

CATALYSING THE GROWTH OF AN INNOVATION DRIVEN BIOTECH ENTERPRISE



Biotechnology Industry Research Assistance Council
(A Government of India Enterprise)

March, 2013

OUR REINFORCED AND RENEWED “VISION & MISSION”

Empowering
And Enabling
The Biotech
Innovation
Ecosystem
For Affordable
Product
Development

Vision

“Stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly start-up's and SME's, for creation of affordable products addressing the needs of the largest section of society.”

Mission

“Facilitate and mentor the generation and translation of innovative ideas into biotech products and services by the industry, promote academia – industry collaboration, forge international linkages, encourage techno entrepreneurship and enable creation and sustainability of viable bioenterprises.”

About BIRAC

Department of Biotechnology, Ministry of Science & Technology, Govt. of India made a policy statement in October, 2007 that PPP would be promoted and a separate organization would be set up to nurture and promote industrial R&D innovation. On 20th November 2011, Govt. of India took a landmark decision to create a unique organisation Biotechnology Industry Research Assistance Council (BIRAC), the first of the kind, which would work with a focussed mandate to strengthen and empower the innovation research capacities of the biotech entrepreneur and provide an enabling ecosystem.

BIRAC was incorporated on 20th March 2012 as a Section 25, ‘Not for Profit’ Company. BIRAC is a new industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and hand-holding schemes that help bring innovation excellence to the biotech firms and make them globally competitive.

In its 1st year of existence, BIRAC has initiated several schemes, networks and platforms that help to bridge the existing gaps in the industry-academia innovation research and facilitate novel, high quality affordable products development through cutting edge technologies. BIRAC has initiated partnerships with several national and global partners to collaborate and deliver the salient features of its mandate.

BIRAC serves as a single window for the emerging biotech industries. BIRAC is guided by an Independent Board of Directors comprising of senior professionals, academicians, policy makers and industrialists.



As a Government of India enterprise, it endeavours to bring professionalism, transparency and efficiency into its functioning while providing support to catalyse the transformation of the emerging Indian bio-economy.

The BIRAC Philosophy

One of the primary mandate of BIRAC is *“to trigger, transform and tend, biotech start-ups to convert innovative research in public and private sector into viable and competitive products and enterprises”*. BIRAC's key philosophy is to foster innovation and promote the translation of discovery and exciting new inventions to market ready technologies and products.

BIRAC's Core Values

- Integrity
- Transparency
- Team work
- Excellence
- Commitment

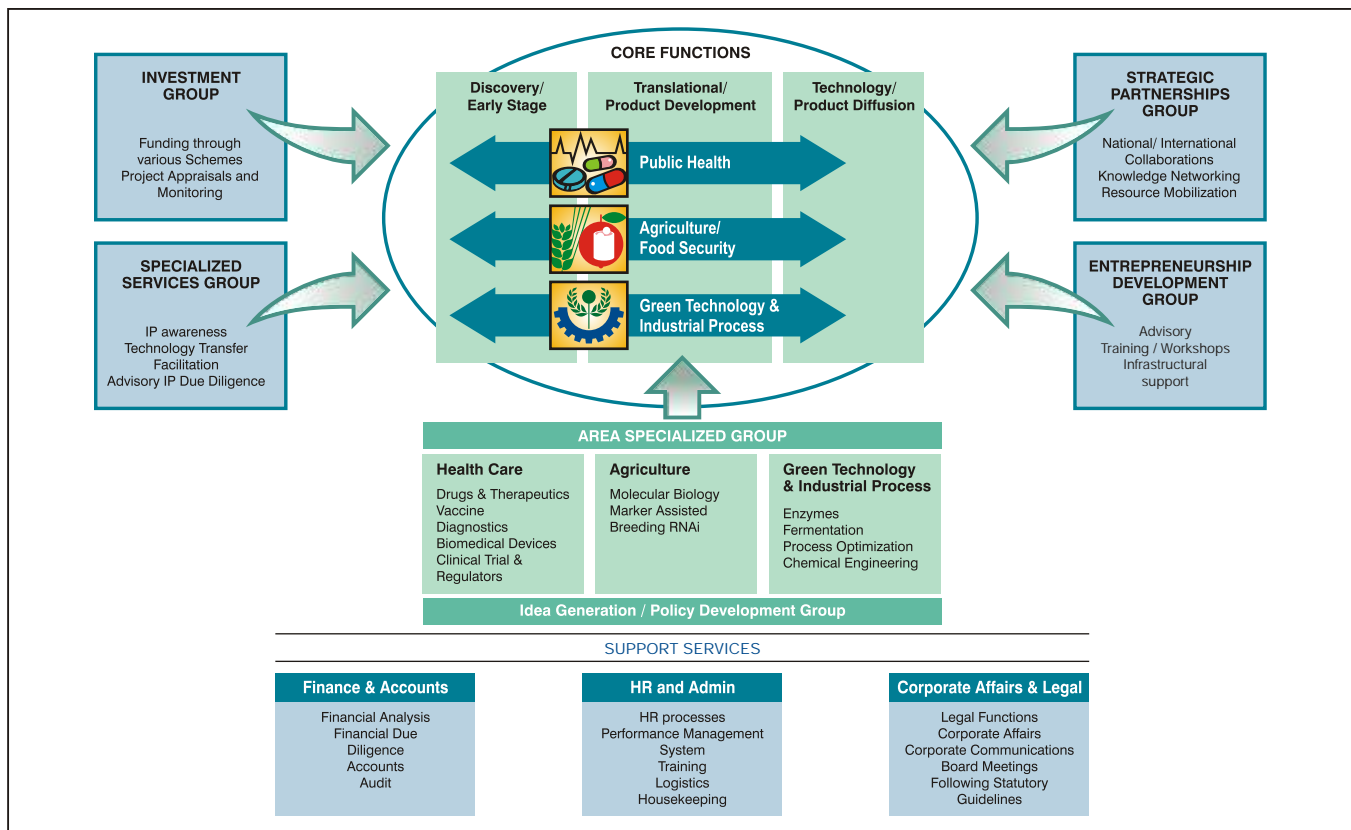
BIRAC's endeavour is to provide value to the crucial and critical steps in converting discoveries to product. While the public sector scientists concentrate on developing early leads, close interaction and partnership with the industry are essential to translate these into products. BIRAC through its investment schemes provides necessary opportunities to the Public Sector Researchers, 1st generation entrepreneurs, early start-up's and SMEs to take forward their discovery and innovation research and work together to promote affordable innovation in key social sectors and through commercialization of the discoveries, ensure global competitiveness of the Indian enterprises.

