जैव प्रौद्योगिकी विभाग
Department of Biotechnology
Ministry of Science & Technology
Government of India
सत्यमेव जयते

बाइरैक
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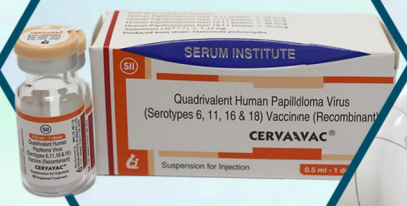
BIRAC

IMPACT REPORT 2026

iNCOVACC®
WORLD'S 1ST INTRANASAL COVID-19 VACCINE
FOR PRIMARY AND BOOSTER DOSES



Indigenous MRI machine

14 Years at a Glance

MESSAGE

Biotechnology is rapidly transforming the global scientific landscape, enabling breakthrough solutions for human health, food security, environmental sustainability, and industrial transformation. Nations that successfully integrate scientific discovery with translational innovation and scalable manufacturing will lead the next wave of economic growth. As the world transitions toward a knowledge-driven bioeconomy, India has positioned biotechnology as a strategic sector to drive innovation-led growth, technological self-reliance, and sustainable development.

The Department of Biotechnology (DBT), Government of India, has consistently worked to build a robust ecosystem that fosters scientific excellence while enabling the translation of research into impactful technologies and products. A key institutional pillar in this effort has been the Biotechnology Industry Research Assistance Council (BIRAC), established as a dedicated interface to catalyse innovation at the intersection of academia, start-ups, and industry.

Over the past decade, BIRAC has played a transformative role in nurturing India's biotechnology innovation ecosystem by enabling risk-tolerant funding, strengthening incubation infrastructure, promoting academia–industry collaboration, and facilitating technology translation. Through programs spanning ideation, proof-of-concept development, early-stage innovation, and late-stage commercialization, BIRAC has supported thousands of innovators and enterprises, leading to the development of technologies and affordable products addressing national priorities.

The impact of these initiatives is reflected in the emergence of a vibrant start-up ecosystem and the commercialization of indigenous innovations in areas such as vaccines, diagnostics, therapeutics, medical devices, agricultural biotechnology, and industrial biotechnology. Programs such as BIG, SBIRI, BIPP, BioNEST incubators, mission programs, and equity funding initiatives have collectively strengthened India's innovation pipeline and contributed significantly to the country's expanding bioeconomy.

These efforts align closely with national priorities including Make in India, Start-up India, and Atmanirbhar Bharat, and support the broader vision of building a bio-based, circular, and innovation-driven economy. They are also aligned with India's ambition of achieving a $300 billion bioeconomy under the BioE3 Policy—Biotechnology for Economy, Environment and Employment.

This Impact Report captures the scale and depth of BIRAC's contributions to advancing translational biotechnology in India. It highlights not only measurable outcomes in terms of products, intellectual property, and enterprises created, but also the broader systemic impact of fostering a culture of scientific entrepreneurship and innovation-led development.

India today stands at the cusp of a new phase of bio-innovation, driven by advances in genomics, synthetic biology, artificial intelligence, and precision biomanufacturing. The convergence of these technologies presents unprecedented opportunities for India to emerge as a global hub for affordable, scalable, and sustainable biotechnology solutions.

I commend BIRAC and its partners across academia, industry, start-ups, and incubators for their continued commitment to strengthening India's biotechnology ecosystem and accelerating the translation of science into solutions for national and global well-being.

Dr. Rajesh S. Gokhale
Secretary-DBT, Director General-BRIC,
Chairman-BIRAC

FOREWORD

Innovations in biotechnology is inherently complex—requiring deep scientific inquiry, long gestation periods, high-risk investment, and sustained collaboration across disciplines and institutions. Recognizing these challenges, the Biotechnology Industry Research Assistance Council (BIRAC) was established by the Department of Biotechnology (DBT) to serve as a catalytic interface between science and enterprise, enabling the translation of innovative ideas into impactful products and technologies. Since its inception, BIRAC has served as a critical bridge between academia, start-ups, industry, investors, and global partners.

At the heart of BIRAC's approach lies the creation of a structured innovation pipeline. Flagship initiatives such as the Biotechnology Ignition Grant (BIG), the Small Business Innovation Research Initiative (SBIRI), the Biotechnology Industry Partnership Programme (BIPP), PACE, BioNEST bio-incubators, Grand Challenges India, National Biopharma Mission, and Mission IndCEPI have collectively strengthened India's Biotech, Biopharma, MedTech and Health-tech start-up ecosystem. These programs have empowered thousands of innovators and supported the development of numerous products and technologies addressing critical needs in healthcare, agriculture, environmental sustainability, and industrial biotechnology.

Complementing grant-based support, BIRAC has also pioneered innovative financing models through equity-based initiatives such as the SEED and LEAP Funds, enabling start-ups to scale technologies and attract private investment. These interventions have played an important role in de-risking early-stage innovation and catalysing venture capital participation in the biotechnology sector.

BIRAC has also remained committed to inclusive innovation, supporting student researchers, young entrepreneurs, and social innovators through programs such as E-YUVA and SPARSH. These initiatives have helped expand the base of the innovation pyramid and foster a culture of scientific entrepreneurship across institutions and regions. Today, India's biotechnology ecosystem includes over 10,000 biotech start-ups, reflecting the rapid growth of innovation-driven enterprises across the country.

This Impact Report highlights BIRAC's role in nurturing India's translational biotechnology ecosystem and showcases the achievements of innovators, start-ups, incubators, research institutions, investors, and policy partners working together to address pressing societal challenges.

As we look toward the future, the convergence of transdisciplinary sciences with biotechnology will open new frontiers of discovery and innovation. BIRAC remains committed to strengthening this ecosystem and accelerating the translation of science into solutions that contribute to national priorities and global well-being, in line with the vision of Viksit Bharat 2047.

Dr. Jitendra Kumar
Managing Director,
BIRAC

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I. Executive Summary

Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8 company under Companies Act 2013 and a Schedule B, Central Public Sector Enterprise, (CPSE) under Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and set up as an interface agency to strengthen and empower the emerging biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs. BIRAC implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make them globally competitive. In its fourteen years 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 product development through cutting edge technologies. BIRAC has also initiated partnerships with several national and global partners to collaborate and deliver the salient features of its mandate.

VISION

The vision of BIRAC is to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly start-ups and SMEs, for creation of affordable globally competitive products addressing the needs of the largest section of society.

