists from within the country and abroad to spend time in NII laboratories for collaborative efforts. The range of these visits could be from one to three months. For this activity, both mid-career and senior scientists will be invited. It is proposed that these scientists will be provided accommodation in the Dwarka campus along with laboratory facilities and necessary fellowships. The number of visiting faculties is restricted to 10 each year.

Human Resource-Retirement benefits proposal

NII has achieved its excellence within a short period of time as a result of its dedicated manpower at scientific, technical and administrative staff. NII has planned to undertake a pension plan for this purpose, and the proposal has been discussed and approved by the NII Governing Body. The actuarial reports commissioned by NII suggest that a one-time corpus grant from the government for this purpose will serve the needs to NII for the foreseeable future.

Teaching and Training

The doctoral programme in academic affiliation with the Jawaharlal Nehru University (JNU) is expected to have an increased annual intake of 25-30 students during the forthcoming plan period with a projected increase of 2 Ph.D. students per faculty, thus, making it a total intake of 70 Ph.D. students per year. Institute will also explore the possibility of registering Ph.D. students in universities other than JNU. The Institute is planning to renovate/modernize various facilities at student hostels during 12^{th}plan.

During the plan period, it is envisaged that at least one international meeting will be held annually on topic of relevance to the Institute's programme. On the national scale at least three symposia, seminars, or conferences are planned annually.

National Institute of Immunology, New Delhi

- **Basic Research in Immunology**: Infectious diseases like TB and their intervention strategy, Aging and Bone diseases
- **Translational Research programmes**: Vaccines, Microbicides, Inhibitors against infectious pathogens, Cancer diagnostics
- **Centre** for genetically modified Macaque strains
- **New campus**: Dwarka campus and NII-2 campus as a part of Faridabad bio-cluster
- **New programmes**: Alzheimers, Systems biology, International Postdoc fellowship, Visiting Scientist programme, Cryoelectron microscopy/Tomography facility, Retirement benefits for the employees, Extension of the student hostel facility
- **Teaching and Training**

3.16.2 National Centre for Cell Sciences, Pune, Maharashtra

The institute has been in the forefront since it’s establish in cell science through it services of cell culture supply, high quality science and publications of repute. NCCS has major R&D areas in cell biology, signal transduction, cancer biology, diabetes, biodiversity, infection and immunity, chromatin architecture and gene regulation, stem cells, proteomics, bioinformatics and regenerative biology.

Basic and use Inspired Research

NCCS has a very strong background in studying the cells at cellular and molecular level and the institute continues to put its efforts to explore the fundamental aspects

related to cell and leading to various diseases. The understanding of the basic processes is also essential to identify the suitable targets and to design either the biological and chemical molecules. The institute has thrust on:

- Understanding the basic processes in detail related to the central dogma of molecular biology i.e. the chromatin architecture and its regulation
- Study of various basic cellular pathways and their application in different diseases such as osteoporosis and cancer
- The maintenance, growth and differentiation of embryonic stem cells and their application in various clinical conditions
- The signaling pathways required to understand the basic cellular mechanism at molecular and structural level and their application to find out the target for diseases such as diabetes as well as their intervention strategies
- The role of immune system in various pathogenic and infectious diseases
- NCCS will also pursue the study of diversity and evolutionary relationships in different organisms using advanced molecular methods such as whole genome sequencing and meta-genomic analysis
- To unravel the complex microbial ecosystem in the mid-guts of humans and insects of clinical importance

Translational Research Programmes

Tuberculosis Network Program

Tuberculosis is a major problem in India and worldwide. Therefore, NCCS initiated a network program aiming at founding new principles of drug development and anti-tubercular immunotherapy.

Systems Biology of Global Regulatory Networks

The systems biology includes unraveling sequence features in Promoters that dictate tissue-specificity of gene expression.

DBT Inter-institutional Network program on HIV

In NCCS, number of novel anti-HIV compounds has been identified that have potential use as microbicide formulations against HIV/AIDS. The institute has plans to further develop these molecules and take them to the commercial stage.

In addition, NCCS is working in the development of peptide and non-peptide based inhibitors for various pathogens and diseases.

New Centre's for Translational Research

- Centre for cell and tissue engineering
- Centre for Immuno-thereupatics

Mission Programmes

- Diabetes - Novel means of intervention by using stem cells
- Identification of anti-viral compounds with potential for development of microbicides to prevent HIV infection and transmission

Infrastructure Development

- BSL-3/P3 facility is needed for ongoing work on Infection and Immunity in continuation of the 11^{th} plan
- Building of more laboratory space both at Pune University Campus and the Jopasana Campus
- Expansion of the animal house infrastructure to provide certain specialized/premium services like - Histopathology and clinical biochemistry of laboratory animal samples

Repository

The following activities have been planned as services to the scientific community in India that will widen the horizons of the repository services and will be major value addition in the institute's commitment to increasing scientific services. The repository has the following objectives:

- Complete characterization of cell lines of the deposited cells and their certified distribution
- Distribution of new cell types like murine stem cells
- Preparation of feeder layers for propagation of stem cells
- Fusion of primary B cells with myeloma and preparation of hybridomas on non-mercantile basis for some important antigens, their maintenance and distribution
- Transfection services using animal cell cultures
- Cryopreservation of embryos for important genetically tailored animals

- The center will also focus on basic research in the areas of microbial diversity, taxonomy, genomics and proteomics

New programmes proposed

Establishment of NCCS-II (Translational Research)

NCCS-II would investigate the cause of human diseases at the cellular and molecular levels using genomic, proteomic, cellular, and immunological technologies to elucidate disease mechanisms. Its development and progress would be of particular interest for future planning of research in the increasingly important area of clinical research. The Institute will endeavor to investigate methods of rational therapy and, wherever possible, strategies for the prevention of human diseases. NCCS-II will serve as a platform where scientists and clinicians can interact closely and think differently so that an innovative approach will be possible. The NCCS II would have research and development laboratories, service laboratories, and network of clinical centers specializing in treatment of various human diseases, and informatics network besides other support facilities.

Programme on Infection and Inflammation

Under the programme, NCCS will study the interplay of immune and other human system to understand the development of autoimmune disease and cancer progression. The programme involves the use of advanced techniques such as multi-photon scanning microscopy and imaging flow cytometry.

Individually Ventilated Caging (IVC) system upgradation

The breeding and maintenance of SPF mice/rats require a higher degree of isolation/barrier so as to minimize the risk of microbial and other infection in these animals. It is proposed that the existing system of conventional caging for laboratory mice and rats at the experimental animal facility (EAF) be replaced entirely with Individually Ventilated Caging Systems (IVCs). The replacement is proposed to be done in a phased manner.

New initiatives in emerging areas

Signaling and differentiation aspects related to cancer progression and infection

Teaching and Training

The Centre aims to continue development of technical manpower by way of:

- Increasing the number of research scholars, postgraduate summer trainees and project students being imparted training at the institute,
- Teaching at universities and colleges (for students and teachers),
- Provide training opportunities for the scientific/technical personnel from different institutions in the areas of laboratory animal science.
- Mass education programmes for awareness in science and technology and the experimental animal house facility will initiate a mandatory training program in the various areas of laboratory animal handling and experimentation for the benefit of the research scholars of the Institute on a yearly basis.

National Center for Cell Sciences, Pune, Maharashtra

- **Basic Research**: Cell Biology, Cancer, Osteoporosis, Diabetes, Chromatin architecture and regulation, Infection and Immunity, Systems biology, Embryonic Stem cells
- **Translational Research Programmes**: Vaccines, microbicides, inhibitors against infectious pathogens, Cancer diagnostics
- **Mission Programmes**: Diabetes, Identification and development of anti-HIV compounds
- **Infrastructure Development**: NCCS-II complex, Animal house upgradation, BSL-3/P3 facility further development, Laboratory extension
- **Repository**
- **New Programmes**: Epigenetic regulation of Cancer and its progression, Infection biology
- **Teaching and Training**

3.16.3 Centre for DNA Fingerprinting and Diagnostics, Hyderabad, Andhra Pradesh

During the 12th Plan period, the CDFD may enhance the volume and scope of its existing activities in a focused manner in selected areas of Research, as detailed below:

Major/Network Projects

- CDFD proposes a new initiative on 'Cell signaling in human health and disease': The overall goal is to uncover novel signaling mechanisms and yet undiscovered roles of pre-existing signaling mechanisms in functioning of eukaryotic cells and the understanding of underlying diseases of high relevance to the Indian population.
- The bacterial pathogens are causative agents of many seasonal diseases in India and understanding their basic biology will be helpful in identifying the targets for inventing them.
- Microbial forensics: This discipline deals with analyzing evidence from a bio-terrorism act, bio-crime or inadvertent microorganism/toxin release for attribution purposes. Establishment and development of facilities to support such scientific endeavors.
- In order to harness the recent advances in genetics and genomics of silkmoths and to improve silkworm strains in terms of quality and quantity of silk they produce and to produce disease free silkworms, a dedicated centre has been set up by the DBT in CDFD. This centre has to be further strengthened with enhanced activities during the proposed 12^{th} Plan.
- Human population analysis with a view to elicit signature profiling of different caste populations of India to use them in forensic DNA fingerprinting and develop DNA databases.

Diagnostic Services

The CDFD provides two kinds of paid services, namely, DNA fingerprinting and DNA diagnostics. During the 12^{th} Plan, the endeavor may be to progressively reduce the quantum of support from core funds for these services without compromising on quality or societal needs, and for this purpose alternative formats may be explored such as the establishment of not-for-profit clusters within the CDFD, public-private partnerships, and so on.