BIRAC efforts are to empower, enable and catalyse the innovation driven biotech enterprise to fulfil India's Vision of **“a. US \$100 billion Biotech Industry by 2025”** and create a true “Indian Bio-Economy”

BIRAC- A Novel Organization Structure

Since BIRAC is a unique organisation, the only of its kind set up in the country to nurture and support growth of the biotech sector; it requires a very special and unique governance structure for successful and effective functioning.

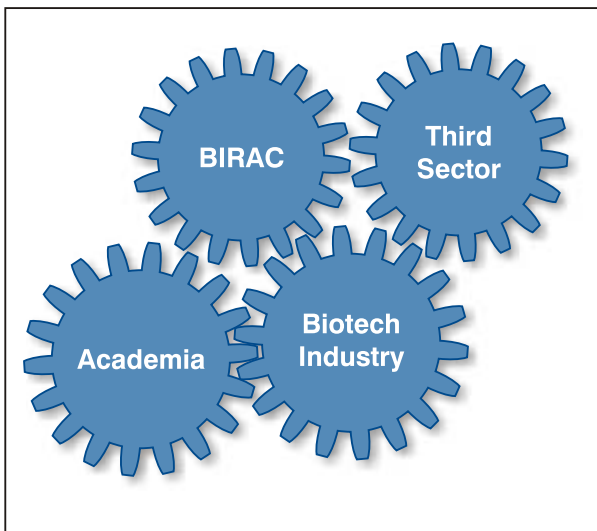
BIRAC's core mission is to work as a 'Development Agency' in the field of biotechnology and address the national needs of health and food security problems through bottom up competitive grant approach or through top down product development programmes. To achieve this aim, BIRAC would be working in partnership with private, public and international groups.

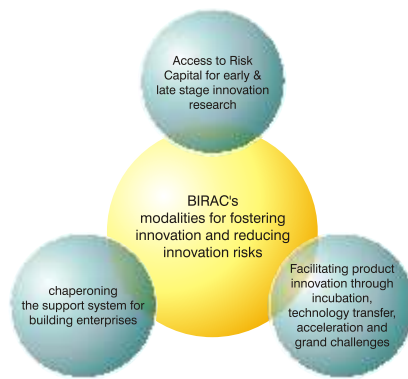




BIRAC's Focus

- Play a catalytic role in fashioning, building and scaling a true Indian bio-economy that puts biotechnology at the centre stage of the growth story of India, addresses the multitudes of challenges that the country faces and helps in delivering solutions that are innovative and affordable.
- Bring a transformational change to the biotechnology sector of the country by fostering and nurturing the next generation of 'enterprise builders' who would help deliver innovative biotechnology products and services that can solve the unmet needs of the country be it in healthcare, agriculture, bio-energy and industrial biotechnology.
- Reduce the risk inherent in the innovation pipeline from the origination of an 'idea' and its journey through several hurdles, be it at prototype or at pilot and scale up stages, to become a successful commercialised product.
- Provide a 360° mechanism for biotech firms to take their idea to final commercial product.
- Provide support to other foundational structures of a biotech innovation ecosystem namely bio-incubators, technology transfers and high end technology platforms that provide access to high end technology tools.
- Create new models of engagement among industry, academia and the third sector and build porous boundaries for critical and important information to flow among all stakeholders. For this to be realised, BIRAC envisages itself to be at the intersection of each of the dynamic ecosystems viz. industry, academia and the third sector.
- Kindle the spirit of bio-preneurship in academia and enable spin outs from academic and public funded research centres.
- Build national and international partnerships with similarly aligned organisations in delivering its mandate.





Modalities for fostering innovation and reducing 'innovation risks'

BIRAC employs several implementation modalities to positively impact the biotechnology industry sector. These constitute providing access to “risk capital” for early and late stage innovation research for affordable product development, facilitating product innovation and commercialisation through incubation, technology transfer, acceleration and grand challenges and by chaperoning the support system for building enterprises.

BIRAC Key Strategies

- Foster **innovation** and **entrepreneurship**
- Promote **affordable innovation** in key **social sectors**
- **Empowerment** of start ups & small and medium enterprises
- **Contribute** through **partners** for capability enhancement and **diffusion of innovation**
- **Enable commercialization** of discovery
- Ensure **global competitiveness** of Indian enterprises

Risk Capital for early and late stage innovation research for developing affordable products

As a public enterprise with a mandate to energise the biotechnology sector through innovation, BIRAC understands that one of the key modalities for reducing “innovation risk” is to provide entrepreneurs, early start ups and SMEs access to risk capital such that they can bridge “**valleys of death**” that they encounter while taking the idea to commercialisation stage. This is achieved by “targeted funding” combining a smart mix of grants and soft loans to innovative product development programmes .