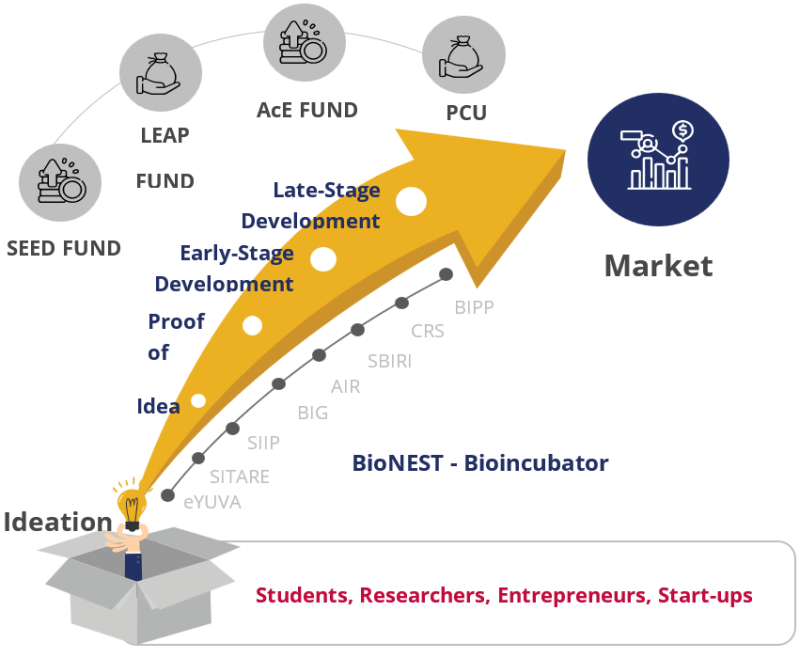
MISSION

The mission of BIRAC is to 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 bio enterprises.

The impact of BIRAC is significant and multifaceted, playing a catalytic role in transforming the Indian biotechnology landscape. Its various schemes and programs have a direct influence on fostering innovation, supporting start-ups, and enabling the translation of research into marketable products.

Biotech sector is a multi-disciplinary and knowledge intensive area with long gestation periods. It requires patient risk-capital with access to high end infrastructure and cost intensive consumables and equipment. For Biotech sector to innovate and translate scientific knowledge into products and technologies, an enabler is needed that could support and holistically nurture the ecosystem. BIRAC has emerged as a recognized enabling agency that has nurtured the biotech innovation ecosystem in the country. BIRAC's ability and commitment has demonstrated with evidence seeding of a globally competent biotech ecosystem. It has resulted in progression of hundreds of innovations into commercialized products and technologies to address the societal unmet needs. With support from the Department of Biotechnology, today India's Biotech Innovation ecosystem is recognized not only locally but globally as well.

BIRAC has been instrumental in creating and expanding the base of the 'Innovation Pyramid'. It has successfully inculcated a culture of biotech entrepreneurship in the country. This ecosystem is growing year on year and requires handholding that is constantly evolving. Need assessment followed by actionable measures are required on a constant basis, to bridge the gap and expedite the growth. BIRAC, known for its agility and strategic initiatives, has initiated several schemes, enhanced strategic capacity building and expanded the partnership network in order to bring new and value- added opportunities for Biotech Start-ups, Entrepreneurs across the stages of product development cycle.

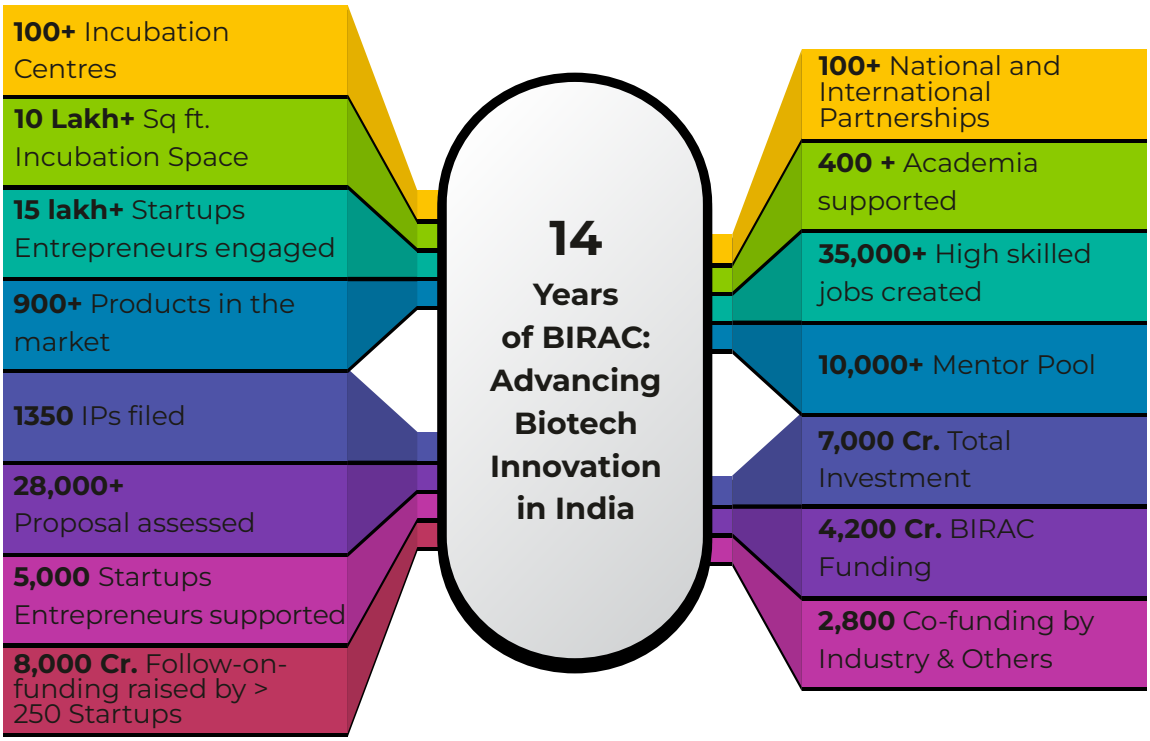


BIRAC Support through different stages of product development cycle

BIRAC has initiated several flagship programs such as BioNEST, BIG, SBIRI, BIPP, SPARSH, CRS, Equity Funds (SEED, LEAP, ACE) that bridge the gaps in the biotechnology innovation pipeline including funding (from ideation stage to commercialization), incubation, patent assistance, capacity building through training and mentoring including business and technical mentoring.