<u>DNA fingerprinting services</u>

CDFD's mandate will be to enhance its offering of services, training, extension and quality control activities and to setup the regional Centre's for the providing the service at State Government level. This mandate is to be achieved through the following approaches:

The institute has plans to expand its capability in training of personnel and improving the technical skills during 12th plan not only for the in-house personnel but also for the personnel employed at their regional centres. Develop a Laboratory Information Management Systems (LIMS), which is designed to automate evidence handling and casework management, to improve the integrity and speed of evidence handling procedures, and to ensure proper chain of custody.

(i) *National Facility for Training in DNA Profiling (NFTDP):* Recognizing that large numbers of trained DNA examiners are needed to be located at various institutes and laboratories in the country in order to increase the contributions of DNA profiling to the criminal justice delivery system, establishing a new National Facility for Training in DNA Profiling (NFTDP) in the CDFD is required. The NFTDP will offer training courses in the latter areas as well. The courses to be offered by NFTDP will thus include the following:

- Diploma in DNA fingerprinting and diagnostics of one year duration
- Post Graduate Diploma in DNA fingerprinting and diagnostics for two years duration
- Refresher courses of one-month duration
- Three months course on DNA fingerprinting & diagnostics
- Summer training for two months
- Project training for six months
- Training courses for forensic scientists for one month duration
- Training courses for police officers and judicial officers for one month duration
- Proficiency Testing Program
- Conferences/Workshops/Seminars etc.

(ii) *Disaster Victim Identification Cell (DVIC)*: It is also proposed to set up a Disaster Victim Identification Cell (DVIC) for DNA profiling of victims of various disasters such as train accidents, fire accidents, air crashes, earthquakes, terrorist attacks, tsunami, etc. in order to assign bodies/victims to the respective families and to maintain their databases. The DVIC will not only be able to help in providing proper identification of the bodies but will also be able to assist the Authorities during settlement of financial claims or insurance compensation. The manpower and the infrastructure created at the NFTDP would be used for the activities of the DVIC.

(iii) *Secretariat for DNA Profiling Advisory Board and Creation of National DNA Database:* The CDFD has been instrumental in preparation of the draft DNA

Profiling Bill 2006 which is shortly expected to be introduced in Parliament for enactment as a law. As envisaged in the draft Bill, the CDFD should house the Secretariat of the DNA Profiling Advisory Board. In addition, it is proposed to create and maintain the National DNA databank and database in the CDFD, comprising DNA profiles of different populations and of convicts and suspects. This activity in turn would be synergistic with other aspects of DNA profiling/training described above.

(iv) *Quality control and accreditation:* As provided for in the draft Bill, the CDFD should undertake the activities of quality control, quality assurance, and accreditation of the DNA profiling laboratories set up in the country in both the public sector and the private sector.

(v) *Other DNA profiling services:* The DNA fingerprinting services to cover the areas of forensic genetics including forensic zoology and forensic botany, microbial forensics (especially in relation to potential agents of bioterrorism), wildlife conservation, identification of plant varieties and accessions, silkworm and livestock breeding, and certification of Genetically Modified Organisms (GMOs).

DNA Diagnostics Services

Even with its limited staff, the CDFD diagnostics group has been providing excellent referral services and counseling to children and families with inherited genetic diseases, and it is recommended to strengthen the same substantially by investments in equipment and recruitment of suitably qualified and experienced personnel. The following areas are listed for diagnostics services:

- Molecular genetics,
- Cytogenetics,
- Biochemical genetics,
- Newborn screening center, and
- Develop National Database for genetic disorders:

Infrastructure Development

To develop a state-of-the-art rodent laboratory for generation, breeding and experimentation with mouse models, and a bio-safety level 3 (BSL3) laboratory for experimentation with pathogens including *Mycobacterium tuberculosis*.

New Centres Proposed

The institute proposed to establish the following laboratories and centres to expand its R&D capabilities and also its association with International scientific community during the 12th plan:

- To set up a state of the art 'Centre for DNA informatics and Computational Biology'under CDFD. It would support research and training in areas that connects biology with the computer sciences, mathematics, physics and engineering. This Centre would support, develop and manage programs in several areas of computational biology.
- To establish a 'Centre for Familial Cancer' which will function in close association with hospitals within Hyderabad including the MNJ Institute of Oncology and Regional Cancer Centre and the Nizam's Institute of Medical Sciences. The Centre will generate a database of major genes and mutations that cause familial cancer in India. This will have a significant bearing on treatment modalities for patients having familial cancer.
- Strengthening of the 'Centre of Excellence in Genetics and Genomics of Silkmoths' to improve the silkworm strains in terms of quality and quantity of silk. The Centre was set up by the DBT during 11th plan and needs further strengthening with enhanced activities during the 12th Plan.
- The 'Centre of Excellence in Microbial Biology' established during 11th plan is engaged in areas of bacterial genetics and molecular and systems biology. The Centre further wish to continue its scientific activities with excellence at International level.
- Setting up of 'Silkworm Stock Maintenance and Breeding Centre' to conduct transgenic field trials through building up of infrastructure facilities.
- CDFD plans to set up a 'Centre for Genetically Modified Organism and Genetic fidelity testing' for periodical monitoring of GMO releases and fidelity testing.
- Setting up of 'DNA Fingerprinting Regional Centres' by entering into a Memorandum of Understanding (MoU) with various State Governments of India including one in North-East, South and North India. The Centre will serve as local technology enabled bodies for criminal justice delivery inside the country.

Teaching and Training

CDFD has number of Ph.D., JRFs/SRFs and Research Associates for training. In addition the institute provides training to various Government Department personnel in the area of DNA fingerprinting and Diagnostics.

Centre for DNA Fingerprinting and Diagnostics, Hyderabad, Andhra Pradesh

- **Major/Network Projects**: Familial Cancer, DNA informatics and Computational Biology, Silkworm biology, Cell Signaling and diseases
- **Diagnostics Services**
- **Infrastructure Development**: Rodent laboratory, BSL-3/P3 facility development
- **New Centre's proposed**: DNA Fingerprinting Regional Centres, Silkworm stock maintenance and breeding centre, Centre for Genetically Modified Organisms (GMO's) and fidelity testing
- **Training and Teaching**

3.16.4 National Brain Research Centre, Manesar, Haryana

The mandate of National Brain Research Centre (NBRC) is to be a Centre of Excellence in Brain Research with state-of-the-art facilities, to evolve the centre through a networking approach and generate highly trained human resource. NBRC functions as a comprehensive brain research institute, which has been envisaged as a novel institute of its kind in having both intramural and extramural responsibilities. A unique role for NBRC is that it will act as a node with linkages to other centres carrying out neuroscience research in the country, acting in effect as the "hub of the wheel" rather than the wheel itself. NBRC has taken a number of initiatives in the advanced research area of Brain and Neurology.

Brain Research Initiatives

- *Development of rationale therapies for neurodegenerative and infectious diseases of the nervous system through understanding of pathogenic mechanisms*: This programme includes many projects of national and pharmaceutical importance such as evaluation of the pharmacological potential

of traditional medicinal preparations used in the treatment of dementia including Alzheimer's disease, Proteasomal dysfunction and Parkinson's disease and identification of the modulators of ubiquitin proteosome system, Evaluation of neurological consequences of HIV-C vis-à-vis HIV-B using human neural progenitor cells and Evaluation of the pharmacological action of new chemical entities and active pharmaceutical ingredients from plant source as a therapy for Japanese Encephalitis.

- *Development of Cognitive Retraining Modules for Improving Brain Function in Head Injury Patients:* Developments in Cognitive Neuroscience have found the brain bases of cognitive functions. The outcome of this programme would be an inexpensive, patient friendly, scientifically based, clinically validated treatment programme, which can be used for psychiatric and neurological patients all over the country.
- *Development of Computational Tools for Speech Analysis*: The current focus is on studying speech samples from children with autism and their speech difference with normal children for diagnostic purpose. The possible advantages would be the approach is non-invasive, low cost and rapid.
- *Cognitive Science:*Using functional neuroimaging, first time uncovered the reading networks for Devanagari. These results clearly show that processing the non-linearity in Devanagari requires involvement of both hemispheres.
- *Stochastic Activation for MR Imaging - Enhancement and Identification:* Stochastic activation and entropic classification techniques are used to enhance and identify images of brain lesions, including infection, inflammation, vascular insults, benign and malignant lesions. The technique has been used to lessen the dose of expensive gadolinium organometallic compounds needed for MR contrast imaging.
- *Systems Neurobiology/Neuroscience:* Research in systems neurosciencehas been ongoing to understand basic sensory processes including vision, touch, hearing, the movement system and the spatial navigation system.
- NBRC is working on treating the brain and spinal cord related disorders using the Stem cells.