Working with high level experts, BIRAC funding modalities recognise and evaluate the 'staged risks' and the 'innovativeness' of several product development proposals. The funding schemes cover all aspects of the innovation pipeline. New ideas that have a potential for commercialisation to bubble and grow are encouraged. Support is provided for 'proof of concept', alpha prototype projects, late stage product development through clinical and field trials, pilot stage and scale up. Many of the funding schemes endeavour to bring together industry and academia to work in partnership underlying BIRAC's commitment to build strong bridges between these two important stakeholders of the biotech ecosystem.

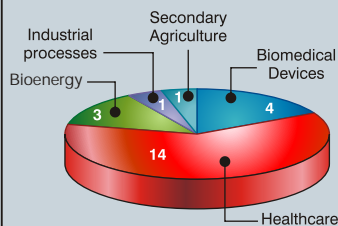
Biotechnology Ignition Grants (BIG): “Planting green shoots of biotech innovation”

BIRAC believes that the “**bio-innovation capital**” of the nation would come from novel ideas which have a commercialisation potential and that evolve out from

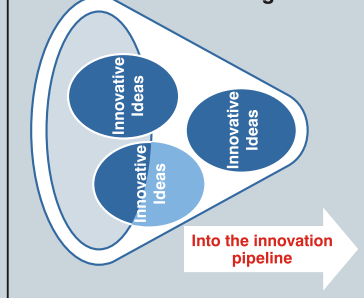
The purpose of the BIG Scheme

- Foster generation of ideas with commercialisation potential
- Upscale and validate of proof of concept
- Encourage researchers to take technology closer to market through a start up
- Stimulate enterprise formation

Distribution of the first BIG grantees, Dec 2012



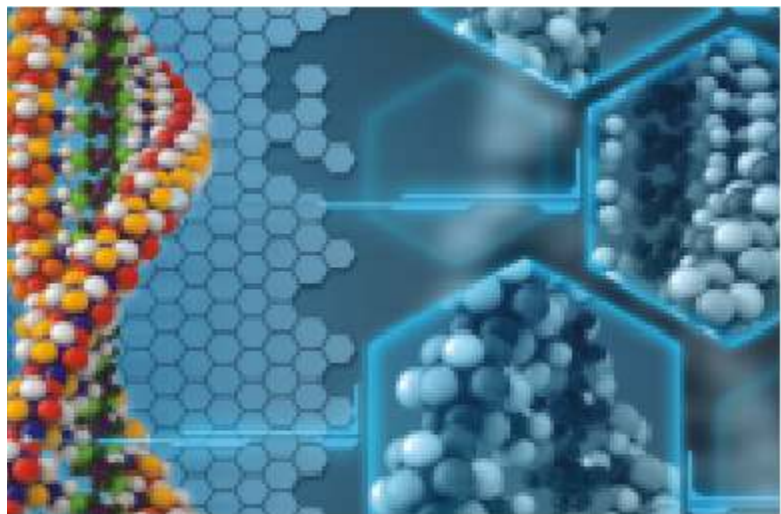
The BIG Programme



start-ups or academic spin-offs. BIRAC's strategy is therefore to populate the start of the innovation funnel with numerous exciting ideas which have an unmet need for funding and mentorship. This strategy is fulfilled through a grant funding scheme called **Biotechnology Ignition Grant (BIG)** which is available to scientist entrepreneurs from research institutes, academia and start ups. The scheme is designed to stimulate commercialization of research discoveries by providing very early stage grants to help bridge the gap between discovery and invention.

The call for proposal is announced twice a year. As part of this scheme, successful BIG Innovators receive up to ₹ 50 lakh (approx. \$100K) for research projects with commercialisation potential with duration of up to 18 months. Additionally, the BIG Innovators receive mentoring and networking help from three 'BIG Partners'. The scheme is implemented in partnership with 3 BIG partners (C-CAMP, Bangalore, IKP Knowledge Park Hyderabad and FITT, IIT Delhi) during the course of the project.

The first call was announced on 1st June 2012, 133 proposals were received and 20 proposals were selected for funding, which include 11 start-up and 9 individual entrepreneurs. Grant money amounting to ₹ 820 lakhs (USD \$ 1.6m) has been committed. Several exciting ideas from novel methods of extracting Butanol from sea algae to aptamer based detection of TB were selected. A snap shot of projects is provided.



A snapshot of BIG supported projects

| Healthcare | Industrial & related | Devices, Diagnostics & platforms |
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| <ul style="list-style-type: none"> • Development of an aptamer-based platform to detect novel Tuberculosis markers in human serum • Cancer treatment through autologous activated dendritic cells • Study, Design and Development of Hit Molecules for Type II Diabetes • Novel inhibitors of DNA Gyrase for the treatment of multidrug resistant infections • Pharmacological Evaluation of N-oxide Metabolite of Antipsychotic Drug for Type 2 Diabetes • Expression of therapeutic diabody against TNF-alpha and IL-17R • Engineered stable, nano-sized bubble liposomes - a commercially viable drug delivery platform • Novel Oncotherapeutic Measles Virus using eSAME system | <ul style="list-style-type: none"> • Metabolic Engineering of marine bacteria for the production of isobutanol in salt water • Enzymatic maceration of mango pulp to produce quality wine • Biochemical R&D to improve the efficacy of a dry, thermophilic, anaerobic reactor • Application of the pentose utilizing yeast strain(s) for higher ethanol production from hemicelluloses | <ul style="list-style-type: none"> • Rapid Detection of Acute Myocardial Infarction by sensing Cardiac Markers using Micro Cantilever Technology • Development of Diagnostic Reagents for Acute Myocardial Infarction • Intraosseous Device • A Platform for Rapid Antibiotic Susceptibility Testing (AST) and Assessment of Bacterial Load • Fetal Electrocardiogram and Uterine Activity signal extraction from maternal ECG eliminating the need for the use of conventional transducers • Modular Resilin-mimetic Elastomeric Platform |

Small Business Innovation Research Initiative (SBIRI):

“Helping to take the incremental step towards commercialisation”

The leap from idea to “proof of concept” and a further an alpha- prototype stage product has several hurdles and requires several iterations. The SBIRI funding programme, successfully initiated by DBT in 2005, would now be managed by BIRAC from April 2013. SBIRI funding is a mix of grant and soft loans.