Over the last 14 years, BIRAC has contributed significantly to the growth of biotech ecosystem. Constantly growing numbers of applications received for funding support, increasing number of Start-ups, awards, recognition of Indian start-ups at national and international platforms, and commercialization of Made in India products reflect a tangible growth of the Biotech Start-up Ecosystem in the country. BIRAC has over the years supported ~ 5000 beneficiaries.

With the launch of the 'Make in India' initiative, Biotechnology is recognized as one of the 25 economy driving sectors for GDP growth. BIRAC is committed to being a transformative force for India's biotech-driven development by empowering innovation, creating jobs, and fostering inclusive, sustainable growth. Through its various schemes BIRAC has been able to create the following impact so far.



Impact of BIRAC

II. Building a start-up Ecosystem

BIRAC has catalysed a vibrant biotechnology start-up ecosystem by providing early-stage funding to late-stage funding, incubation support, and mentorship to innovators.

Through targeted programmes and partnerships, BIRAC has enabled start-ups to translate cutting-edge research into market-ready products addressing healthcare, agriculture, and environmental challenges. This has accelerated innovation, strengthened industry–academia collaboration, and positioned India as an emerging global hub for biotechnology entrepreneurship.

II.1. Financial Assistance at different stages of product development cycle: Early stage

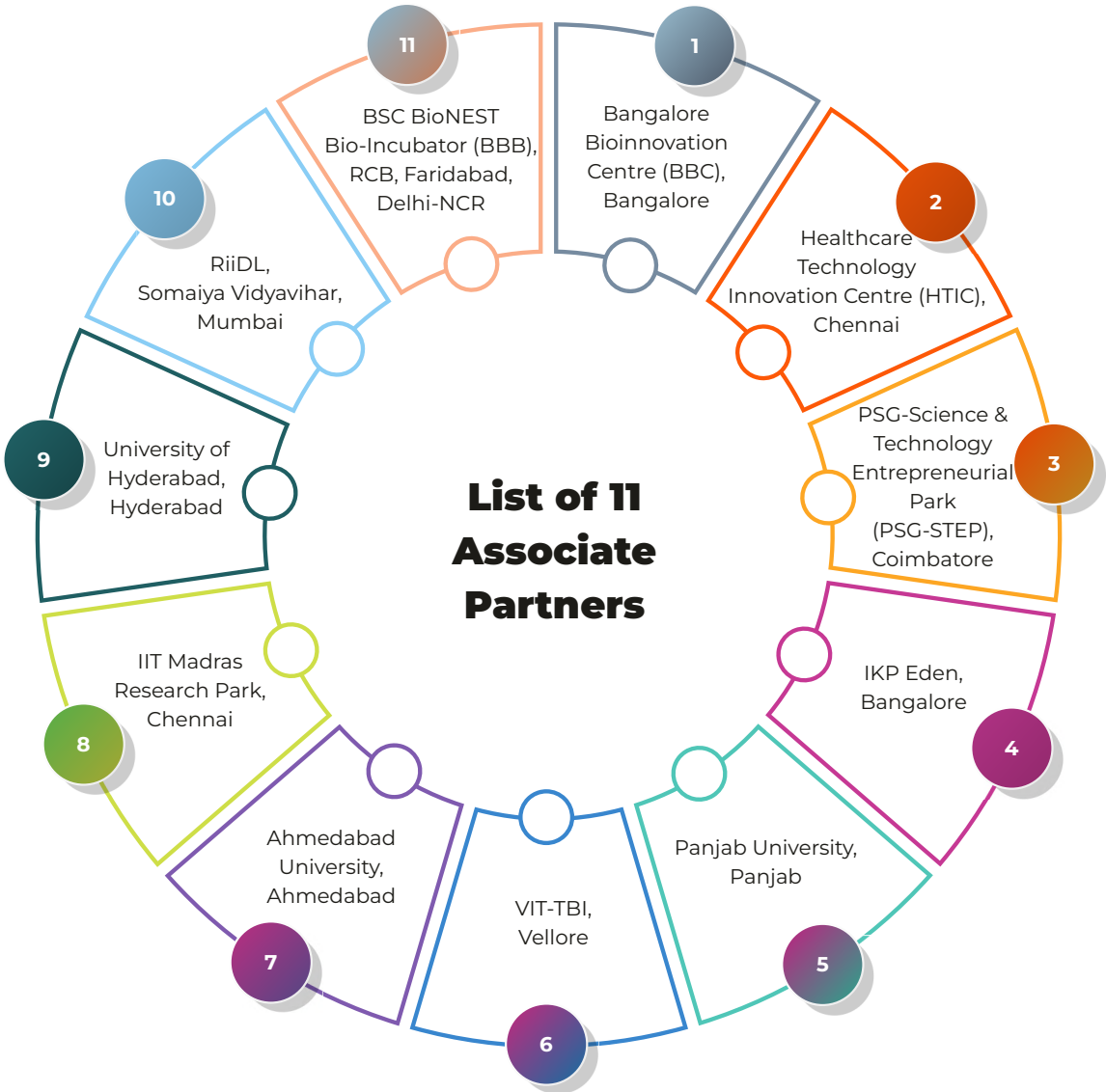
II.1.1 Biotechnology Ignition Grant (BIG)

The Biotechnology Ignition Grant (BIG) is the flagship early-stage funding program of BIRAC, designed to support innovators and young start-ups with high-risk, high-impact biotech ideas. Launched in 2012, the BIG scheme has grown into India's largest and most credible early-stage biotech funding mechanism, providing not just financial support but also critical ecosystem access.

The scheme offers a grant-in-aid of up to INR 50 lakhs for a period of 18 months, enabling innovators to translate their ideas into proof-of-concept. The program is implemented through a network of 8 mature BioNEST incubators (BIG Partners), which offer end-to-end handholding, technical mentoring, business support, IP guidance, and regulatory navigation.

BIG Partners

To strengthen outreach and inclusivity, additional 11 BioNEST incubators have been engaged as Associate Partners, tasked with raising awareness and mentoring applicants from Tier 2/Tier 3 cities and underserved regions.