During the 12th Plan, the institute would like to do the following activities:

- Understanding of pathogenic mechanisms of neurodegenerative disorders such as Alzheimers, Parkinsons, Huntington's and Lafora disease for the development of their rational therapies
- Delineation of molecular mechanisms of virus-induced neurodegeneration in JEV and HIV throughsystems biology approach, cellular and molecular biology of viral latency, study of neural cells and pathogens

- Understanding the molecular basis of synaptic plasticity and learning and memory formation and molecular mechanisms of cognitive deficits in Alzheimer's disease and Angelman syndrome (a autism spectrum disorder)
- Role of Glioma cells in cancer and inflammation and their intervention strategies
- Study of basic biology of retinal neurodegeneration and their protective mechanism
- Study of basic cellular processes underlying Stroke and Brain injuries
- Neuro-degeneration studies in animals especially in Zebrafish to understand the effect of agonists and antagonists
- Undersatnidng the process of literacy, behavioral aspects through neuro-imaging

New Programmes

- Understanding the Hypoxia and Ischemia reperfusion injuries
- Systems Neurobiology
- Cognition process study in Crows

Infrastructure Development

- Hostel building, Faculty house and Director's residence, Animal house
- Central Instrumentation facility, Computational and Neuroimaging facility, Animal MRI facility, DNA sequencing facility
- Expansion of the primate facility
- Neural tissue, CSF and DNA banks
- Building of BSL-3 containment facility
- Transgenic/Knockout mice facility to study brain disorders
- Bioinformatics and systems biology platforms
- MRI Chemical Exchange Saturation Transfer (CEST) scanning facility
- Establishment of Academic Clinical Neuroscience Centre

New Initiatives

- Developing inducible pluripotent stemcells (iPS) as a model to study healthy and diseased brain
- Multi-Institutional Programme on Molecular Genetics and Pathogenesis of Complex Neurodevelopmental Disorders
- Neurophysiological Studies On Ageing and Alzheimer's Disease

- Developing Neuroimaging and Systems Biology Platform for Monitoring and Optimizing Therapeutic Performance in Stroke and Vascular Dementia
- Development of Biomarkers (MRI/MRS) For various Neural, Neurodegenerative and Psychiatric Disorders
- Development for a Community Programme with capability of cohort studies
- Neuroimaging and Genetics of typical and impaired readers of Hindi and English
- Infrastructural hospital based facility in Gurgaon civil hospital
- The MEG (Magnetoencephalogram) as national facility

National Brain Research Centre, Manesar, Haryana

- **Brain Research**: Neurodegenerative disorders, Autism, Viral infections, Cognition, behavior, Stroke and spinal cord injuries
- **Infrastructure Development**:BSL-3/P3 facility, Hostel, Faculty and Director house, Neuroimaging facility, computational & MRI & DNA sequencing facility, Knockout mice facility, Neural tissue & CSF bank, MRI scanning facility, Bioinformatics and systems biology platforms
- **New Initiatives**: Neural stem cells, Neurodegenerative disorders, Biomarkers, Community programme, hospital infrastructure, Cognition imaging, MEG as national facility
- **Teaching and Training**

3.16.5 National Institute of Plant Genome Research, New Delhi

The National Institute of Plant Genome Research was established in 1998 with the objective of conducting and promoting research of high caliber in basic and applied plant biology. The research programmes at NIPGR are aimed to understand the structure, expression and function of genes in plant genomes and use this understanding of plant genes/genomes to genetically improve crops for high yields and better quality. The highlights of the scientific achievements of the institute during the 11^{th} plan are given below:

Plant Biology

Basic Research

- An automated computational procedure was developed for the identification of plant proteins using Profile Hidden Markov Model. In addition, a highly

accurate search algorithm 'PLecDom' was developed for the identification of novel lectin domains from un-annotated sequence data and their classification into one of the known families. Furthermore, in order to gain functional and biological insights from the vastly growing plant genomic data, efforts were made to identify microsatellites (or SSR seqeunces) in available plant nuclear genomes as well as chloroplast genomes.

- 'Chick-pea' genome and transcriptome analysis as well as their molecular mapping have been carried out.A public data resource 'Chickpea Transcriptome Database' has been developed, which provides a searchable interface to the chickpea transcriptome data. The construction and development of a 'Genome Browser for chickpea' has been undertaken to enable users to search information about genes and view functional aspects of genomic units as well as gene structures within the underlying DNA sequence. 278 novel STMS markers were developed using microsatellite enrichment techniques.
- Understanding the role of abiotic and biotic stress among different economic crops such as rice, chickpea, grasspea and millets.
- Nutritional genomics: Identification of new genetic tools and materials for enhancing the shelf life of fruits and vegetables, genetic modification of crops such as rice to improve their nutritional quality, reduction of oxalate toxicity in edible crops.
- Genetic and molecular investigations of regulatory proteins involved in light controlled plant growth and development.
- Molecular, biochemical and functional characterization of proteins involved in seed vigor, viability and stress tolerance.
- Understanding the regulation of lateral root stem cells and root architecture.
- Isolation and characterization of pathways involved in plant immune response especially in Rice and Chickpea and plant defense system response to infectious agents.
- RNA biology revelation: Analysis of gene silencing pathways in plants through siRNAs and role in DNA replication and gene expression.
- Development of National Plant Gene Repository (NAPGER), Plant Growth Facility, Central Instrumentation Facility.

Translation Research

Transgenics Evaluation and Technology Transfer: NCPGR plans to expand the research activities by setting up of a unit to develop transgenics and its evaluation and technology transfer which would include management of patents, material-transfer and other IPR related work. This single innovative programme would require substantial additional financial support to the extent of Rs 40 crores.

Network Programmes

NCPGR has been able to successfully network with other institutions engaged in research in plant genomics/development of transgenic crop. It has five international collaborative programmes and has developed a close working linkage with various research institutions within the country such as IARI, PAU, HAU, UAS, CTCRI, ICRISAT, etc. The Centre would continue to work in close coordination with these and other crop improvement institutions. An effective inter-institutional programme in this respect would be of utmost importance for employing molecular markers in breeding suitable cultivars for farmers. A state of the art Crop Bioinformatics Centre shall also be established.

The institution plan during 12th plan are as follows:

Research and Development

- Support for the ongoing research and innovation facilities viz. computational biology capability, genome analysis, molecular breeding and mapping, nutritional genomics, plant immunity, molecular mechanism of abiotic and biotic stress and their implications.
- New Research activities: Epigenomics, Molecular breeding, Root biology and Nutrition, Stem cell research.

Infrastructure Development

Expansion of National Plant Genome Repository and Central Instrumentation facility, Building of guest house cum community centre, Extramural research centre, vehicle replacement, Access to scientific journals.

New Programmes

- NIPGR translational Centre
- Inter-institutional network
- New campus i.e. NIPGR-2 (Translational Centre) at Faridabad cluster
- Root biology and Stem cell Research

Teaching and Training

NIPGR has number of Ph.D., JRFs/SRFs and research associates for training in advanced Plant biology. The Institute is solely involved in the genomics of plants and have number of International collaborations.

National Institute of Plant Genome Research, New Delhi

- **Plant Biology**: Computational genomics, Genome, Proteomics and transcriptome analysis, molecular breeding and mapping, nutritional genomics, plant immunity and infection, molecular mechanism of abiotic and biotic stress and their implications, plant growth and development, seed vigor and stress tolerance and plant RNA biology
- **Infrastructure Development**: : NIPGR-2 (Translational Centre) Expansion of National plant genome repository and Central Instrumentation facility, Building of Guest house cum community Centre, Extramural research Centre, vehicle replacement, Access to scientific journals
- **New Programmes**: Root biology, Stem cell research
- **Teaching and Training**

3.16.6 Institute of Bio-resource and Sustainable Development

Core activities/strategies

Bioresources database development, including local traditional knowledge, for the priority flora, fauna and microbes of North-East Region using bioinformatics tools and techniques for Bioresources conservation, development and utilization.

Ex-situ conservation through biotechnological interventions, molecular characterization and molecular taxonomic studies for the potential priority/targeted plant, animal and microbial bioresources of the North-Eastern region of India for need based utilization and conservation.

Prospecting of identified plant, animal and microbial bioresources of North-East Region of India for target based bioactive molecules for therapeutic use, aromatic compounds, dye yielding compounds, novel genes and gene products for possible utilization.

Genetic improvement through molecular breeding approaches for chosen plant, animal and microbial bioresources of North-East Region for food, nutrition and environment security.

Development of ecologically sound rehabilitation packages for maintenance of soil fertility, prevention of soil erosion, regeneration of degraded hill and wetland ecosystems for biodiversity conservation and survival of bioresources.
Bioresources based rural technology package development for value added products and processes for employment generation and economic progress of the North-East region.

Bioresources education for capacity building on bioresources conservation and development to students, researchers, etc. and technology transfer for bioresources utilization through training of bio-entrepreneurs and biovillage development.
Multi-institutional collaborative and networking approaches to achieve the institute objectives within a time frame.

New Activities

Innovation Centre: Genome Club, an innovative approach may be setup for regular interaction between bio-entrepreneurs, graduate students and researchers on biodiversity conservation and bioresources management. The main features of Genome Club shall be invited lectures, discussions, seminars, workshop etc. Such an approach may also act as a good idea generation system by hybridizing the traditional knowledge and scientific knowledge to develop the local demand or need which may ultimately lead to the development of problem oriented research agenda.

Network multi-institutional programme

Network programme for integrated development on value addition for ginger and turmeric of N.E. Region for commercial exploitation
Network programme on standardization and value addition for fermented bamboo shoots of N.E. Region for commercial exploitation.

3.16.7 Institute of Life science, Bhubaneswar, Orissa

The core research programme of ILS during the 12^{th} plan will be strategically addressing issues on infectious disease biology in an interdisciplinary fashion. The objective is to increase the dimensions for solving the challenges associated with Infectious diseases. ILS developed itself as an Institute of expertise in

Nanotechnology and plans to develop novel drug targeting strategies for solid tumors and other extracellular Infectious pathogens. Simultaneously, an interdisciplinary Center of Viral Biology is involved in unfolding the viral host-pathogen relationship and interaction mechanisms, pathogenesis cycle and intervention strategies for the same. The institute is also active in the field of Immunology and engaged in finding out the adjuvants, which can activate innate immune system.

