

# Empowering and Enabling the Biotech Innovation Ecosystem



**Biotechnology Industry Research Assistance Council**

A-254, Defence Colony, New Delhi-110024 (India)  
E-mail : [birac.dbt@nic.in](mailto:birac.dbt@nic.in) Website: <http://www.birac.nic.in>

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

Strengthen and empower the emerging biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

## Our **Vision**

"To stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly SME's, to make India globally competitive in biotech innovation and entrepreneurship, for creation of affordable products addressing the needs of the largest section of society."

## The **Mission**

"Facilitate and mentor the generation and translation of innovative ideas into biotech products and services by the industry; promote academia – industry collaboration; international linkages and encourage techno entrepreneurship and enable creation and sustainability of viable bio-enterprises."



## About **BIRAC**

Biotechnology Industry Research Assistance Council (BIRAC) a Section 25 *Not-for-Profit Company* of Government of India, registered under Indian Companies Act 1956, has been set up as Department of Biotechnology's interface agency, which serves as a single window for the emerging biotech industries. BIRAC is guided by an Independent Board of Directors comprising senior professionals, academicians, policy makers and industrialists.

BIRAC aims to become a dynamic organization, applying unique methodologies for nurturing the high risk projects which hold potential for commercialization. BIRAC would like to position itself as an organisation nurturing and promoting innovation led research and will play an important role as a facilitator and not merely a service provider.

## BIRAC Mandate

- To trigger, transform and lend, biotech start-ups to convert innovative research in public and private sector into viable and competitive products and enterprises.
- Conceptualize and support development of affordable, novel, deployable products and technologies in Healthcare, Agriculture, Environment, Bio-energy, and other industrial products and processes involved in manufacturing through public private partnership
- To support and strengthen small scale and medium enterprises through gap filling interventions that facilitate high risk research, innovation and product development.
- To provide financial, infrastructural, institutional and mentoring support so that barriers to entry are reduced for the budding entrepreneurs.
- To encourage knowledge networking among biotech entrepreneurs at national and international level to maintain the technological advantages and scientific edge.
- To provide all other policy and institutional support for all stakeholders involved in converging biotechnological innovations into an enterprise.

## Aligning the Goals with the Vision

- Promoting innovation research and entrepreneurial development in the biotech industry.
- Finding solutions for unmet national needs in the area of Healthcare, Food Security, and Energy.
- Creating nationally relevant, novel and affordable products for public good.
- Engaging with major stakeholders such as DBT, ICAR, ICMR, DST, MSME, CSIR and other agencies to promote and support their biotechnology developmental activities
- Building national and international strategic partnerships for leveraging strengths to enhance competence of the biotech enterprises in key sectors.



## Key Strategies

Fostering innovation in the biotech enterprise requires special emphasis on empowerment of researchers, start ups and SME's, for which our strategies are:

- Foster **innovation** and **entrepreneurship** in all places of research
- Promote **affordable innovation** in key **social sectors**
- Higher focus on **start ups & small and medium enterprises**
- Contribute through **partners** for capability enhancement
- Encourage **diffusion of innovation** through partners
- Enable **commercialization** of discovery
- Ensure **global competitiveness** of indian enterprises.

## BIRAC Verticals

BIRAC is as an organization with 3 unique verticals to support it's mandate:

### Fostering innovation and Enterprise Building

Entrepreneurship Development & Enterprise Building is a critical component of BIRAC. It alone addresses many of the visions. Creation of start ups which are the fuel for innovation is a priority. BIRAC would be addressing key areas of creation of enterprises, giving access to mentors and providing hand-holding schemes. Start up needs are diverse-from access to early stage funds, understanding business plans to Intellectual Property, and other information such as market analysis & competition.

#### I. Fostering Innovation by:

- Promoting and supporting Public Private Partnership Innovation programmes.