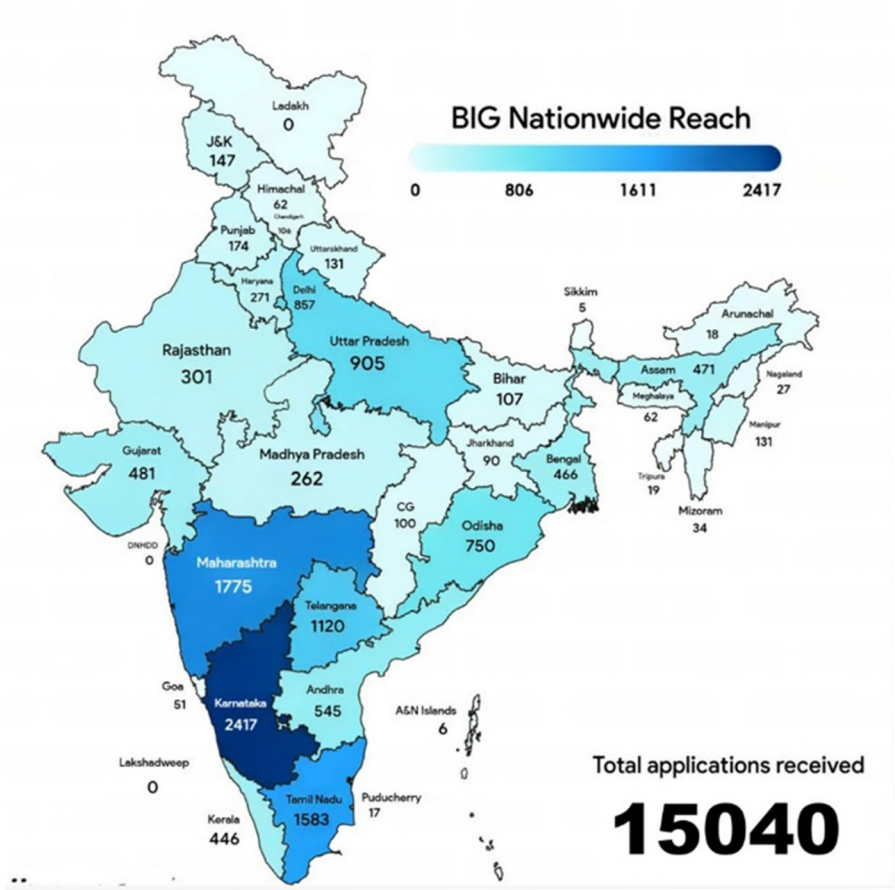


Through its collaborative network of mentors, investors, corporate partners, and policy stakeholders, BIG also supports innovators on their go-to-market strategy, fundraising, pilot access, and commercialization pathways. Over the years, the BIG scheme has played a catalytic role in nurturing a culture of science-led entrepreneurship in India's biotech sector. Its impact is visible in the emergence of successful start-ups, deep-tech innovations, and an increasingly vibrant early-stage ecosystem.

Scale and Reach

Over the past 14 years, the successful implementation of the Biotechnology Ignition Grant (BIG) scheme has significantly fostered a robust culture of biotech entrepreneurship across India. Since inception, the BIG scheme has:

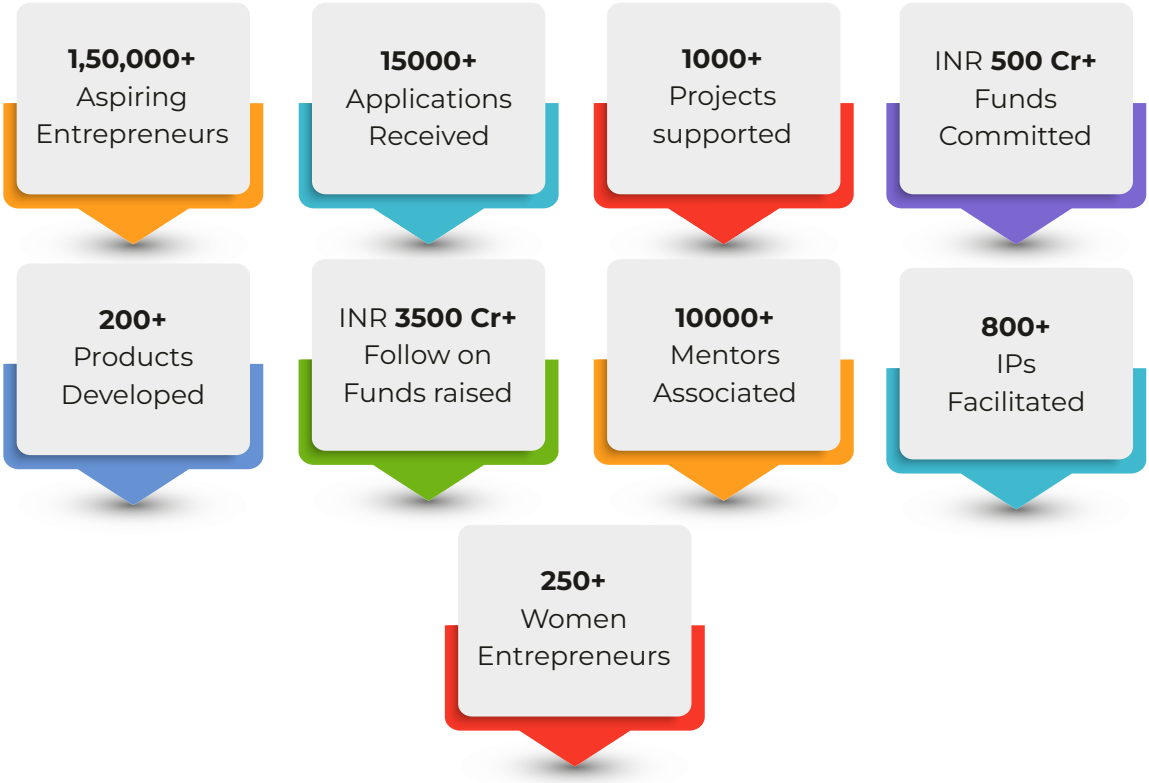
- Received 15,000+ applications
- Supported 1,000+ high-potential projects across multiple calls
- Committed INR 500+ Crores in early-stage funding



The scheme has particularly empowered:

- First-time entrepreneurs and faculty innovators
- Innovators from non-metro and rural geographies
- Women-led enterprises through proactive outreach and mentoring

BIG has become a cornerstone of India's early-stage biotech innovation landscape.



Impact of BIG scheme

The impact of BIG has been far-reaching, it has enabled the creation of numerous start-ups, led to the development of over 200 innovative products and technologies, and facilitated the filing of more than 800 IPs. The scheme has also played a key role in promoting inclusive innovation, with nearly 250 women entrepreneurs supported, and has contributed to the creation of a highly skilled workforce of over 3,500 professionals. Many BIG grantees have gone on to achieve national and international recognition, winning prestigious awards and accolades. Notably, over 150 grantees have collectively secured more than INR 3,500 Crores follow-on funding from private investors—underscoring the scheme's effectiveness in de-risking early innovation and catalyzing scale-up and commercialization.