Over the years, over 800 projects have been evaluated and SBIRI has supported 134 projects amounting to ₹ 190 crores (USD \$ 38 m) with grant (₹ 30 crores or USD \$ 6m) to soft loan (₹ 160 crore or USD \$ 32m) ratio being roughly 1:5. A further ₹ 200crores (USD \$40m) has been invested by the firms on these projects. The total cumulative investments for all projects is ₹ 390 crores (USD \$78 m).

Snapshots of some of the innovative projects developed through SBIRI support

Recombinant Uricase for treatment of tumor lysis syndrome developed by **Virchow, Hyderabad**



Malariscan- Diagnostic kit for malaria developed by **Bhat Biotech, Bangalore**



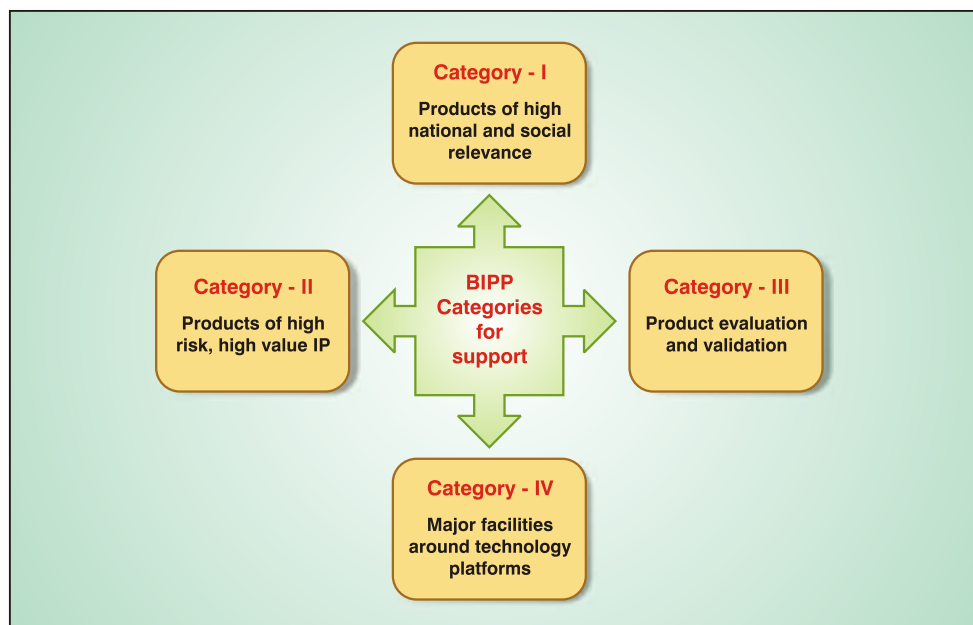
Categories for BIPP support

The range of funded projects supported by SBIRI is diverse and covers all aspects of biotechnology. Many of the projects are joint collaborations between industry and public research institutes thus highlighting the bridges between academia and industry being fostered by SBIRI.

Biotechnology Industry Partnership Programme (BIPP): “Providing a ladder for the next level of cutting edge innovation”

Many national priorities in healthcare, agriculture, bio-energy and green chemistry are addressed through path breaking projects in frontier technologies, that require substantial injection of funds. These frontier projects need de-risking in a partnership mode where there is a need for joint contribution of funds from BIRAC as well as industry. BIPP understands and maps these priorities and is the funding scheme that addresses the specific needs of the industry with a funding modality that is a mix of soft loan and grants. Approved by the Government of India in 2008, BIPP is an industry partnership scheme for high risk, discovery lead innovation research.

Eligibility for BIPP funding extends to Indian biotech companies registered under Indian Company Act 1956 with 51% Indian shareholding (including NRI's) who have