- Funding high risk, highly innovative projects by itself and on behalf of multiple partners providing the necessary support throughout the innovation value chain, viz: early stage innovation research, product development, product validation and commercialization.
- Create innovation clusters and Centres of Excellence for Entrepreneurship
- Enabling access to research resources and creation of Translational facilities.
- Providing necessary support for incubation, technology platforms

### ii. Knowledge, Technology Mapping and Management

- Enhance the proportion of exciting life science invention that can be translated to innovation and application.
- Mapping and cataloguing of exciting research in India to identify novel inventions.
- Creating a National Life science Invention Database.
- Fostering and nurturing inventions via mentorship and technical / business assistance programs.
- Transforming exciting inventions into market-ready technologies/products.

### iii. Technology Transfer, Licensing and Acquisition

- Ensuring smooth flow of knowledge and IP from academics and public research to Industry.
- Enhance the capacities for technology transfer licensing in academic institutes, universities, Start-ups and other key organizations and also providing necessary hand holding and mentorship to start ups and entrepreneurs.
- Acquiring national and global technologies and making them available to start ups / SMEs and small biotech industries for affordable product development of public good.

#### BIRAC Support for taking discovery to product development



## Provide enabling services for promoting the innovation ecosystem

Providing essential need based research and innovation services to the Industry, particularly start ups and small and medium industry is a critical requirement for promoting the innovation ecosystem. Specialized services such as IP management, project management, legal and contract services for licensing, capacity building for skill augmentation and other innovation support services, particularly for regulatory product evaluation are supported and facilitated.

BIRAC is currently serving the Biotech Industry by operating an IP & Regulatory cell, Business Development & Entrepreneurship cell, Technology Transfer and Acquisition cell and Legal & Contracting Cell to begin with, which provide the major support services to the in-house programmes and activities and also specialized services required to create, nurture and support new enterprises.

## Build Strategic Alliances

BIRAC's special strength is its ability to network and partner with like minded organisations to reach out to all its stakeholders and accomplish its mission effectively. Leveraging national and international strength and partnering with other stakeholders is BIRAC's key philosophy in promoting and nurturing innovation research, technology validation and product development. These partnerships and alliances are an important tool to build on the existing expertise and work together for achieving a common goal of affordable product development.

## How does BIRAC accomplish its Mission

### i. Ensuring Entitlements

- **Igniting new ideas-** By making available Biotech Ignition Grant schemes (BIG) centred on or around individuals, or a team of individuals that will help mature nascent ideas into to a stage where a startup company can be envisioned.
- **Supporting early stage research for proof of concept, validation-** Small Business Innovation Research Initiative (SBIRI)

- **Partnership with industry for high risk discovery led innovation research-** Biotechnology Industry Partnership Programme (BIPP)
- **Facilitating technology validation and development** – Contract Research Scheme (CRS)
  - Constant endeavour to create such innovative support schemes in future

**(II) Empowering for Achieving Excellence**

- Create schemes that facilitate the acquisition or license of innovative technology from any source (including overseas) which can be used to start new bio-enterprises or facilitate the growth of existing bio-enterprises.
- Technology mapping for identifying patentable technologies which have a commercial potential and to ensure smooth flow of technology for public sector to industry for product development.
- Create common service facilities in public and private sector to serve the needs of Start Ups.
- Create world class quality Incubation space (Bio-incubators) for entrepreneurs and start-ups.
- Create capacity in various fields required for successful Bio enterprises, some examples
  - Intellectual property protection
  - Technology Licensing and negotiation
  - cGMP manufacturing
  - Entrepreneurship development
  - Regulatory and Ethical issues
  - Product evaluation
  - Data management
  - Designing Field Trials for Agriculture
  - Designing and implementation of clinical trials
  - Wet labs workshops for Skill augmentation
- Facilitate and provide information and background business related research and analysis for critical decision making and provide technology policy research inputs directed towards encouraging bio-enterprises in India.

## Taking Discovery Forward to Product Development

### Biotechnology Ignition Grant - BIG

BIRAC offers **Biotechnology Ignition Grant (BIG)** to scientist entrepreneurs from research institutes, academic private sector and start ups, who have an exciting idea which may be in the nascent and planning stage. This scheme is designed to stimulate commercialization of research discoveries by providing very early stage grants for the development and maturation of those discoveries into marketable product or intellectual property (IP), in particular to help bridge the gap between discovery and invention.