Illustrative Success Stories

Below are select examples demonstrating the breadth and transformative impact of BIG-supported innovations:

- **Bugworks Research Private Limited, Bengaluru, Karnataka** a deep-tech start-up, is focused on discovering and developing novel antibiotics and immune-oncology therapies to address the global challenge of antimicrobial resistance (AMR) and serious infections. Bugworks' drug candidate, a dual-target gyrase-topoisomerase inhibitor, supported by CARB-X, is a novel broad-spectrum agent targeting critical bacterial infections implicated in serious hospital, community and bio-threat indications. The company has raised $19 million across funding rounds.

- **GPS Renewables Private Limited, Bengaluru, Karnataka**, a pioneering Indian clean-tech start-up, has emerged as one of the world's leading full-stack biofuels companies. Since its inception, the company has steadily scaled its operations across the renewable energy spectrum, specializing in compressed biogas (CBG), 2G ethanol, sustainable aviation fuel (SAF), and green hydrogen. GPS Renewables achieved a significant milestone by surpassing ₹1000 crore in revenue. With over 100 commercial plants commissioned and a team of more than 600 professionals, the company has made remarkable contributions to India's green energy transition. The company has raised $20 million across funding rounds.

- **Pandorum Technologies Private Limited, Bengaluru, Karnataka**, a deep-tech start-up, specializing in tissue engineering and regenerative medicine, develops proprietary platforms to create functional human tissues (e.g., cornea and liver) and advanced exosome-based therapies that promote tissue regeneration. They have developed Kuragenx, a therapeutic aimed at corneal regeneration (targeting corneal blindness and neurotrophic keratitis), which has received Orphan Drug Designation from the US FDA. The company has raised $43 million across funding rounds

- **Eyestem Research Private Limited, Bengaluru, Karnataka** a deep-tech start-up, is developing stem-cell-based therapies for incurable retinal diseases, most notably Dry age-related macular degeneration (AMD), using its lead cell therapy candidate Eyecyte-RPE™. The startup completed the first set of human patient injections for its Dry AMD cell therapy in Phase 1 clinical trials across three leading ophthalmology centres in India, marking a key translational milestone from preclinical to human studies. The company has raised $19.9 million across funding rounds.

- **Kritsnam Technologies Private Limited, Secunderabad, Telangana** has emerged as a national leader in smart water innovation, particularly through the successful

deployment of its Irrigation Scheduling using real-time data on Water Availability (IShWAR) system. The system has been implemented across multiple irrigation command areas, covering over 50,000 hectares of agricultural land. This has resulted in water savings of up to 30%, improved crop productivity, and reduced conflicts over water distribution. The company has raised $2.86 million across funding rounds.

- **Turtle Shell Technologies Private Limited, Bengaluru, Karnataka** through its product Dozee, has transformed patient care in India by pioneering real-time, contactless remote patient monitoring. Built on Ballistocardiography (BCG) technology, Dozee enables continuous tracking of vital parameters such as heart rate, respiratory rate, and sleep cycles without the need for physical contact. Dozee has been deployed in over 70 hospitals and 10,000+ beds across India, contributing to early detection of clinical deterioration, reduction in ICU transfers, and improved patient outcomes. With over ₹260 crore in revenue and employment for 230+ people, Dozee is fully indigenized and holds USFDA 510(k), CDSCO, ISO 13485, HIPAA. The company has raised $39.1 million across funding rounds.

- **Anabio Technologies Private Limited, Bengaluru, Karnataka** is addressing a long-ignored challenge by developing India's first flushable, biodegradable sanitary pads, designed to combine convenience, and environmental responsibility. At a time when conventional sanitary waste can take over 400 years to degrade, Anabio's solution brings together performance, skin safety, ease of disposal, and sustainability—without compromise. The company has acquired Microbe Investigations Switzerland (MIS), a Zurich-based company in microbial research and diagnostics.

- **Kanpur Flowercycling Private Limited, Kanpur, Uttar Pradesh** known by its brand Phool.co has established itself as a leading force in the circular economy and sustainable product innovation landscape in India. The company has developed biodegradable incense sticks, organic vermicompost, and the world's first biodegradable floral leather, "Fleather". The company has successfully upcycled over 20,000 metric tonnes of floral waste collected from temples and religious institutions. Notably, Phool.co's workforce is primarily composed of women (~ 500) from underprivileged communities, and the company provides them with training, fair wages, and safe working conditions. The company has raised $12.7 million across funding rounds.

- **Capsber Agrisciences (AgBio Innovation) Private Limited, Bengaluru, Karnataka** an agritech company, has developed biological solutions that enhance crop productivity and commercialized a suite of next-generation agricultural biologicals, including the world's first prolonged-release male and female fruit fly trap, significantly reducing pesticide usage in fruit cultivation. The start-up has achieved ₹35 Crore in revenue, and entered a strategic joint venture with IFFCO.

- **Haystack Analytics Private Limited, Mumbai, Maharashtra** a frontrunner in genomics-based clinical diagnostics in India, has deployed its AI-powered whole genome sequencing and bioinformatics platform across 100+ hospitals and diagnostic centers, enabling faster, accurate diagnosis of infectious diseases, antimicrobial resistance (AMR), and genetic disorders. The product supports tuberculosis diagnosis and drug-resistance profiling within 48 hours, making it a game-changer for public health and TB elimination goals. The company has raised $16.6 million across funding rounds.

- **Tan90 Thermal Solutions Private Limited, Chennai, Tamil Nadu** is revolutionizing the cold chain ecosystem in India with its energy-efficient, passive thermal management systems. The company has deployed its innovative PCM (Phase Change Material)-based cold storage solutions across agriculture, pharma, and logistics sectors, especially benefiting rural and remote regions lacking cold infrastructure. Tan90's products have been adopted by state health departments and agri-exporters, with operations scaling to multiple Indian states and Southeast Asia. The company has raised $4.6 million across funding rounds.

- **Pragmatech Healthcare Solutions Private Limited, Vadodara, Gujarat** is transforming cervical cancer screening with India's first CDSCO-approved at-home self-sampling kit, CERVICHECK™, a portable, non-invasive cervical cancer screening device designed for primary and remote healthcare settings. The device has been deployed across 150+ health centers and screening camps, particularly in underserved rural and semi-urban regions, enabling the screening of over 50,000 women for early signs of cervical cancer.