Recombinant fuzeon for AIDS developed as a biosimilar product by **Virchow**

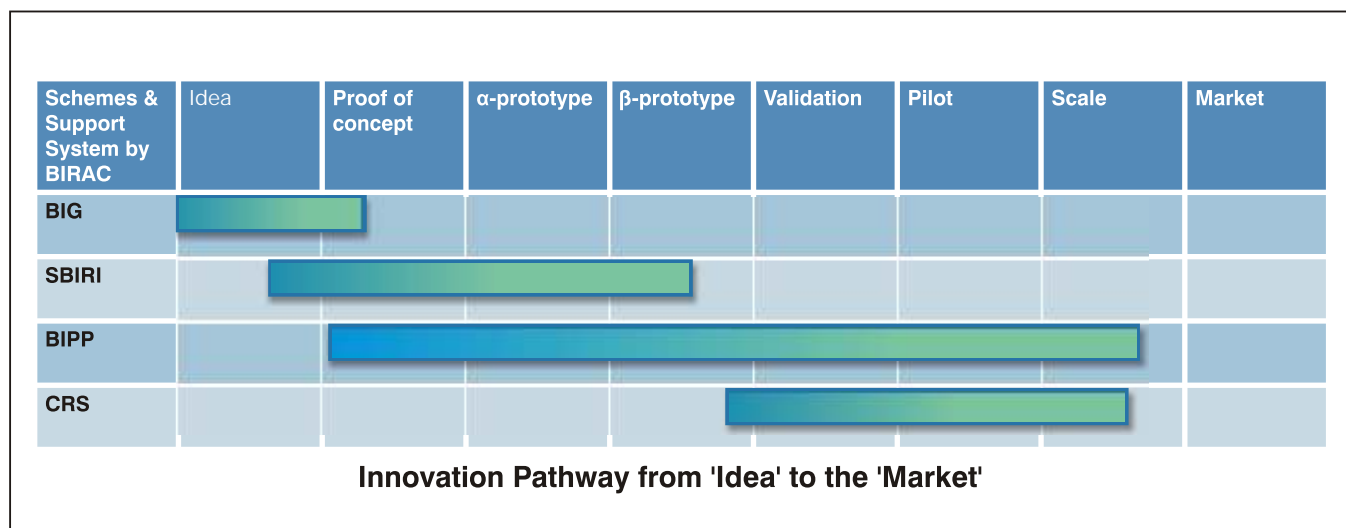


DSIR recognized R&D unit are entitled for BIPP funding, either independently or in collaboration with companies, not for profit organisation or academics partners.

Besides supporting high risk innovative research for affordable product development, BIPP's funding also extends to product evaluation and validation through support for limited and large scale field trial for agriculture products, clinical trials (Phase I, II, III) and support to technology platforms.

Till date, BIRAC had set forth 27 specific BIPP calls, received over 800 proposals, 102 agreements have been signed with 93 companies involving around 75 startups and SMEs. A total of investment of ₹ 797 crore (US \$ 147 m) has been committed with Rs. 298 crore (US \$ 55 m) by Govt. of India and contribution of ₹ 499 crore (US\$ 92 m) from the private sector.

BIPP in its short history has supported development and commercialisation of several important affordable products.



BIRAC's flagship schemes encompassing different stages of product commercialization

Robio-The medical tool positioners for use in image guided interventional procedures with an emphasis on oncology was validated and the two variants viz. ROBIO-EX and ROBIO EZ, have been commercialized following the standard guidelines by **Perfint, Chennai**



Health Care

Affordable Product Development

Drugs

Trials

- 2 novel Drugs under Phase II trials for treating Cardio metabolic risks - Torrent Pharmaceuticals Limited.
- Preclinical study completed for Diabetic Foot Ulcer - V Life Sciences Technologies Pvt. Ltd. Phase I trials will commence shortly.



Research & Development

- Development of Pharmaceutical Cocrystals of anticancer drug Temozolomide for pre-clinical trials - Crystalin Research Pvt. Ltd.
- Developing Novel combination therapy for treatment of resistant and non-responsive cancers - Leadinvent Pvt. Ltd., Sphaera Pharma Research & Development Pvt. Ltd., International Centre for Genetic Engineering and Biotechnology.
- Developing Novel inhibitors of fatty acid biosynthesis for treating drug resistant *S.aureus* bacterial infections - Vitas Pharma Research Pvt. Ltd.



Vaccines

Trials

- Phase III Clinical trials of Japanese Encephalitis vaccine successfully concluded by Biological E Ltd., Hyderabad. Market license obtained in India for the age group of >1 yr to 3 years and >18 years to <40 years. Support for trials for the age ≥ 1 to <3 years groups provided.
- Phase III trials of oral Rotavirus Vaccine successfully completed. Market Surveillance going on.
- H1N1 pandemic influenza vaccine named PandylfluTM - Panacea Biotech, Delhi is in the market.



Research & Development

- An affordable, Asia specific 15valent Pneumococcal Polysaccharide - Protein Conjugate Vaccine under development - M/s. Tergene Biotech Pvt. Ltd., Secunderabad.
- 13-valent Pneumococcal conjugate vaccine including capsular polysaccharides from serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F individually conjugated to carrier protein under stage of Proof-of concept/validation - Panacea Biotech, Delhi.
- HPV Vaccine - Serum Institute of India Ltd.



Recombinant follicle-stimulating hormone - Developed by Bharat Serums, Hyderabad, is now marketed as Foligraf. Foligraf is a subcutaneous injectable preparation used in infertility treatment regimen.



RBC phenotyping kit- produced by Mediclone, Chennai.

The kit was developed as an affordable import substitute. The entire range of Monoclonal Antibodies for blood phenotyping is bulk Produced and packaged for retail, OEM and bulk customers.



Health Care

Affordable Product Development

Diagnostic and Devices

- A rapid cost-effective point-of-care diagnostic device with microPCR to diagnose multiple diseases presently Malaria, Dengue & Typhoid developed - Bigtec Pvt. Ltd. Bangalore is ready for market.
- The device for execution procedure for tumor ablation using Maxio (The Integrated planning navigation and Training Platform for Tumor Ablation) launched in the market - Perfint Healthcare Pvt. Ltd.
- Immunodiagnostic kit for detection of autoimmune diseases developed - Amar Immunodiagnostics Pvt. Ltd.

Prototype development

- Affordable fluorescence reader for point-of-care diagnostics being developed - Design Innova, International Centre for Genetic Engineering and Biotechnology, New Delhi.
- DX Phone - Software platform for using mobile phone to analyse blood glucose test strips - Janacare Solutions Pvt. Ltd., All India Institute of Medical Sciences, Narayana Hrudayalaya Hospital.



Agriculture

Marker Assisted Breeding

- Rice - enhanced drought and multiple diseases and pest resistance - Advanta India Ltd. biotic stress resistance - Kaveri Seeds Company Limited.



- Nutritionally improved mustard - Nirmal Seeds Pvt. Ltd., The Energy and Resources Institute (TERI)
- Improved yield potential of maize under drought stress - Kaveri Seeds Company Limited.
- High yielding pigeonpea - Krishidhan Seeds pvt. Ltd., International Crops Research Institute for the Semi-Arid Tropics (ICRISAT).