Basic and Applied Biology

Some of the key areas of R&D during the 12th plan are as follows:

- Understanding the basic biology of viral infection, their role in cellular transformation and relationship to various viral diseases including cancer, sepsis
- Study of DNA replication and their associated molecules in humans and pathogenic organisms. Metagenomics and Functional genomics of microorganisms for gene prospecting
- Development of a whole cell microbial biosensor for the detection of environmental toxic compounds
- Nanotechnology based drug delivery
- Development of Plant derived mammalian immune responsive defensin proteins/peptide and its implication in translational research
- Small RNA profiling from different Physiological and Genetic backgrounds of rice and tomato plants
- Pathogenesis of *Vibrio cholera* and Genetic diversity, virulence potential and *in-vivo* formed biofilm in antibiotic resistance and transmission of *Staphylococcal* infections
- Elucidating the cellular and molecular mechanism of development of severe *P. falciparum* malaria in humans
- Infection and Immunity and their potential implications
- Aging and Cancer relationship
- Understanding regulatory aspects of salt and drought tolerance in crop plants using high throughput differential gene expression techniques

Infrastructure development

It is proposed to construct faculty residence, visiting Professor's Lodge, Student's Hostel and a Science Outreach Programme Centre in a new campus (already acquired) of 3 acres located close to the current ILS campus during the 12th plan period.

ILS with its expertise available on *C.elegans* nematodes is well placed to set up a national repository of *C.elegans* so that several groups in the country could use the model system as an effective tool.

New Centre's proposed

- An 'Advanced Centre for Nano-Science and Drug Delivery' is proposed for the 12th plan, which has to be established in a 30.00 acre land in Bhubaneswar earmarked for Institute of Life science.
- Establishment of a platform technology for Imaging and Cytometer for providing advanced training to the students in the eastern part of the country. ILS also proposing to build a Flow cytometer based on white laser. Furthermore, establishment of Zebra-fish facility to assist investigators for developing *in-vivo* model systems to study the pathogenic diseases.

Teaching and Training

During 12th plan, ILS is planning to appoint 12 new faculties in its new campus and also plans to increase the intake of Ph.D. trainees corresponding to the number of recruited faculties. During the 12th plan, the institute proposes to enhance its Ph.D. students per year through development of its new campus. In addition, ILS is proposing to initiate a science outreach programme for the class-X student to teach them practically the tools and techniques of modern biology and biotechnology. For training and teaching purpose, ILS continues to hold workshops, seminars and symposiums for the national and International delegates.

Institute of Life science, Bhubaneswar, Orissa

- **Basic and Applied Biology**: DNA replication, Viral biology, Infectious disease, Cancer, Nanotechnology, Infection and Immunity, adjuvant development, aging and drug delivery systems, abitotic and biotic stress on plants especially rice, Malaria, Hepatitis
- **Infrastructure Development**: New campus, Faculty residence, visiting faculties lodge, student hostel
- **New Centre's proposed**: Advanced Centre for Nano-science and drug delivery, Platforms for Imaging, Science outreach programme
- **Teaching and Training**

3.16.8 Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram, Kerala

The centre is established to understand the infectious and chronic diseases and development of drug, molecular medicine for the respective diseases. The Centre is currently running 11 programmes of intensive R&D in areas namely – Integrated Cancer Research Programme, Human Molecular Genetics programme, Molecular Reproduction Programme, Chemical Biology programme, Mycobacterium Research programme, Cardiovascular Biology, Molecular Neurobiology, Environmental Microbiology Programme, Dengue and Emerging Viral Infections Programme, National Swine Fever Programme, Plant Biotechnology. In addition, during 11th plan, the Institute established some world class facilities such as Central tissue and cell line facility, Regional facility for Molecular diagnostics, Regional facility for DNA Fingerprinting, Bacterial Culture facility.

Basic and Applied Biology

For 12th plan, the institute proposed the following programmes for its research and development activities:

- Development of Swine fever vaccine, Vascular biology of Dengue and elucidation of virulence determinants in Chikungunya virus
- Genomic and proteomic analysis of the TB
- Testing of drugs of natural origin in different types of cancer & TB and development of the promising lead molecules for clinical trials
- Analysis of cancer associated fibroblast on cancer stem cell behavior
- Genomic and transcriptomic profiling of the Black pepper
- Bioprospecting and identification, development of lead molecules of microbial and plant origin
- Understanding the signaling pathways associated with calcium channels and neural stem cell maintenance and its fate, retinal ganglion cell fate of embryonic stem cells
- Isolation of antimicrobial peptide from the Frogs skin, their structure-function studies as well as their developing them as intervening agents
- Development of Nanotechnology based drug delivery systems for cancer and pulmonary TB
- Molecular characterization of *Zingiber-Pythium* interactions

New Programmes

- Gene mining for biotic stress resistance in Black Pepper and Ginger
- Identification of cellular and molecular diagnostic markers for the early detection of vascular disease in patients with type-2 diabetes
- Vascular biology and remodeling of cardiac endothelium in heart failure, genetic and molecular basis of vascular diseases, congenital heart diseases, chronic venous diseases, cell cycle regulation in adult cardiac stem cells
- Establishment of transgenic animal facility

New Initiatives

- Development of novel animal models using cancer cell lines for screening of anti-cancer drugs
- Development of diagnostic devices in heart failure and metabolic profiling of Indian patients with coronary heart disease
- Peptide based drug design and delivery

Teaching and Training

RGCB is a newly established institution and slowly building its capacity for recruitment and training of the Human resource.

Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram, Kerala

- **Basic and Applied Biology**: Dengue & Chikunguniya Viral biology, Cancer, TB, Nanotechnology, drug development & delivery, bioprospecting, antimicrobial peptides, Stem cells, Genomic and transcriptomics of Black pepper,
- **New Programmes**: Gene mining, Diagnostic markers, Cardiovascular disease, transgenic animal facility
- **New Initiatives**: Novel animal models, diagnostic devices, peptide based drug design and delivery
- **Teaching and Training**

3.16.9 National Institute of Biomedical Genomics, Kalyani, West Bengal

The National Institute of Biomedical Genomics (NIMBG) was established by DBT as an autonomous institute in 2009 and starts functioning from an interim facility in 2010. During 11^{th} plan, the institute established its permanent campus, recruitment of faculty members and administrative staff. Currently, institute is performing the Indian

component of the International Cancer Genome Consortium (ICGC) project with the goal of cataloging inherited and acquired genomic changes in oral cancer using massively-parallel DNA sequencing.

During 12th plan, the institute is proposed to do R&D in the following areas:

Genomics

- Indian component of the International Cancer Genome Consortium Project– ongoing activity
- Initiation of work on host-genomics of Tuberculosis and Malaria
- Genomics of cancers associated with human papilloma virus infection, with special reference to cervical cancer
- Expression of genes and genomic changes in breast and oral cancers, in relation to therapy
- Evolutionary genomics of Indian ethnic populations
- Genomics of host-susceptibility to infectious diseases

Infrastructure development

- Kalyani Cohort Study: Formation of a platform for biomedical genomics research through the formation of a cohort of 20,000 individuals
- Completion of construction of the new campus of the Institute
- Establishment of two new biomedical genomics centre and a Centre for Statistical and Computational Genomics
- Establishment of imaging, proteomics and model systems facilities

New Centre's proposed

- Biomedical Genomics Centre
- Centre for Statistical and Computational Genomics

Teaching and Training

- Recruitment of faculty members and administrative staff - filling of sanctioned positions
- Initiation of formal coursework for Ph.D students and initiation of M.Sc. programme in Biomedical Genomics

National Institute of Biomedical Genomics, Kalyani, West Bengal

- **Genomics**: Malaria, TB, Infectious disease, Cancer, Indian ethnic population
- **Infrastructure Development**: New campus, New platform, Imaging, proteomics and model systems facility
- **New Centre's proposed**: Biomedical Genomics Centre and Centre for Statistical and Computational Genomics
- **Teaching and Training**: M.Sc. Programme in Genomics, Faculty and Staff recruitment

3.16.10 Regional Centre for Biotechnology, Faridabad, Haryana

Continuation of Programmes (Number of Projects- including Infrastructure, Construction Activities and Financial Implications) and being an institution of education, training and research established by the Department of Biotechnology, Government of India under the auspices of UNESCO, it is a newly created autonomous institution currently established by an executive order of the Government of India dated 20.04.2009 and will operationalize in full swing in 12^{th} Five year plan, pending a bill to be introduced in the parliament.

The Centre is aimed to focus on multi-disciplinary education, training and research programmes which will be constantly evolving to provide scope for intense experimentation to germinate innovation in Biotechnology. It is earnestly hoped that the international nature of this Institute and the partnership with UNESCO will create access to new ideas in education and training on a worldwide basis. This will thus help India to participate with both dignity and profit in the biotechnology revolution on a wider scale to create solid bedrock for spin offs from outstanding fundamental research for potential biotechnological nurturing and development.

The Centre will be open to industry for enhancing their skills in specific areas. Domain-specific programmes will also be designed in order to create a cadre of highly specialized scientists for technology development in the relevant areas. An important focus of expertise building will be regulation, product development, scale up, manufacturing sciences and bio- entrepreneurship. The Centre is working in close co-operation with several prominent Indian Universities to facilitate admission of international students within the region for the post-graduate course in biotechnology sponsored by the Department of Biotechnology, Government of India.