- **Kcat Enzymatic Private Limited, Bengaluru, Karnataka** is driving innovation in sustainable biocatalysis through its enzyme platforms: Greenaminase® (transaminase) and Greenhydroxylase® (hydroxylase). These engineered enzymes are tailored for the pharmaceutical industry, enabling efficient and green synthesis of active pharmaceutical ingredients (APIs).

- **OmniBRx Biotechnologies Private Limited, Ahmedabad, Gujarat's** proprietary "CellBRx®" single-use bioreactor technology is the first-of-its-kind bioreactor device with complete automation which makes it a most reliable platform for vaccine manufacturing. CellBRx® SUBs are developed upon the concept of Dynamic bed reactor technology, which ensures nutritional & gaseous homogeneity across the cell carrier bed resulting into ultra-high-density cell culture. The company has raised $5.47 million across funding rounds.

- **Padcare Labs Private Limited, Pune, Maharashtra** has developed and launched the world's first smokeless sanitary napkin recycling solution. Padcare operates in 24 Indian cities, serving over 685 clients and having recycled more than 4.9 million

pads, reducing CO2 emissions by over 249 metric tons. The company has raised $3.74 million across funding rounds.

- **Innaumation Medical Devices Private Limited, Bengaluru, Karnataka** is a medtech start-up focused on medical devices addressing rehabilitation and quality-of-life challenges. Its flagship product, Aum Voice Prosthesis, is a cost-effective solution that helps restore voice function for patients who have lost their ability to speak due to throat or laryngeal conditions (e.g., cancer surgery).
- **Bonayu Lifesciences Private Limited, Bengaluru, Karnataka** is a health-tech start-up recognized for pioneering advanced drug-delivery and nutritional supplement technology, particularly in the form of high-dosage, fast-dissolving oral strips and topical. The start-up has developed a patented, 100% solvent-free technology capable of loading up to 500 mg of active ingredients per oral strip which significantly surpasses the conventional industry limit of roughly 40 mg for thin-film, mouth-dissolving strips. The company has raised $1.3 million across funding rounds.
- **Blackfrog Technologies Private Limited, Manipal, Karnataka** has developed Emvólio a portable, battery-backed biomedical cooling system designed for last-mile transport of vaccines, biologics, and other sensitive medical supplies to maintain cold-chain integrity. Emvólio, a WHO-prequalified cold-chain device now deployed across India, Africa, and the Middle East. The start-up has raised INR 17.86 crore across funding rounds.

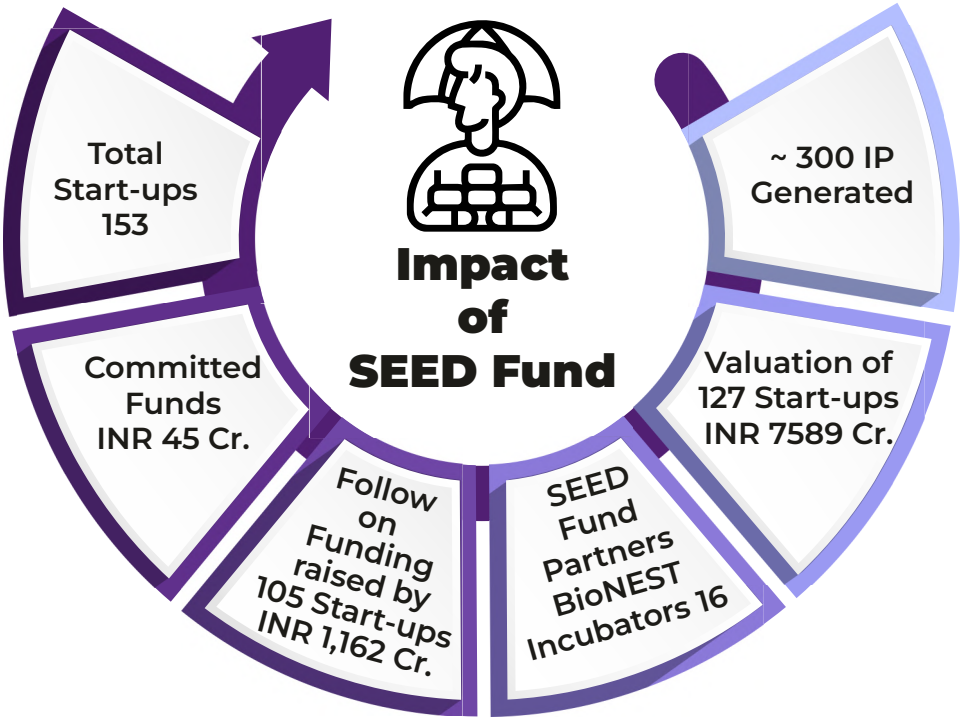
II.1.2. BIRAC SEED Fund

The Sustainable Entrepreneurship and Enterprise Development (SEED) Fund is a flagship initiative by BIRAC, launched in 2016, aimed at providing early-stage capital assistance to biotech start-ups with innovative, high-potential ideas and technologies. The fund serves as the first equity-based financial support of up to INR 30 lakhs for start-ups that have reached the Proof-of-Concept (PoC) stage. This support enables start-ups to graduate to a level where they are able to raise investments from angel investors or venture capitalists, or reach a position to seek loans from commercial banks or financial institutions.

BIRAC implements SEED Fund through its selective 16 BioNEST incubators. These incubators then identify and invest in start-up companies through a structured selection process.

LIST OF 16 SEED FUND PARTNERS

To date, the SEED Fund has empowered 153 high-potential biotech start-ups through a strategic investment of INR 45 crore, unlocking remarkable downstream success. These start-ups have gone on to attract over INR 1,162 crore follow-on funding from a diverse pool of investors, including angel networks, high-net-worth individuals (HNIs), and institutional backers, underscoring strong investor confidence. Collectively, the portfolio has achieved a staggering valuation of 127 start-ups over INR 7,589 crore, with 24 start-ups crossing the INR 50 crore mark and 12 start-ups surpassing INR 100 crore in valuation. The programme has also recorded nine successful exits, reflecting portfolio maturity and early return realization.



Impact of SEED Fund scheme

Beyond financial growth, the programme has significantly strengthened India's bio-innovation ecosystem through the generation of 221 granted patents, approximately 70 additional patent filings, and 108 trademarks, reflecting strong intellectual property creation and commercialization potential. The supported ventures have also generated around 3,000 direct and indirect employment opportunities, contributing meaningfully to skilled workforce development and economic growth. These achievements are a testament to the program's role in de-risking innovation, catalysing market-ready biotech ventures, and laying the groundwork for significant future returns and sectoral growth.