RNAi

- Insect pest and virus resistance tomato - Advanta India Ltd., Indian Agriculture Research Institute, New Delhi (IARI).



- Insect pest resistant Brinjal - Sri Biotech Laboratories India Ltd., University of Delhi South Campus.

Contract Research Scheme (CRS): “Bridging the industry-academia Gap”

One of BIRAC's major focus is enabling public funded research to be commercialised and creating effective linkages between academia and industry.

Through the CRS funding, BIRAC extends support to academic institutes across the country to take forward their research leads through validation and translation by industry. Funding is in the form of grant which is given to both the academic as well as the industrial partner. While the industry performs its role as a 'validation partner' and engages on a contractual basis, the IP rights reside solely with the academic partner (s).

CRS's overall aim is to enable validation of academia research that have commercialisation potential and engage the contract research and manufacturing (CRAMS) industry to carry out the validation of a process or a prototype. These validations can range from exploratory to small scale or even large scale.

Besides providing for funds, BIRAC helps academic scientists on several fronts such as extending help for FTO search, IP management, preparation of Material Transfer Agreement (MTA), Non-Disclosure and IP protection contracts and licensing agreements as well as technology transfer.

Facilitating product innovation and commercialisation through incubation, technology transfer, acceleration and grand challenges

Bio-Incubator Support Scheme (BISS) & Translation Accelerator

Bio-incubation allows harnessing of the entrepreneurial potential of start ups by providing access to infrastructure as well as mentoring and networking platforms that the start ups could use during their fledgling days.

BIRAC intends to establish world class bio-incubation facilities as well as upgrade and strengthen existing incubation facilities at certain strategic locations in the country. Ideally it is envisaged that the new bio-incubation centres would be established around DBT clusters.

BIRAC supported bio-incubation facility would have the following salient features:

- Provide good incubation space to Start-ups and Entrepreneurs.

Agriculture

- Virus resistant Okra - Nirmal Seeds Pvt. Ltd., University of Delhi South Campus.

Improved productivity and production

- Mustard - Mother Dairy Fruit and Vegetable Pvt. Ltd., University of Delhi, South Campus.
- Rice with drought and salinity stress tolerance - Bioseed Research India Ltd., International Centre for Genetic Engineering and Biotechnology .



- Herbicide & Stress tolerant' transgenic Onion - Bejo Sheetal, International Centre for Genetic Engineering and Biotechnology
- Maize and rice - Metahelix Life Sciences Private Ltd.
- Stress Tolerant Rice - Maharashtra Hybrid seeds company Limited

- Provide access to a pool of special equipments in the common equipment facility.
- Connect industry and academia and enable interactions for efficient exchange of knowledge as well as facilitate technical and business mentorship.
- Provide enabling services and required mentorship for IP and technology management, legal and contract, resource mobilization and networking platform.
- Establish efficient governance models.

BIRAC Incubation facilities

- Entrepreneurship Development Center (trademark: Venture Center), NCL, Pune.
- IKP Knowledge Park, Hyderabad
- Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore.
- Zonal Technology Management - Business Planning and Development Unit" - ZTM-BPD, IARI, New Delhi.
- Indian Institute of Technology, Madras,
- Society for Biotechnology Incubation Centre, SBTIC, Genome Valley Hyderabad
- Kalinga Institute of Technology, University-TBI Business Incubator, Bhubaneswer
- Foundation of Innovation and Technology Transfer, Indian Institute of Technology, Delhi,
- B.V. Patel Pharmaceutical Education & Research Development (PERD) Centre, Ahmadabad Gujarat.
- Indian Institute of Technology, Delhi
- Gujarat State Biotechnology Mission, GSBTM, Baroda
- Science & Technology, Park, Pune

Twelve existing Bioincubators across the country have been strengthened and establishment of a new world class bioincubator has been approved at the DBT-Faridabad Bio-cluster. Approximately 70,000 Sq.ft of bio-incubator space has been created all over the country to support start ups.

BIRAC understands that an innovation ecosystem in addition to a vibrant university system, with industry connect points and good incubation facilities

Clean Energy and Industrial processes

Biofuels

- Pilot plant for 3000 Litre ethanol/day production at India Glycols Limited using technology from DBT-ICT Centre for Energy sciences Lignocellulosic biomass.
- Technology platforms development for generating Biological Hydrogen - Nagarjuna Fertilizers & Chemicals Limited.

Scale-up

- Viable Enzymes production using Agro waste/produce as raw material - Rossari Biotech Ltd.
- Single step extraction of cottonseed with miscella refining - Abhay Cotex India Pvt
- Development of Value added Corn steep liquor and powder suitable for food and fermentation industry upto pilot scale (1 TPD) - Anil Ltd., National Chemical Laboratory (NCL).
- Development of Technology Platform for Rare Sugar Production - Nagarjuna

also require other elements that enable product commercialisation. **Translation Accelerator** combines the operational efficiencies of an incubation centre with access to risk capital, develop prototype and product commercialisation professional to give a head start to start ups. BIRAC intends to set up 'Translational Accelerators' with special focus on a few important sectors.

BIRAC's partnerships: Delivering impact through the power of collaboration

Bio-innovation does not follow a linear trajectory but comprises several interlinked processes and pathways that require collaborative efforts amongst several players to find innovative solutions. BIRAC's intention as an organization fostering and facilitating growth of the biotech enterprise is to find synergies with similarly aligned organisations to deliver excellent programmes that alleviate the challenges of the country especially in areas of healthcare, food and fuel security.

Several strategic partnership dialogues have been initiated with national and international agencies and many are in different stages of maturity.