**The purpose of the BIG Scheme is to:**

- Upscale and validate of Proof of Concept
- Encourage researchers to take technology closer to market through a Start Up
- Excite interest of potential licensees or investors

The scheme is managed by the **BIG Partners** who work with the Ignition grantees (**BIG Innovators**) to provide mentoring and hand-holding for activities related to mobilizing resources, IP management, legal and contracts and other business development related activities for the BIG innovators. The BIG Partners monitor targeted milestones for disbursement of funds and also organize workshops and networking meetings for facilitating interaction with senior experts.

**Target Groups-** The Biotechnology Ignition Grant (BIG) scheme is for potential entrepreneurs from Academia or an incubatee (PhDs, Medical degree holders or Biomedical Engg. Graduates) who have an exciting idea which may be in the nascent and at a planning stage and have an unmet need for mentorship and funding from Angel Investors or Venture Capitals in India. The Biotechnology Ignition Grant would help to support and nurture these high risk early starters and their concepts



## Affordable Product Development Supported under BIPP

### H1N1 pandemic influenza vaccine

- H1N1 pandemic influenza vaccine named Pandifylu™ is in the market developed by Panacea Biotech, Delhi



1, 18,480 doses of the vaccine supported to Government of India in 2011.

## Biotechnology Industry Partnership Programme - BIPP

Biotechnology Industry Partnership Programme (BIPP) is a government partnership with Industries for support on a cost sharing basis for path-breaking research in frontier futuristic technology areas having major economic potential and making the Indian industry globally competitive. It is focused on IP creation with ownership retained by Indian industry and wherever relevant, by collaborating scientists.

BIPP supports the development of appropriate technologies in the context of recognized national priorities in the area of agriculture, health, bio-energy, green manufacturing, when the scale of the problem has serious consequences for social and economic development. BIPP is an Advanced Technology Scheme only for high risk, transformational technology/process development. It is for high risk futuristic technologies and mainly for viability gap funding. The uniqueness of this scheme is that it is for "Break through research" which enables product and process development and is patentable, with IP ownership rights resting with industry.

### Uniqueness of BIPP

- Support for high risk, highly innovative accelerated technology development especially in futuristic technologies.
- Support for very high risk, nationally and socially relevant areas, with no assured market. This would be more of translational research in such cases. It is envisaged that public institutes would be useful partners, so that the basic R&D leads can be translated to product development by the industry.
- Provides for product evaluation and validation through support for limited and large scale field trial for agriculture products and clinical trials (Phase I, II, III) for health care products.
- Supporting research project for novel IP generation.

### Target Groups

Indian Biotech companies regulated under Indian Company Act 1956 with 51% Indian shareholding (including NRI's) who have DSIR recognized R&D are entitled for BIPP funding; either independently or in collaboration with companies, not for Profit organisation or academics partners.

### Japanese Encephalitis (JE) Vaccine

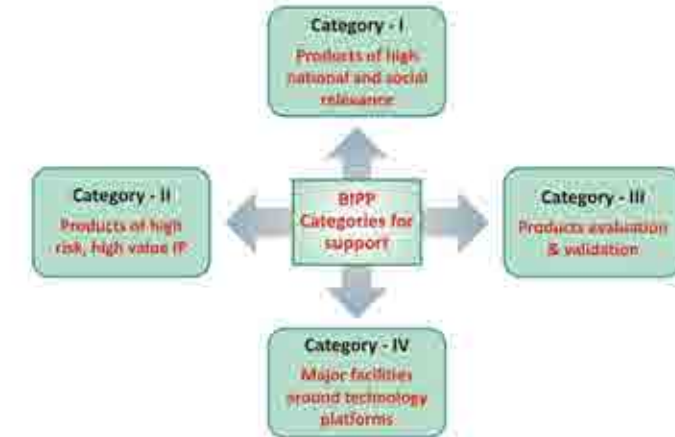
- Phase III Clinical trials of JE vaccine successfully concluded by Biological E Ltd, Hyderabad. Market license obtained in India for the age group of >1 yr to 3 years and >18 years to <40 years.