Illustrative Success Stories

1. **Dozee (Turtle Shell Technologies) Bengaluru, Karnataka:** – A remote patient monitoring system. Start-up enabled a 2.5x exit within 1.5 years. The company subsequently raised USD 38 million and reached a valuation of USD 130 million, reflecting strong investor confidence in India's digital health ecosystem.

2. **Predible Health, Bengaluru, Karnataka** – Developed AI-driven radiology solutions and facilitated a 1.85x exit before being acquired by US-based Nference for INR 16 crore, demonstrating the global acquisition potential of Indian health tech ventures.

3. **Inito, Bengaluru, Karnataka** – An at-home fertility diagnostics company that resulted in projected exit returns of INR 1.16 crore (3.86x) and scaled internationally, reaching a USD 50 million valuation after entering the US market.

4. **Brainsight AI, Bengaluru, Karnataka** – A neurodiagnostic imaging start-up that raised USD 5 million in follow-on funding and reached a valuation of INR 175 crore, exemplifying the clinical impact and deep tech potential in neuroscience.

5. **Leumas, Bengaluru, Karnataka** – Received initial seed funding and went on to raise INR 24 crore in follow-on investment, achieving a valuation of INR 133 crore, reflecting strong commercial scalability.

6. **Janitri Innovations, Bengaluru, Karnataka** – Focused on maternal health, the company raised INR 20 crore, reached INR 100 crore valuation, and gained national visibility through Shark Tank India, reinforcing investor interest in health tech innovations.

7. **Eyestem Research, Bengaluru, Karnataka** – Developing iPSC-based therapies for retinal degeneration, Eyestem received IND approval in the US, completed India's first in-human trials, and reached a valuation of INR 371 crore, setting benchmarks for global deep tech validation.

8. **Primary Healthtech, Noida, Uttar Pradesh** – Developed Mobilab, an IoT-based diagnostics device. With INR 8.5 crore raised, valuation increased from INR 25 crore to INR 60 crore, and INR 4.7 crore in revenue, it is projected to deliver a 4x exit return.

9. **BioPrime Agrisolutions, Pune, Maharashtra** – Scaled its agri-biologicals platform, raised INR 74.5 crore in follow-on funding, delivered a 3.9x exit return, and expanded globally with partnerships in Brazil, Thailand, and the US

10. **Blackfrog Technologies, Manipal, Karnataka** – Commercialized Emvólio, a WHO-prequalified cold-chain device now deployed across India, Africa, and the Middle

East. The start-up has raised INR 17.86 crore and reached a valuation of INR 66 crore.

11. **ImmunoACT, Mumbai, Maharashtra** – Developed India's first indigenous CAR-T therapy, raised INR 133.74 crore, achieved a valuation of INR 816 crore, created 168 jobs, and delivered a high-value exit.

12. **Haystack Analytics, Mumbai, Maharashtra** – Specializing in AI-driven TB and AMR diagnostics, the company raised INR 83.75 crore, reached a valuation of INR 404.5 crore, and was nationally recognized by the Hon'ble Prime Minister at the Biotech Start-up Expo.

II.1.3. BIRAC LEAP Fund

The LEAP Fund (Launching Entrepreneurial Driven Affordable Products) is a strategic initiative by BIRAC, launched in 2018, to accelerate the commercialization of innovative biotech solutions through targeted equity support. Start-ups under this program can access up to INR 100 lakhs for product validation, scale-up, and market deployment.

The program is implemented through BIRAC's BioNEST incubators, designated as LEAP Fund Partners.

Currently, 6 BIRAC-recognized LEAP Fund partners are operational, evaluating start-ups on technological strength, commercial readiness, and scalability. So far, 62 biotech start-ups have been supported through a strategic investment of INR 40 crore, catalysing significant private capital participation. Of these, 44 start-ups have collectively raised over INR 893 crore in follow-on funding, while 59 start-ups have achieved a cumulative valuation of INR 4,632 crore, demonstrating strong market validation and investor confidence. The scheme has also recorded four successful exits, indicating maturing ventures and early return realization within the portfolio.

Impact of LEAP Fund scheme

In addition to financial growth, the supported start-ups have generated nearly 1,300 employment opportunities, contributing to high-skilled workforce creation in the bioeconomy sector. The programme's innovation strength is further reflected in the generation of 131 granted patents, 24 additional patent filings, and 23 trademarks,

underscoring its role in fostering intellectual property creation and commercialization-driven growth.

Illustrative Success Stories

1. **Dozee (Turtle Shell Technologies), Bengaluru, Karnataka:** A 3.25x partial exit was realized within 1.5 years. The start-up went on to raise INR 317 crore and reached a valuation of INR 1,084 crore, reflecting strong investor confidence in remote health monitoring solutions.

2. **Eyestem Research Private Limited, Bengaluru, Karnataka:** Advanced to Phase I/II clinical trials for its iPSC-based therapy for retinal degeneration, with international trials underway. Currently holds a valuation of INR 371 crore, highlighting India's growing leadership in cutting-edge cell and gene therapies.

3. **Padcare Labs Pune, Maharashtra:** Commercialized an eco-friendly sanitary waste recycling system, having recycled 70 MT of sanitary pads and impacted over 4 lakh women. The company has generated INR 14.36 crore in revenue, showcasing deep social and environmental impact.

4. **EzeRx Health Tech Bhubaneswar, Odisha:** Developed EzeCheck, a non-invasive hemoglobin testing device. A 2x return was realized in 2022. With INR 28 crore in revenue and a valuation of INR 150 crore, the startup exemplifies inclusive and scalable healthcare innovation.