The Centre will continue the programmes in the realm of Biomedical sciences initiated during the eleventh plan period. These included analysis of complex diseases for identification of Cellular and molecular approaches. Application of novel engineering and material science approaches to contemporary biotech problems such as understanding and building tissue architecture, or nanoscience-driven design of novel devices for diagnostic and therapeutic utility.

Understanding the physiological processes of self-nonself discrimination in terms of physicochemical principles of molecular interactions and comparative exploration of the proteomes of edible seeds towards correlation of structural, physiological and antigenic properties of seed proteins which have been linked to allergy will also be continued. Other continued research interest is to illuminate the basic molecular mechanisms of mitosis and its underlying impact on shaping important biological processes. Nano-science for biotechnology, wherein the emphasis is on design of novel nano-devices for biosensing, diagnostic and therapeutic utility for cancer and other diseases. Application of novel engineering and material science approaches towards understanding and building tissue architecture will continue to be among the priority areas.

New Programmes proposed:

(i) New Initiatives in emerging and evolving areas

(a) Research:

Biotechnology is a knowledge-based technology which needs to be driven by continuous flow of new ideas and concepts towards development of new tools for research and innovative processes. Rapid responses are needed to meet the challenges as they unfold and there is a lack of specialized skills. While some aspects of Biomedical research have been initiated last year during the 11th plan period when the programmes got initiated, towards generating correct harmony with the interdisciplinary education and training programmes, the research programmes of the Centre will be organized into following five components. While all these components are substantially inter-linked as also with basic natural sciences, each component is proposed to be developed into a major group with critically required faculty strength recruited so that the academic and training programmes will also be provided wide diversity and enable flexible approach in optimizing pre-research training. The domain-wise focus will be:

- Biomedical Science
- Bioengineering & Devices
- Biochemical and Biophysical Sciences
- Climate Science, Agriculture and Environment
- Biotechnology Regulatory Affairs, IPR and Policy

Biomedical Science is a continually changing and dynamic subject and therefore is enormously challenging and it involves analyses of life processes to gain an understanding of health and the methods for diagnosing, analyzing and treating disease. Pre-clinical research including molecular science, the screening and evaluation of new drugs, and the relationship between the environment and health are important themes to be addressed. Areas within the above domains being currently initiated include analyses of complex diseases for identification of intervention points and development of knowledge-based drug discovery approaches. Thrust areas for research in this domain during 12th plan include regenerative medicine and tissue engineering, clinical pharmacology and pharmacogenomics, high throughput clinical genomics.

Application of the principles of engineering and natural sciences to tissues, cells and molecules could be described as Bioengineering and is closely linked with modern biotechnology. It advances knowledge for the molecular to the organ systems levels, and develops innovative biologics, materials, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease as well as improvement of crops and quality of biosphere. A contemporary activity that fits well in the context of bioengineering and devices is tissue engineering & regenerative medicine. Application of novel engineering and material science approaches to understanding and building tissue architecture would also be very exciting. Nano-science for biotechnology, wherein the emphasis would be on design of novel nano-devices for bio-sensing, diagnostic and therapeutic utility would be among the priority areas.

Biochemical and Biophysical studies at molecular and cellular level and as part of systems biology foster progress in comprehending the mechanisms underlying the control of cellular physiological processes and the consequences of its perturbation. Emphasis is placed on the relationship between molecular structure and the nature of the specific property/function under investigation through physico-chemical approaches.

Climate change, agriculture and environment are interrelated processes, and they take place on a global scale. Global warming is projected to have significant impacts on conditions affecting agriculture, including temperature, carbon dioxide, glacial run-

off, precipitation and the interaction of these elements. These conditions determine the carrying capacity of the biosphere to produce enough food for the human population and domesticated animals. The overall effect of climate change on agriculture will depend on the balance of these effects on environment. Modern biotechnologies approaches to understand and analyze remedial measures for agriculture as well as biosphere would be important areas to focus on. Integration of climate models with design strategies for transgenic crops and environmental impact of climate change using mathematical as well as physical approaches are also being envisioned to be priority areas.

A major aspect of biotech revolution concerns addressing regulatory and IPR issues as well as policy analyses. The infrastructure of this domain will be of a different nature as compared to the rest of the areas. However, the inter-relationship of policy & IPR exists with every aspect of biology and therefore this domain will grow synergistically along with other interdisciplinary areas. The faculty in this domain will have skills in technology transfer, IP management, finance and enterprise creation.

These domains should have faculty strength of about 25 each, for optimally generating international quality research and academic programmes. It is desirable to have any give faculty member be part of more than one domain considering the overlapping focus among these programmes. Each of these domains will carve out niche research areas for themselves but also develop together graduate school programmes in wide range of themes. Partnerships with other Institutions within the cluster and outside will also be proactively sought.

(b) Academic programmes: Graduate schools in Biotechnology

The design and processes of the education at this Centre will be such that it will generate scientists of highest caliber, technology savvy solution finders/creators, science entrepreneurs/ knowledge economy entrepreneurs and R&D leaders. RCB is set to be a Biotechnology University with unique canvas of specialized doctoral and masters programmes, domain specific training programmes and high quality research and development in specific areas aimed at producing a highly specialized cadre of scientists capable of not only making discoveries of fundamental nature but also translating laboratory research to actual practice for societal benefit.

Purpose of such interdisciplinary programmes is to educate students at the interface of engineering, agriculture, medicine and physical sciences via a flexible structure that permits explorations at the intersections of these disciplines. The hallmark of the educational programme at the Centre is creating opportunity to engage in research and

a curriculum which enables the students to begin their own translation of innovation from laboratory to field. The students are not only expected to develop expertise in one area but be sufficiently versed in many areas to be able to traverse and interact with professionals of multiple disciplines. Essential feature of education will be a mix of compulsory and optional courses to allow a maximum possible flexibility to acquire proficiency across disciplines.

In-house academic programme will be primarily Ph.D in all aspects of biotechnology practiced at the Centre described above. As soon as the Centre's formal enactment by the parliament, Integrated MSc-Ph.D programme will be established. The broadly proposed strategy at the Masters level is the placement of students in the existing DBT programmes across the country; the Centre will assist in enriching the content and quality of these programmes.

The interdisciplinary educational programmes at the Centre will be constantly evolving for relating to realistic contemporary developments and needs, as there will be a scope for lot of experimentation and will be a source of new ideas and methods in teaching in biotechnology for the University system in the country to adopt. International nature of this institute and partnership with UNESCO will create access to new ideas in education and training on a worldwide basis. The Ph.D programmes of the Centre will be open to Indians as well as students from the Asian region. The Centre is aimed to be an autonomous degree granting institution. Till such time it acquires such a status through an Act of Parliament, it will seek affiliation with established Universities.

c) **Training Programmes**

The Centre will provide disciplinary as well as interdisciplinary short term training programmes by networking through diverse institutions. The Centre will be open to industry for enhancing their skills in specific areas. Domain-specific programmes will also be designed in order to create a cadre of highly specialized scientists for technology development in the relevant areas. An important focus of expertise building will be regulation, product development, scale up, manufacturing sciences and bio- entrepreneurship.

Workshops in other contemporary areas of biotechnology such as nanomaterials, proteomics and genetically modified plants were planned in collaboration with other sister Institutions. The key goal is to be able to arrange/organise personalised or user-friendly opportunities for career development. The cell will organise structural training courses for physicians and engineers (intending to enter biology), science

managers and industry personnel in specific areas where they require skill enhancement, for example: short-term science and technology training will be arranged for physicians intending to enter biology and networking through local hospitals will provide clinical exposure to engineers and biologists.

The Centre's IPR/Policy and Regulatory affairs division will be open to industry for enhancing their skills in specific areas. Structured training courses for employees of pharmaceuticals, biotech or medical device companies who are seeking career opportunities or advancements will be conducted in the following areas: IPR/Technology Transfer, Bio-enterprise/Management in Biotechnology, Platform technologies, GMP/GLP, Regulatory Procedures, Bio-safety & ethics, Preclinical Toxicity and Clinical Trials and Bio-statistics and Epidemiology.

Specialized domain specific programmes of 3-6 months duration will also be designed for people from basic sciences in nanotechnology, Implants and Devices, Vaccine Development and Stem cell biology in order to create a cadre of highly specialized scientists for technology development in these areas. There will be a special programme for need identification and design.

The number of training programmes to be taken up in a year will depend on industry need and need of other participants. The training cell will draw up a calendar of the programmes which will be announced periodically to invite participants.

(ii) Major Projects, Networks, Centres and facilities

(a) Expansion of the laboratory space and teaching infrastructure: Expansion of Laboratory space and Teaching/Scientific Infrastructure is aimed at providing: (a) Ready to use Laboratory space for extra mural Scientists for innovative R&D Project programmes, and (b) Unique Teaching programmes specific to structured training courses for Physicians, Engineers, Science Managers and Industry Personnel in specific areas where they require skill enhancement and career development.

(b) Operationalization of the Faridabad campus - creation of the BSC Cluster Cell for management of the activities of the permanent campus until the BSC Board is established: To streamline and canalise the flow of funds and their management through a single agency on behalf of BSC constituents, RCB through its Executive Director has been authorised by the Department of Biotechnology, Government of India to organise and oversee pooling of resources and facilities for infrastructure development, construction activities

and maintenance of facilities exclusively for setting up of NCR-BSC Cluster Campus at Faridabad. Accordingly, the Cell has been made operational at RCB and is working under the authority of its Executive Director. The Cell will continue to function until a regular Cluster Board is duly constituted by the DBT.