### Pneumococcal Vaccine

- Asia specific 15 valent pneumococcal polysaccharide – CRM 197 protein conjugate vaccine – studies on one India specific serotype completed by Terigma Biotech Pvt. Ltd, Secunderabad.

### Clinical trials

- Phase I studies completed for a novel molecule TRC150094 a novel Diiodothyronine (T2) analogue, for the treatment of cardiovascular (CV) risk factors defined by Metabolic Syndrome (MS) aimed at increasing Resting Metabolic Rate (RMR) by Torrent Pharmaceuticals Ltd, Ahmedabad.
- Phase III clinical trial of oral Rota virus vaccine developed by public sector, being implemented by 3 public sector organization and coordinated by Bharat Biotech India Limited, Hyderabad. Enrollment of subjects completed.



So far 88 agreements have been signed with 72 companies involving approx. 50 startups and SMEs. Scheme provides for both soft loan and grant. A total of investment of US \$ 141m has been committed with US \$ 50m by Govt. of India with a matching contribution of US\$ 91m coming in as private sector contribution.

## Small Business Innovation Research Initiative - SBIRI

The Small Business Innovation Research Initiative (SBIRI), a scheme launched in September, 2005 by the Department of Biotechnology (DBT), aims to encourage small and medium scale industries to take up risk in innovative R&D in biotech sector.

The main focus is on supporting proof of concept and early stage research in start-ups and SMEs.

Over 100 projects from small and medium entrepreneurs have been supported. SBIRI has deployed \$36 million, of which \$5 million in grants and \$31 million in soft loans, with a debt-to-grant ratio of roughly 6 to 1. Public SBIRI funding has leveraged an additional \$33 million in private investment by recipient enterprises as their core contribution, for a total investment of \$69 million across approved projects.



**Diagnostics**

- A rapid cost-effective point-of-care diagnostic device with microPCR to diagnose multiple diseases like Malaria, Dengue & Typhoid has been developed by Bigtec Pvt Ltd, Bangalore and is ready for validation.



## Contract Research Scheme - CRS

BIRAC endeavours to extend its support to Academia in the form of grant-in aid for validation of the Proof of Concept (PoC) by an Industrial partner.

The CRS scheme supports the academia-industry interaction between research institutes, universities, public funded research laboratories, governmental organizations, research foundations and companies / industries under the Public-Private Partnership (PPP) mode.

**Target Groups-** Under this CRS Scheme, Public Sector Research Institutes, Universities who have already generated or have pre-existing scientifically established proof of concept/leads seek support for specific research and validation process to be performed by a company partners within a defined time frame. The industry partner in turn would complete the Validation Phase in a Contract Research mode. The IP rights belong solely to the academic partner(s).

In addition, if the Academic group requires some specific services from the industry such as toxicology, sequencing, use of specific equipment etc. are also supported under this scheme. Public and/or Private Universities and Research Institutions are eligible to apply under the Contract Research and Services Scheme with pre-determined company partner(s) having DSIR recognized R&D/Service unit(s).

For **Contract Research**, available leads should be at a level which provides sufficient data for Scale up/Validation and may fall under the following categories but not limited to

- Exploratory validation of technology
- Small scale contract research resulting in generating several batches of process or multiple prototypes.
- Large scale validation of prototype to commercial design

BIRAC not only funds the validation of proof-of-concept but works closely with academic research scientist to provide them enabling services of FTO search, IP management. The Legal and Contracts Cell facilitates preparation of required Material Transfer Agreement, Non-Disclosure Contracts, IP protection contracts and when required licensing agreements. BIRAC ensures complete protection of IP rights of the academia scientist and also facilitates technology transfer.