BIRAC international partnership strategies aim to accomplish the following:

- Promote excellence through collaborative opportunities between Indian and international researchers that builds Indian capabilities for product development.
- Enable international good practices and capacity building.
- Ensure access to world class infrastructure and information.
- Promote mobility of researchers and entrepreneurs internationally.
- Promote free flow of ideas.

Some of the recent synergistic partnerships of BIRAC is currently involved are:

• DBT-BIRAC International Industry Partnership Programme

BIRAC partners closely with the DBT 'International Co-operation' (IC) (IC-DBT) division to develop and establish a framework for a multitude of Industry Partnership Programmes with international organisations and countries. This framework provides detailed procedures for review, funding and implementation of international public-private partnerships driven by BIRAC-DBT.

- **Management of the of DBT-Gates Foundation BIRAC Partnership Programme**

DBT and Gates Foundation have signed a MoU for supporting priority areas of research. BIRAC has been entrusted the responsibility to be the “Technical Management unit” for the joint partnership. In this regard, BIRAC would establish a Programme Management Cell and administer programmes in partnership with DBT and Gates Foundation, which are in area of health care, agriculture and focus on affordable product development.

- **BIRAC- University of Cambridge Entrepreneurship Education Programme in Biotechnology**

BIRAC and Centre of Entrepreneurial Learning (CfEL) of Judge Business School, University of Cambridge have initiated a partnership that would enable five BIRAC supported applicants to take part in CfEL's flagship intensive entrepreneurial boot-camp programme called “IGNITE”, which is aimed at providing academics (PhDs, post-docs and scientists) entrepreneurial opportunities to explore their innovative ideas and transform them into a business project. CfEL will provide one week intense mentorship and training to the BIRAC supported candidates and for another week expose them to Cambridge's entrepreneurial cluster.

The first batch of 5 BIRAC supported IGNITE candidates from the pool of its Ignition Grant awardees and SIB fellows selected would be in Cambridge in early July 2013. BIRAC and CfEL are exploring other partnership engagements.



Technology Transfer: Banana Bio-fortification

BIRAC has signed an agreement with Queensland University of Technology (QUT), Australia on the technology transfer related to Bio- fortification and Disease Resistance in banana to India.



- **Partnership with CDSA for management of BIRAC supported clinical trials**

BIRAC's flagship BIPP funding programme supports several clinical trials during the product development cycle. The clinical trials require specialised services, protocol design, regulatory compliance and monitoring of clinical data. BIRAC is in dialogue with CDSA (part of THSTI) to partner for:

- Clinical trial management
- Capacity building through training and mentoring SME's and start-up's
- Technical advisory services related to clinical trials operations

Chaperoning the support system for building enterprises: Connecting the dots

Biotechnology enterprise formation and strategies for growth of a biotechnology firm especially those that are based on innovation and product development need several supporting ladders such as understanding the IP landscape of the arena, patentability of the product, regulatory burden and market opportunities. BIRAC provides support in many of these areas to start ups and SMEs in particular as well to academic institutes.

Technology Mapping, Transfer and Acquisitions: Helping Indian Industry leap frog to the next level

One of the major policy interventions by any public agency, such as BIRAC, that aims to foster innovation is to provide access to academic research leads, ensure osmosis of knowledge between academia and industries and provide access to cutting edge technologies that help industry to overcome bottlenecks.

BIRAC engages with the academic institutions and the biotech industry and critically looks at the R&D being conducted. Part of this process involves mapping of both knowledge and technologies in organisations involved in innovation research. BIRAC has initiated technology mapping exercises of national institutions especially those that receive major funds from BIRAC and DBT. BIRAC also facilitate transfer of publicly funded technology and from start-ups to industry technology.

In order to acquire new important technologies either nationally or globally, BIRAC has the mandate for technology acquisition and its launching a **Technology Acquisition Fund**. This would be for technologies for development of novel and



affordable product for public good. For a technology to be transferred (either nationally or internationally) or acquired from overseas, BIRAC conducts a thorough due diligence of the technology and its relevance to India as well as the benefits that would accrue.

BIRAC has facilitated discussions on technology transfer of cardiovascular drugs, infant care systems and formalized technology acquisition from Queensland University Australia for bio-fortification of banana.

IP Support: Safeguarding the Indian biotech innovation

The in-house IP cell in BIRAC provides support to start ups and SMEs on various aspects of IP (landscaping, patent filing, freedom to operate). BIRAC undertakes an extensive IP evaluation of proposals that are sent to its flagship funding programmes such as BIPP, CRS, SBIRI and BIG as well as providing clarity on many of the IP issues in collaborative projects including international projects.

BIRAC has set up an 'IP Management and Technology Commercialisation' (IPM-TC) unit at DBT- ICT Centre for Energy Bio-Sciences at Mumbai and intends to set up a similar centres in different institutes which can provide competent IP services to the local ecosystem.

The IP cell also organises several capacity building workshops on various aspects of IP.





Legal Advisory Support

BIRAC's 'Legal and Contracts Cell' provides a complete due diligence required for all legal activities of the organisation and its programmes including formulation and execution of various research funding schemes, technology transfer, licensing agreements, contract research, MoUs, agreements between BIRAC and its partnering organisations. The cell also extends its support to the industry as per their needs on a case to case basis.

The 'Legal and Contracts Cell' opines on related issues and has standardized the templates for different PPP models of support to company, consortium, technology transfer, collaborative programmes between industry and academia.

Policy and Analysis Cell: Evidence based strategic policy formulation

BIRAC's in-house Policy and Analysis Cell gathers and analyses various information related to biotechnology industry and informs the strategic decision making process within the organisation as well as forms the basis of advising stakeholders. The latest market and industry reports are reviewed and the information is then provided to relevant experts.

The cell is involved in preparing techno-economic reports on numerous proposals that BIRAC receives for its flagship programmes.