(c) Creation of the Advanced Technology Platform Centre: The technologies platforms available within the Advanced Technology Platform Centre will cater to the needs of researchers and entrepreneurs for multi-disciplinary research to translate scientific and technological advancements into innovations for improvisation of public health for RCB as well as other partner institutions within the Cluster as well other institutions in the neighborhood and in the country.

(d) Setting up of Data-intensive Discovery Centre: The multi-disciplinary programmes in biotech sciences by necessity require analysis of large quantities of informational data. Therefore data-intensive discovery approaches would be an essential component for RCB It is recognized that the expertise and innovation in the core domains of systems biology, computational biology, bioinformatics and other branches of theoretical biology and analyses of clinical/ epidemiological/ biodiversity data is critical for the development of novel perspectives in biotechnology. The Centre would be important not only for RCB but also for other cluster component institutions for participating in this shared adventure to transform the biotech sciences.

(e) Dwelling Units and Accommodation for Housing Hostels & Guest House: State Environment Impact Assessment Authority (SEIAA) of Haryana Government has approved an area of 9200 Sq. M. for residential accommodation. As the laboratory building complex at Faridabad is likely to be ready within next two years, the permanent residential quarters and hostel/guest house facilities are required to come up as soon as the permanent laboratories become functional in about three years time. In order to facilitate efficient management control and progress and to foster sustained research and academic work the faculty, essential services staff, students, and visiting faculty/fellows need to be enabled to move in to the campus. As soon as the laboratories are operational. Construction of these facilities more pressing is an essential in view of non availability of such facilities in the neighborhood of the campus.

Regional Centre for Biotechnology, Faridabad, Haryana

- **RCB Bill**
- **R&D**: Infection and immunity, Nano-science & nano-devices Regulatory affairs & IPR, Agriculture & climate science, Network of excellence, regenerative medicine, Tissue engineering, Clinical pharmacology, Drug discovery, Technology platform, Assessing safety of new risks, Genomic initiative on fruit crops
- **Infrastructure Development**: Extension of laboratories, Advanced technology platform centre, Institute building, Hostels & housing, Data intensive discovery centre
- **Teaching and Training**: Integrated M.Sc.-Ph.D programme, Collaboration with global universities/institutions, workshops, seminars etc.

3.16.11 National Institute of Animal Biotechnology, Hyderabad

NIAB is aimed to harness novel and emerging biotechnologies and take up research in the cutting edge areas for improving animal productivity and health. The Institute's focus of research is on infectious diseases, breeding, reproduction and nutritional enrichment. The institute aims at translational research leading to the development of novel vaccines, diagnostics and improved therapeutic molecules for farm animals. During the 12^{th} plan the institute proposed to engage in the following R&D activities:

Research and Development

- Research in the cutting edge areas of biotechnology for improving animal productivity and health
- Strengthening the Indian industries via development of diagnostics, vaccines and therapeutic molecules
- Development of high yielding and disease resistant livestock and poultry
- Development of strategies for conservation of indigenous livestock and poultry
- Establishment of gene banks for genes of interest, cell lines, semen and embryo etc.
- Bioinformatics
- Nodal agency for animal bio-safety and ethical issues planning and policy

Business Development

- Initiating partnership between Industry and Academia
- Developing a portfolio of innovative research and products leading to commercialization of products

Infrastructure Development

- Hiring of interim facility
- Preparation of master plan and the designs for construction of the laboratories, animal house, animal farms, biosafety labs, hostels, guest house, quarters, etc within the land allotted for NIAB
- Auto-purification system
- High throughput screening facility
- Software and Hardware for Molecular modeling

New Initiatives

- Drug discovery and development

Teaching and Training

- Hiring of the Scientific, Technical and Administrative staff
- Combined Masters and Ph.D. in Animal biotechnology
- Workshops/Training programs and summer training on IPR and entrepreneurship

National Institute of Animal Biotechnology, Hyderabad

- **R&D**: Animal productivity and health, High yielding and disease resistant livestock & poultry development, Genebank, Vaccines, Diagnostics and lead drug molecules
- **Infrastructure Development**: Interim facility, Institute building, High throughput screening facility, Auto-purification facility, Molecular modeling facility
- **New Initiative**: Drug discovery and development
- **Teaching and Training**: Combined M.Sc. and Ph.D. Programme in Animal biotechnology; Scientific, technical and administrative staff recruitment, workshops, seminars etc.

3.16.12 Translational Health Science and Technology Institute, Faridabad Infrastructure

- Operationalization of the Faridabad campus of THSTI
- Creation of the BSL3 facility for working with infectious organisms
- Creation of animal facility to work with infectious organisms
- Expansion of the laboratory space for THSTI centres
- Establishment of extramural clinical centres at Gurgaon and/or Faridabad civil hospital/s
- Establishment of a small research hospital in the Faridabad campus
- Establishment of satellite research units in hospitals
- Establishment of service labs for intramural and extramural research
- Provision of on-campus accommodation for scientists and scholars

Human Resource

- Recruitment of scientific staff as per the existing approval
- Creation of additional scientific and administrative positions necessary for the growth of various THSTI centres
- Creation of various fellowship programs for the young scientists

Scientific and Technical

- Expansion and strengthening of existing THSTI centres
- Creation of new program centres of THSTI
- Initiation of at least 2 grand challenge scientific programs:

Proposed programmes for 12th plan

Continuation of programmes (Number of projects including infrastructure, construction activities and financial implications)

Scientific and Technical

Three program centres were created by the DBT at THSTI through the SFC mechanism during the 11th plan period. These are:

- Vaccine and Infectious Disease Research Centre (VIDRC)
- Pediatric Biology Centre (PBC)
- Centre for Biodesign (CBD)

These program centres were provided manpower, and research consumable and equipment support, for up to a 5-year period in the 11th plan. Besides these, support was provided for the purchase of land for setting up the centres and seed money to initiate the laboratory buildings. These programs have recruited key manpower and have begun operating from the interim THSTI building in Gurgaon. The programs are now maturing and will need continued support for manpower, operations and expanded laboratory space. These program centres would require a support of Rs 100 cr over the 12th plan period for their manpower, operations, and infrastructure cost.

Infrastructure

(i) Expansion of THSTI laboratory space

During the 11th plan period when THSTI was initiated a total of 12000 sqm space was earmarked for its scientific and administrative activities. Since then new program centres have begun functioning at THSTI and up to 3 more are being planned during the 12th plan period. Additional space of 8000 sqm will be required to house these new programs. The estimated cost of the additional laboratory and office space is Rs 24 cr over the 12th plan period.

(ii) Expansion of on-campus accommodation for scientists and scholars

Biological research requires presence of the scientists and scholars at odd hours in the lab. This can be facilitated through the provision of on-campus accommodation of such key personnel. Besides, THSTI has to compete with other established research organizations across the country that provides on-campus accommodation to their staff as a perk. In the 11th plan period provision was made for 5500 sqm accommodation. But this is sufficient to house only a part of the key scientific and technical manpower. THSTI would like to expand its on-campus accommodation by 6000 sqm over and it is expected to cost around Rs 15 cr over the 12th plan period.

New programmes proposed

(a) Establishment of BSL3 laboratory

Research at VIDRC entails working with highly infectious pathogens such as the multidrug resistant TB, and viruses such as Dengue, Japanese encephalitis and Chikungunya. In order to provide safe environment for handling such pathogens scientists are required to work in a level 3 bio-safety lab (BSL3). This is a specialized

research facility that requires specially designed infrastructure, and well trained manpower and processes. The commissioning of this facility and its operation is expected to cost Rs 20 cr over the 12th plan period.

(b) Establishment of animal facility for working with infectious organisms

In order to work with highly infectious pathogens (such as those listed above) a dedicated specialized animal handling facility is required to house the experimental animals. This facility for the program centres is expected to cost around Rs. 20 cr over the 12th plan period.

(c) Establishment of new niche centres with programme focus

THSTI is unique in design among DBT autonomous institutions in being cluster of programme centric niche centre. In this plan it is proposed to (i) scale up the vaccine and infection disease centre and pediatric biology centre (ii) establish new niche centre for cancer biology and nano-medicine (iii) Centre for chronic disease biology (iv) Centre for meta genomics of health and disease (v) centre for bio implants and computational science.

(d) Establishment of a small research hospital

To make the "bench-to-bedside' research most efficient; a patient care unit has to be located in close proximity to the THSTI research laboratories. A referral facility with 120 beds and 30 day-care beds is proposed to support the translational activities at the institute. The hospital would run specialty clinics relevant to the THSTI research programs. The facility will provide cutting-edge clinical care using new diagnostic technologies, novel therapies and solutions developed in partnership with the THSTI. The THSTI's clinical set up will facilitate interaction and collaboration among clinicians and researchers. The hospital may be set up in phases as a public-private joint venture or in collaboration with one of the existing academic hospitals such as the AIIMS. The clinical centre will cost Rs 60 cr over the 12th plan period.

(e) Establishment of extramural clinical research centres

As stated above, THSTI requires clinical centre and dedicated staff for conducting large translational programs. While setting up such a hospital of its own will take some time, THSTI will, in the interim, develop a long term partnership with a nearby district hospital in Gurgaon and/or Faridabad. The partnership will create a model of 'grassroots' level implementable clinical research in hospitals and the community.

Additionally, satellite units in hospitals in Delhi and across the country will be established to facilitate clinical research. This will allow THSTI faculty, students and fellows to collaborate with academic physicians across the country to set up translational programs. Consistent with regulatory requirement, medical professionals (clinicians) will be required to provide clinical care to sick subjects, address issues of medical safety assessment and for oversight of field investigators. Large teams comprising of filed investigators, field workers, programmers, data entry operators will be required to handle large data collection, data security and audits, and for maintaining quality assurance. THSTI would require about Rs 10 cr over the 12th plan period for setting up the extramural clinical centre/s.