## Taking public sector technologies forward

- Technology developed by International Centre for Genetic Engineering and Biotechnology (ICGEB) New Delhi for 'Herbicide & Stress Tolerant transgenic Onion' transferred to Bejo Sheetal Seeds Private Limited, Jalna and for 'Developing rice hybrids with improved drought and salinity stress tolerance' transferred to Bioseeds Research India Pvt Ltd, Hyderabad.
- Delhi University, South Campus (UDSC), New Delhi technology on genetically engineered *Brassica juncea* (Male sterility and restorer lines as pollination control mechanism) for heterosis breeding and yield improvement under Confined field trials for biosafety studies, being conducted in collaboration with Mother Dairy Fruit and Vegetable Private Limited, Noida.

## Bio-incubator Support Scheme - BISS

In order to foster techno entrepreneurship in biotechnology, BIRAC has initiated a scheme for **Strengthening and Up-gradation of the existing Bio-incubators** and also to **establish New World Class Bio-incubators** in certain strategic locations. These Bio incubators will provide the incubation space and other required services to start-up companies for their initial growth.

### Strengthening existing Bio-incubators

The Bio-incubators for SMEs and start-ups could be as a stand-alone facility or as a part of an existing University/ Institute or Science Park. The BIRAC Bio-incubator strengthening support is provided to those existing Incubators which have proven experience and competence to run successful incubators, have an existing network for mentoring and handholding of incubatees, and also can provide the enabling services to promote innovation research. There should be a well-structured governance model which allows for such activities to be conducted within the host institute, providing the required autonomy and flexibility for operation.

### Establishing World Class Bioincubators

BIRAC is will also set up a limited number of *new World Class State of Art*, National Bio-incubators at strategic locations, especially in an around the DBT Bio-clusters. These would be closely located to existing Academic hubs and have a well-developed management model. It would provide the required infrastructure, incubation space, access to central equipment and pilot plant and enabling services. Most importantly the proximity to the Academic Centres of Excellence would provide access to the Translational Research strength and capacities. These BIRAC Bio-incubators would benefit from the close interaction with the Academic Institute in the cluster and on the other hand provide opportunities to the scientists / entrepreneurs who could create their own spin offs, or are incubated in close proximity to the Academic Centre of Excellence. The two way flow of knowledge between Academia and Start-up would be beneficial to both and provide a boost and help nurture innovative technologies for affordable product development.

### Service Facilities to Promote Innovation

- A state of art integrated service facility for academia and private sector set-up for high-end structural and functional characterization of protein therapeutics and peptides at Intas Biopharmaceuticals Private Limited, Anandabad
- A cGMP-compliant facility for bulk-production of monoclonal-antibodies for diagnostics as well as therapeutic usage and microbial antigens of diagnostic usage for providing contract-manufacturing services and specialized training to biotech personnel set-up at Span Diagnostics limited.
- A State of art cGMP compliant production facility meeting global regulatory requirements for production of recombinant Bio-therapeutics is being set-up at Genova Biopharmaceuticals Limited, Pune.

A BIRAC Bio-incubator would necessarily take on the following roles and functions

- Provide good incubator space to Start-ups and Entrepreneurs.
- Provide access to a pool of special equipments in the Central Equipment Facility.
- Connect and facilitate Industry – Academia Interaction for both smooth flow of knowledge from Academia to Industry and also for providing the required Technical Mentorship.
- Provide enabling services and required mentorship for IP and Technology Management, Legal and Contract, resource mobilization and networking platform
- Governance models would be cooperative or autonomous.

Seven existing Bio-incubators across the country have been strengthened and approx. 55,000 Sq ft of Bio-incubator space has been created to support start up.

### Product innovation and commercialization for addressing Grand Challenges of national relevance

BIRAC will shortly launch the Grand Challenges Programme, offering researchers and scientist opportunities to innovate and work on scientific and technological solutions for affordable product development to meet national needs. The Grand Challenges have one common defined goal: **"Create Scientific and technological tools to overcome hurdles and find solutions for novel affordable products of national relevance"** High level of innovation, new tools and transformative ideas would be supported. These could be in health care, agriculture and energy

These Grand Challenges Programmes could be implemented in an industry-academia partnership model to be co-funded with strategic partners through both national and global alliance. These could be self-governed consortia with clearly defined milestones, deliverables, management models and IP sharing contracts.