As part of evidence based policy formulation, BIRAC organises several discussion series and roundtables to brainstorm about policy imperatives. Some of the imported issues discussed:

- Strategic and policy meetings and discussions regarding nanotoxicity guidelines.
- FDI in pharma sector.
- Infrastructure needs for agribiotechnology sector.
- Industrial enzymes, medical devices and implants.
- Bio-manufacturing.

Based on this extensive consultation process, BIRAC identifies gaps and challenges and then formulates its schemes that aim to provide solutions to the challenges identified. The discussions have resulted in identifying the need of funding mechanisms which would involve translation of leads in the academic institutes by the industry as contract research, grand challenges in areas like RNAi and marker assisted selection and industry sponsored research.

A 'Secondary Agricultural Innovation Cell' has been established within BIRAC. The cell provides the missing link to facilitate development of secondary agriculture industry especially SMEs. It provides independent secondary producers and processors with critical information to build successful value-added agricultural enterprises.

Mentoring, Networking Platforms and Capacity Building

Bio-innovation, like other innovations, is a contact sports driven by start ups and SMEs. This requires smart mentoring (especially to start ups) and hand holding, access to networking platforms to exchange information and understand technology and business strategies and building capacity in all areas relevant to the biotech industry.

BIRAC has already initiated dialogues to kick start a mentoring scheme for start ups which would essentially help start ups navigate the innovation maze and provide support at a critical juncture of their fledging enterprise journey.

In this regard BIRAC has conducted several workshops on business models and strategies, regulatory landscape and pathways, IP sensitisation and entrepreneurship development.

Over the last year BIRAC organised several workshops :

- Workshop on IP Management held at Delhi, Kolkata, Ahmedabad and Chennai in partnership with World Intellectual Property Organization (WIPO).
- Workshop on Technology Licensing, Valuation and Acquisition for Biotech Sector by Prof. Ashley Steven
- A series of IP sensitization workshops on Intellectual property, technology management and entrepreneurship at Jaipur, Jammu and Dibrugarh
- Regulatory workshop on “Demystifying Indian Drug Regulations for New Product Approvals” in partnership with CDSA.
- A series of grant writing awareness seminars with active participation of industry and public researchers in major cities.





The Future: Gazing into the crystal ball & continuing quest for excellence

The Indian biotechnology sector is growing despite the global economic downturn. The sector however needs continued support especially to the start ups and SMEs and given the right support the sector is predicted to grow and possibly touch \$100 billion in revenues by 2025 and majorly contribute to the Indian economy thus establishing a true Indian bio-economy.

BIRAC in its short history has managed to secure the trust of the stakeholders. This trust is immensely valuable to the organisation and it spurs the organisation to redouble its efforts to play a greater role in catalysing the bio-economy.

BIRAC envisages greater connect with the stakeholders and initiate, implement and deliver several programmes that fill the gaps and help in turbo-charging the Indian biotechnology sector.

BIRAC would endeavour to understand new approaches and technologies that would impact the sector in future be it RNAi, metagenomics, molecular assisted selection (MAS), pathway engineering and green chemistry, m-health and smart devices and diagnostics.

A few initiatives that BIRAC is planning to launch in the future are:

BIRAC Social Innovation in biotechnology

There is an increasing public interest in biotechnology. One of the important deliverables of biotechnology as a sector is to find solutions and addressing the problem of society at large.

There are many areas of biotechnology, which have a deep social impact. Cutting edge technologies, novel processes and products need more focussed attention in the context of affordable product development for societal benefit. BIRAC is envisaging a 'Social Innovation' scheme that is focused on applying innovative tools and technologies for addressing sectoral problems through development of affordable products.





BIRAC Industry Sponsored Research (BISR)

Several of BIRAC's flagship programmes have an important component of bridging the industry-academia gap while aiming to deliver products that solve the unmet needs of the society. BISR is an initiative that hopes to bring industry and academia together in a manner that academia (or a consortia of academic partners) helps in delivering products (that have a economic and environmental benefit) through R&D conducted in academia that is sponsored jointly by the industry and BIRAC. The 'academic intervention' would help Indian industry in developing and deploying new technologies for product development.

BIRAC Grand Challenges in Healthcare and Agriculture, Food & Nutrition

Mission mode approaches in several sectors including biotechnology have been one of the preferred means for creating impact as exemplified by “grand challenges” schemes that are implemented by Bill & Melinda Gates Foundation (BMGF) and Grand Challenges Canada. It is BIRAC's intention to launch a “Grand Challenges programme” especially relating to “Securing Family Health” and “Agriculture, Food & Nutrition”-in partnership with BMGF, and other like minded philanthropic organizations.

BIRAC Translation Facilities

In order to ensure a steady flow of bioproducts, bioprocesses and new technologies there is a need to create a strong infrastructure both for research and commercialisation. In order to translate research into products, a crucial step is to establish a proof of concept and test it under industrial conditions. Often pilot plants or full scale manufacturing facilities are not accessible to researchers, thereby creating problems in the translational of the concepts developed in R&D. It is therefore necessary to have access to scale-up and pilot infrastructures during the research and development stage to develop and test industrial processes, thus reducing both lead time and investment. A need has been felt for national level facilities which can be accessed by start-ups and SME's and public sector researches for taking these research leads to the next stage of validation and trial.

BIRAC would consider setting up of 'Facilities for Translational' Research in partnership and co-governance models of operation. Based on earlier discussions and suggestions received from experts and researchers, a discussion note has been prepared for consideration.

BIRAC envisages to be a flexible and nimble organisation that continues to gain trust of its stakeholders in playing a catalytic and transformational role to build the Indian bio-economy and be the bridge through which several stakeholders connect to bring innovative and affordable products into the market. BIRAC would continue to be the 'connector and catalyser'.





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