(f) Establishment of new Inter Institutional Centre for Biodesign – bioengineering and BioScience.

The first Inter Institutional centre with Bio design training, bioengineering, animal physiology, bio and nano science, platform technology and validation prototype infrastructure will be established. The near centre will be attached at Faridabad cluster linked to THSTI with other partners by AIIMS, IIT Delhi and ICGEB, Delhi. The National Biodesign alliance will be managed by a secretariat to be established at Faridabad Cluster. The secretariat will create linkage with industry and all IITs and partner medical schools and bioengineering centre at IISc. Those with a major national effort for implant, devices, diagnostic and drug delivery systems. The inter-institutional centre will have novel need and opportunity analysis system and business development, IP, technology management skills. An incubator for entrepreneurs will be inbuilt.

(g) Establishment of a GLP-compliant bioanalytical laboratory to support product evaluation

THSTI will set up a bioanalytical laboratory to carry out measurements of trace quantities of endogenous substances, biomarkers, immune responses, therapeutic products and/or their metabolites for the assessment of safety, tolerability, kinetics and efficacy of test articles. This state-of-the-art laboratory will have highly sophisticated and sensitive analytical instruments. The operations of such a laboratory supporting GCP –based trials will need to conform to the guidelines of Good Laboratory Practice (GLP) to ensure standardization, accuracy and reproducibility of the data. This is envisaged as a National facility and is expected to cost Rs 10 cr over the 12th plan period.

New initiatives in Emerging and Evolving Areas

(a) Development of novel TB vaccine candidates

Tuberculosis (TB) continues to be a major infectious disease that requires an improved and effective vaccine. Concerted efforts of a large team are required to tackle this issue. VIDRC of THSTI would like to take up this challenge in association with other partners such as the University of Delhi, ICGEB, and TRC Chennai. This program is expected to cost around Rs 20 cr over the 12th plan period. The laboratory will be managed by clinical development service agency and extramural unit of THSTI.

(b) Novel virus discovery program

Frequent viral disease outbreaks are taking place in various parts of India and often these remain undiagnosed as there may be novel viruses that me responsible for the outbreak. A novel virus discovery platform is proposed to be set up by the VIDRC of THSTI to address this issue. This program is expected to cost around Rs 10 cr over the 12th plan period.

(c) Biology of sepsis and serious bacterial infections of infants

In India, more than a quarter of the one million neonatal deaths are attributed to serious bacterial infections that include pneumonia, sepsis and meningitis. These severe infections are also a major cause of hospitalization in infants 7-59 days of age. The outcomes of these infections in early infancy are poor. Interventions that can immediately improve the efficacy of existing standard therapy of serious bacterial infection in low resource settings are a high priority. We propose to study the biology of serious bacterial infections and evaluate interventions that can influence host responses to infections. This program is expected to cost around Rs 10 cr over the 12th plan period.

(d) Biology of Vaccine immune responses and factors (micronutrients, intestinal flora) affecting these responses

Poor responses to vaccines in developing countries have impeded attempts at disease eradication or control. Lower rates of seroconversion to OPV in tropical climates have been well documented. Vaccine failures impact public health adversely in many ways apart from the costs of the disease due to vaccine failures. We propose to get greater insights of the biological and biochemical correlates of young infants to poor vaccine

response. Deficiencies of micronutrients, some of which are crucial for normal maturation and function of the immune deficiency, are highly prevalent in India throughout childhood. There is little data on the effects of deficiencies of vitamin D and other critical micronutrients such as zinc on immune responses to antigens in the Indian context. Initial programs in this domain will be to evaluate if supplementation of these micronutrients or factors that alter intestinal flora influence host immune responses to vaccines given at birth. Studies to understand the biology of these micronutrients will be undertaken. The program is expected to cost Rs 15 cr over the 12^{th} plan period.

(e) Biology of Prematurity

Neonatal health presents India with a formidable challenge with over 25 million births, with about 2.5 million being premature. We propose to initiate a multidisciplinary program to understand the genetic and epigenetic basis of prematurity. Using proteomic approaches we will study epigenetic phenomena (DNA methylation, histone modifications, modifications in RNA transcripts etc) in prematurity and intrauterine growth restriction in a variety of medical conditions and nutrient deficiencies in the mother, fetus and the newborn. This program is expected to cost around Rs 10 cr over the 12^{th} plan period.

(f) Sustainable low cost diagnostics, implants and devices for health

The biodesign process will be used for developing low cost implants, devices and diagnostics. Development of novel diagnostic tools for risk assessment and for early detection of the disease will help in instituting science based disease prevention and appropriate therapy at an early stage resulting in the improved outcome and reduction of the cost of treatment. Point-of-care tests will influence clinical decision making. Biomarkers will help in science based disease classification with therapy. Advances in in-vitro diagnostics would also result in prediction of chronic diseases and cancer, and bring in new ways of preventive therapy. This program is expected to cost around Rs 10 cr over the 12^{th} plan period.

Clinical Development Services Agency (CDSA)

This is a recently included extramural unit of THSTI, established as an independent society. This is vision is to catalyze regulatory product evaluation capacity in India and provide such services to SME's and public sector for indigenously developed products.

Continuation of Programs (number of projects including infrastructure, construction activities and financial implications)

(i) **Centers of Excellence for Training and Regulatory Trials (10):** CDSA proposes to establish a network of institutions by supporting good existing centres and upgrade them to centres of excellence (COE) for training and regulatory trials as affiliates of CDSA. It will enter into collaborative agreements with at least five Category-I premier organization in the first year to sustain them as centres of excellence to tap the huge potential of the clinical trials market and fulfill public sector need for socially relevant product. CDSA will provide a core grant to these institutions to develop human resource and infrastructure. CDSA will also identify 5 additional centres (Category II) that can be upgraded to CoE level in 5 years. The support level will be lower than CoE's. CoE's (Cat I) will do clinical trial, clinical research and Training. (Cat II) Centre will be site for clinical trials and do research.

(ii) **Clinical Investigator Development Program:** In collaboration with leading international and national agencies, develop and conduct training and development program for clinical investigators

(iii) **Post-graduate Training Program in Drug Discovery and Translational Medicine:** CDSA will seek to establish a tripartite collaboration among academia, industry and CDSA to develop and institutionalize preclinical research capacity in drug discovery and translational medicine.

(iv) **Secretariat for Severe Acute Malnutrition in children (SAM):** CDSA will be coordinating and monitoring the projects awarded under the SAM program. It will continue to hold Technical Advisory Board meetings to review the progress of these projects.

(v) Clinical trials support to SME's for locally developed product, and those acquired through early technology transfer. This service will be provided through the network of 10 clinical trial centres.

New initiatives in emerging and evolving areas:

- CDSA proposes to establish Clinical Trials Centres in collaboration with medical colleges. Such centers will be fully equipped and staffed to conduct GCP compliant clinical trials. This infrastructure is needed to develop the clinical research capacity and capability in India to an International level. We

will help medical school develop CRO's to conduct ethical product evaluation and clinical – translational research.

- Establish a GLP-conforming national laboratory to provide a much-needed bioanalytic support service for clinical trials in the domain of public health diseases. The services would include measurement of biomarkers, pharmacokinetic parameters, vaccine immune response in nutritional biochemistry. The laboratory will be established at the CDSA facility at the cluster in Faridabad in partnership with THSTI and regulatory centre for biotechnology.

Translational Health Science and Technology Institute, Faridabad, Haryana

- **Infrastructure Development**: Institute building with laboratory development including BSL3 & animal facility, Small research hospital with extramural clinical centre, On-campus accommodation
- **New Initiatives**: Niche centres for vaccine, infectious & chronic disease, pediatric biology, cancer biology & nano-medicine, metagenomics of health & disease, bio implants and computational science; Inter-instituional centre for biodesign, bioengineering and biosciences, Prematurity biology, low cost diagnostics
- **Clinical development services agency: Centre for execellence** for regulatory trials, Clinical Investigator development program, Drug discovery & Translational medicine, Secretariat of Severe acute malnutrition in children
- **Teaching and Training**: Scientific, technical and administrative staff recruitment, new fellowship programmes, workshops, seminars etc.

3.16.13 National Agri-Food Biotechnology Institute and Bio-processing Unit, Mohali, Punjab

The institute is a part of Agri-Food Biotechnology cluster being set up at the Knowledge City in Mohali. NABI will be a centre of excellence in translational science and product development, working towards development of innovative food processes and products keeping in view the current and future markets. NABI became functional since February, 2010 and is presently working from an interim facility at Mohali. NABI has signed three MoUs with (i) National Research Council-Plant Biotechnology Institute, Saskatoon, (ii) University of Saskatchewan and (iii) Genome Prairie, Saskatoon for developing collaborative programmes in genomics, bioinformatics and food processing, involving the exchange of faculty and scholars.

The institute is built during the 11th plan and has plans for completion of the construction of the institution building during the 12th plan.