## Services for Entrepreneurial Development

### IP Services

**BIRAC** in-house IP Cell provides assistance to SME's, Start ups and Academia and for prior art, patentability and freedom-to-operate searches. It also gives guidance and advisory services on the Patent filing, IP Policy and IP Management to academia and research institutes. BIRAC organizes various workshop/conferences on IPR to build IP awareness in India.

**BIRAC** conducts an IP due diligence for all the eligible proposals received under various funding schemes of DBT like BIPP, CRS etc. The IP cell also does a patent landscape analysis to identify patenting activities in different domains.

As a first step to enhance the proportion of Life science invention that can be translated, BIRAC has initiated technology mapping of DBT institutes. IP services are also rendered to DBT and Universities. Apart from the various IP services, the IP cell also analyses Patent Policy of India vis-a-vis other countries.





## Technology Transfer and Acquisition

**BIRAC** plays a pro-active role to ensure smooth flow of knowledge from public sector to industry. Mapping of both knowledge and technologies in organisations involved in innovation research is essential. For this BIRAC has initiated Technology mapping at National level & International level.

In order to acquire new important technologies either nationally or globally BIRAC plans to launch a **Technology Acquisition Fund**. These would be for public good novel and affordable products.

The universities and companies interested in technology transfer can approach BIRAC with research leads which have a potential commercial interest. The companies interested in acquiring technology can also approach BIRAC for the same. BIRAC would evaluate the technology, understands technology trends, market potential, and the competitive environment..It would facilitate series of discussions on possibilities of Technology Transfer and Acquisition. The BIRAC Legal Cell has specialized skills to handle the legal issues related to the technology transfer and also provides assistance in drafting technology transfer agreements and necessary contracts. 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 etc.

**BIRAC** will work closely with those research organizations which are involved in innovative research and help to create technology transfer capacity.



## Legal and Contracts

All the activities that are required to facilitate formulation and execution of agreements and contracts for industry research funding, technology transfer and licensing, Intellectual Property and other documents are of special importance. The BIRAC Legal and Contract Cell provides the required services to the industry as per their needs.

The cell has standardized contracts for different PPP models of support for single company, Consortium, Consultancy assignments, Hypothecation deeds, IP Technology Transfer, Collaborative Programmes between Academia and Industry etc. These standard instruments would be very useful for all Government PPP projects.

## Policy and Analysis

**BIRAC** has an in-house Policy and Analysis cell, wherein the latest market reports and analysis on the priority areas of Industry research are reviewed and the information made available to the experts. In addition to facilitating proposal evaluation, this cell provides inputs essential for taking important decisions regarding the support for biotech industry. The Policy & Analysis Cell also helps in acquiring relevant reports and detailed reviews on some priority areas which help in



analysis, BIRAC has organized a number of discussion series and facilitated policy discussion on Nanotoxicity guidelines, FDI in Pharma sector, infrastructure needs for agri industry, Stakeholder Meeting for Bio-incubators etc.

## Mentoring & Capacity Building

Capacity building efforts includes a broad range of approaches, e.g., grant writing, grant management training and development for IP management, technology licensing and transfer. BIRAC helps the industry by conducting capacity building activities in partnership with other agencies in varied fields required for successful Bio-entrepreneur creation.

**BIRAC** has carried out a periodic awareness workshops to enhance the level of response from the private sector and their public partners.

- Training of Trainers Workshop on IP Management held at Delhi, Kolkata, Ahmadabad and Chennai, with World Intellectual Property Organization (WIPO).
- Workshop on Technology Licensing, Valuation and Acquisition for Biotech Sector
- A series of Grant Writing awareness seminars with active participation of industry and public researchers in major cities.

**BIRAC** also commissions surveys and reports to assess the state of industry in terms of research, capacities, facilities, human resource, Industry reference database subscriptions etc.

**BIRAC shall operate as an organization which will act as a connector and catalyser. BIRAC looks ahead to creating a Biotech Innovation Enterprise which is at par with the Global Best.**