Research and Development

- Bioinformatics and systems of the large plant genomes
- Development of Network of Excellence for quality improvement of grain and fruit crops, food safety and quality standard research, Nutragenomic, Functional foods research and their co-relation with diabetes, obesity and micro-nutrient deficiency
- Developing tests for assessing safety of new risks (GMOs, nanostructures, naturally occurring toxins, processing residues etc.) and approaches to toxicogenomics, nutrigenomics and quality assessment
- Development of Technology Platforms for providing high-end services nationally, through joint management with industry in the area of risk assessment, bioinformatics, genomics, proteomics, metabolomics, tissue specific imaging and analysis, transgenic crops, post-harvest chain for quality and stability of farm produce
- Genomic initiatives on mango, guava and litchi genome sequencing

Infrastructure development

- Development of the Infrastructure and facilities for 'National Agri-Food Biotechnology Institute' and 'Centre for Agri-food Bioprocessing'
- Establishment of India reference laboratory for regulatory science and Food quality control research

Teaching and Training: Development of joint research and advanced teaching programmes with globally reputed universities and institutions.

National Agri-Food Biotechnology Institute and Bio-processing Unit, Mohali, Punjab

- **R&D**: Bioinformatics and systems biology, Network of excellence, Technology platform, Assessing safety of new risks, Genomic initiative on fruit crops
- **Infrastructure Development**: Infrastructure and facilities for the two institute
- **Teaching and Training**: Collaboration with global universities/institutions, workshops, seminars etc.

3.16.14 Institute for Stem Cell Biology and Regenerative Medicine, Bengaluru, Karnataka

InStem has initiated its activities from an interim facility created at NCBS, Bangalore. The mandate of the institute is to develop tools and technologies through stem cell and regenerative medicine research. The infrastructure facilities developed at InStem will be available to the investigators of both the institutions i.e. NCBS and InStem. NCBS and InStem also established a not for profit company called as Centre for Cellular and Molecular Platforms (C-CAMP). The centre is established with an objective to professionally manage the available advanced technology platforms, to trained scientist and to provide services. InStem has initiated the following programmes during the 11th plan.

Research Programme

InStem have signed a memorandum of understanding which allows close interaction of InStem with the Centre for Stem Cell Research (CSCR) at the Christian medical college, Vellore. A full GMP facility has been created for generation of Stem Cell for clinical trials. Mouse iPS stem cells have been generated for the first time in India in the centre. The centre is also involved in clinical trials using autologous adult stem cells to treat diseases like acute myocardial infraction etc. The research programme initiated by InStem arebeifly described as follows:

- Development of new human stem cell models
- Development of iPS cell lines from mouse and human
- Creation of knockout mouse models in collaboration with RIKEN-CDB Japan
- Development of two model organism for stem cell research
- Initiation of structure biology programme
- Human mesenchymal stem cell research
- Continued muscle stem cell research

The centre has a programme to support young scientist for long training in stem cell research under DBT overseas schemes.

Training Programme: InStem is organizing several workshops, seminars and symposiums for the exchange of scientific knowledge. The Ph.D. programme of the institute is intended to provide high level training in interdisciplinary interactive science.

Centre for Stem Cell Research (as part of InStem), Vellore

CSCR was initiated in a project mode and is being converted into an institutional mode as part of InStem, Bengaluru under an MOA between DBT, InStem and CMC, Vellore. During the 11th plan, CSCR established the scientific, technical and administrative staff for the translational stem cell research with GMP accredited laboratory facilities. The Centre also helped Government agencies to formulate the National Guidelines for Stem Cell Research and Therapy. Also CSCR sent its scientific staff abroad for scientific training in stem cell research area to upgrade their knowledge through DBT fellowships.

During 12th plan, the scientific focus of CSCR is on developing two areas of research

- The first is towards developing models for understanding human diseases. Different scientists will collaborate with colleagues in India and overseas and utilize different models such as normal and abnormal adult stem cells, disease specific iPS cells, small animal models (including transgenic animals and 3D cellular platforms) and other innovative platforms including in-vivo imaging techniques.
- The second will be towards developing innovative therapies. There is work going on at CSCR already in these areas and we will collaborate with colleagues in India and overseas to introduce novel therapies using AAV or lenti virus based gene transfer strategies using stem cells as well as get into the area of tissue engineering particularly towards vascular grafts.
- Expansion of teaching and training program for scientists, MSc and Ph.D students, some of these in collaboration with institutions and agencies overseas.

Infrastructure development

- Establishing the core facilities for cell culture, imaging, flow cytometry and the molecular genetics laboratories as well as the small animal facility, GMP cell processing facility.
- Intramural grant for the newly recruited scientists and other research personnel.
- Housing facility for the technical and non-technical staff within or near Vellore.

4.0 FINANCIAL PROJECTIONS

The estimations, allocations and expenditure during the period 2007-2012 are given below:

(Rs. in Crores)

Year	Proposed	Budget Estimate (BE)	Revised Estimates (RE)	Actual Expenditure	Percentage Expenditure
2002-07 (10th plan)	2075.00	1450.00	1660.00	1653.10	99.58
2007-08	900.00	675.00	683.00	618.00	90.48
2008-2009	1406.00	900.00	879.00	871.77	99.17
2009-2010	1927.70	1000.00	900.00	882.78	98.11
2010-2011	1700.00	1200.00	1200.00	1121.48	93.65
2011-2012	1600.00	1400.00	1400.00	1400.00 (ongoing)	47% as on 30 th September, 2011
Total of 11th plan	12000.00	6389.00	5062.00	4894.03	*98.96

** It is estimated that as against the overall allocation of Rs. 5062 crores, upto Rs. 4894 crores shall be spent by the end of March 2012 amount into overall average expenditure of upto 98% of the allocation.*

The Estimates for 12th Plan

The main emphasis of 12th Plan is scaling up of existing successful schemes by atleast 3 folds and starting of several new initiatives human resource development, expansion and establishment of new generation research resources, facilities and services, major support to universities and institutions for interdisciplinary research in medical sciences, agriculture, veterinary and biopharmaceuticals, mega national projects on mission mode in specific areas of chronic diseases, agriculture productivity, climate change, bioengineering and bio-fuels, sustained support to newly established autonomous institutions, expansion of existing institutions for setting up innovation and translational centres, setting up of new institutions in the area of marine

biotechnology and bioinformatics, infrastructure development in three bio-cluster and investment in three more bio-clusters, setting up of 50 more centres/units for basic and translational research in priority areas, continuation of public private partnership programmes with new innovation schemes, fully operational of BIRAC and its services, establishment of platforms and incubators for research and manufacture by SMEs and new R&D projects upto 1500 Basic and use Inspired Research & Translational Science and Strategic Research to be globally competitive and finally establishment of Biotechnology Regulatory Authority of India along with series of regulatory testing and validation centres and communication system.

Considering the maximal utilization of allocations and implementational trends of the department, increasing needs of bio-industrial development and clearly focused programmes for 12th Plan the working group after deliberation recommended and investment of Rs. 17.887.81/- crores for 2012-2017 at the rate of3 fold increase over 11th plan allocation. The breakup of the same is given below:

(Rs. in Crores)

Sl. No.	**Name of Programme/Scheme/Projects**	**Twelfth Plan Outlay**
	S & T Sector	
1.	Human Resource Development	600.00
2.	Promotion of Excellence and Innovation	600.00
3.	Research Resources Facilities and Services	700.00
4.	Bioinformatics, Computational and System Biology	200.00
5.	Basic and use Inspired Research	1500.00
6.	Translational Science and Strategic Research	2000.00
7.	Grand Challenge Programmes	800.00
8.	Bio-Clusters and Incubators	1500.00
9.	International Collaborations	300.00
10.	Biotechnology for Social Development	200.00
	Total (A)	**8400.00**
11.	**Autonomous R & D Institutions**	
	(a) Ongoing	
	(i) National Institute of Immunology, New Delhi	535.40
	(ii) National Centre for Cell Sciences, Pune	470.89
	(iii) Centre for DNA Fingerprinting and Diagnostics	450.00
	(iv) National Brain Research Centre, Manesar, Haryana	390.73
	(v) National Institute of Plant Genome Research, New Delhi	265.98
	(vi) Institute of Life Sciences, Bhubaneswar, Orissa	325.00

	(vii) Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram	235.00
	(viii) National Institute of Biomedical Genomics, Kalyani	295.00
	(ix) Regional Centre for Biotechnology, Faridabad, Haryana	589.46
	(x) National Institute of Animal Biotechnology, Hyderabd	344.00
	(xi) Translational Health Sciences and Technology Institute, Faridabad	594.00
	(xii) National Agri-Food Biotechnology Institute and Bio-processing Unit, Mohali, Punjab	792.35
	(xiii) Institute of Stem Cell Biology and Regenerated Medicine, Bangalore	600.00
	(xiv) Institute of Bio-resources and Sustainable Development, Imphal	150.00
	(b) New Institutions	
	(i) Institute of Bioinformatics & Computational Biology	400.00
	(ii) Institute of Marine & Microbial Biotechnology	400.00
	(iii) Biotechnology Regulatory Authority of India (BRAI)	200.00
	(iv) Institute of Biodesign, Bioscience & Bioengineering (includes Medical Centre)	450.00
	(v) Institute of Chronic Disease Science & Biotechnology	300.00
	(vi) Infectious Science & Biotechnology Institute in North East (linking to THSTI as partner for training & Education)	300.00
	Total (B)	**8087.81**
	I&M Sector – Innovation Support Schemes to Industry	
	Innovation Support Schemes to Industry (I&M Sector) • Biotech Parks = Rs. 100 Cr. • SBIRI = Rs.200 Cr. • BIPP = Rs. 500 Cr. • BIRAC = Rs. 250 Cr. • New Initiatives = Rs. 300 Cr.	1400.00
	Total (C)	**1400**
*	**Total (A+B+C)**	**17887.81**

(* 10% of the total budgetary allocations would be made available for programs and schemes of North Eastern Region)