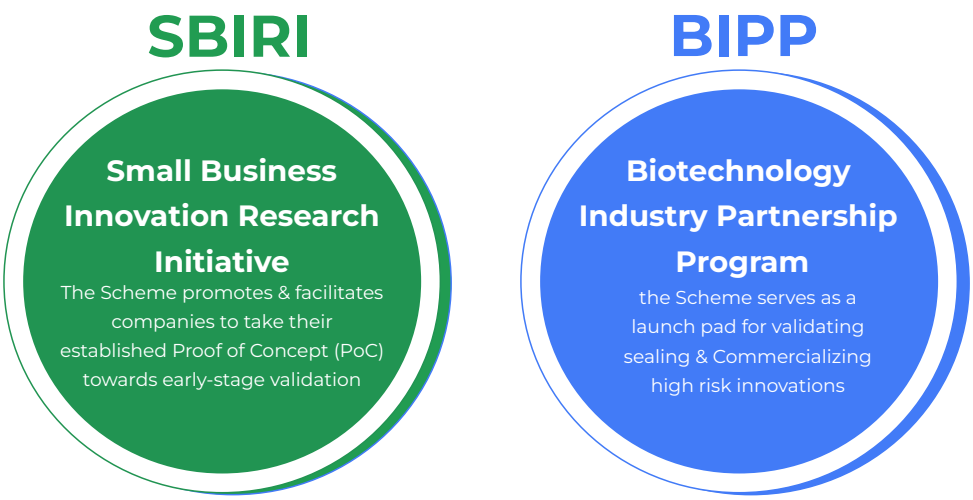
5. **Shuvoneel RAS Bengaluru, Karnataka:** Revolutionized aquaculture through recirculating aquaculture systems, leading to a valuation increase from INR 30 crore to INR 193 crore, and recording INR 127.75 crore in revenue, demonstrating the role of deep tech in driving rural enterprise growth.

II.2. Financial Assistance at different stages of product development cycle: Mid-Advanced stage

II.2.1 Intensifying the Impact of Industrial Innovation (i4): BIRAC promotes innovation and research in the field of biotechnology through i4 programme (Intensifying the Impact of Industrial Innovation). The scheme supports start-ups, companies and academic institutions as collaborators. Two calls for proposals are announced every year for i4.

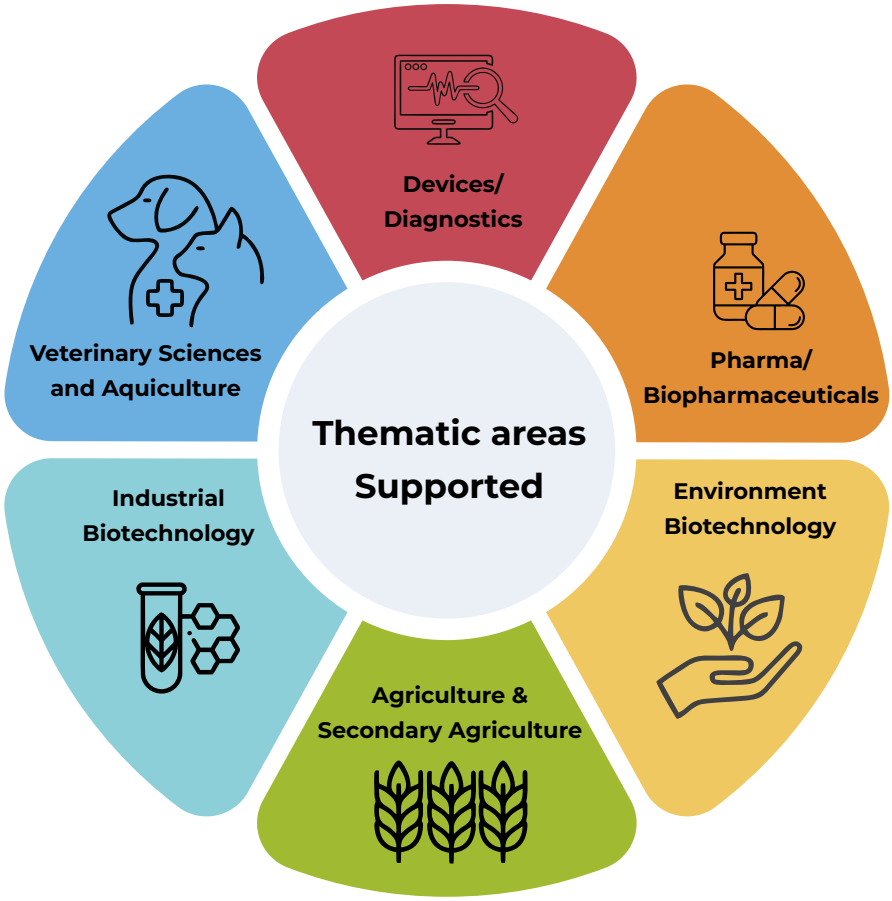
The details are as below:

- i4 supports biotechnological product/technology development by strengthening R&D capabilities of start-ups/companies/LLPs. The programme is operated through two schemes based on the Technology Readiness Level (TRL):



i4 Program is operated through two schemes

The i4 scheme supports product and technology development under the following thematic areas



Thematic Areas supported under i4

II.2.1.1. Small Business Innovation Research Initiative (SBIRI)

SBIRI scheme supports development and initial validation of products/technologies (up to TRL6). The Small Business Innovation Research Initiative (SBIRI) is a flagship funding scheme of BIRAC aimed at nurturing early-stage R&D-driven innovation in the biotech industry. Launched in 2005 and further strengthened under BIRAC since 2012, the scheme supports start-ups, SMEs, and LLPs engaged in biotechnology-based research with significant potential for commercialization and societal impact.

Since the inception of the scheme, a total of 350+ projects have been supported benefiting 450+ beneficiaries. Overall, 316.75 Cr in funds was committed to drive innovation and development efforts. These supported projects generated 804 employment opportunities, demonstrating a strong impact on job creation. In addition, the supported projects led to the filing of 53 patents and the development or commercialization of 90 products and technologies, highlighting significant progress in research, innovation, and market-ready solutions.

Impact of SBIRI scheme

A few notable examples developed under SBIRI are listed below:

- ✓ **Virchow Biotech Pvt Ltd., Hyderabad** has developed and commercialized Biosimilar to Rasburicase. It is a Recombinant powder for injection which is a potent uricolytic agent for the treatment and prophylaxis of hyperuricemia patients.
- ✓ **Aristogene Biosciences Pvt. Ltd., Bengaluru** has developed and commercialized Vibrioshield which is a Bacteriophage based control of Vibrio harveyi infection in shrimp. It is an all-natural, non - chemical antimicrobial preparation for controlling the Vibriosis.
- ✓ **Fibroheal Woundcare (P) Ltd (Earlier Healthline (P) Ltd), Bengaluru** has commercialized silk based wound care products (Ag Sheet, Ag Foam, Ag Powder & Ag ointment).
- ✓ **VIVIRA Process Technologies Pvt. Ltd., Pune** has developed VoDCa® which is a vortex Diode based cavitation device commercialized for industrial waste water treatments. The reductions in COD achieved are very cost effective.
- ✓ **Actorious Innovations & Research Pvt. Ltd., Pune** has commercialized OncoDiscover Liquid Biopsy Technology. Oncodiscover is the proprietary technology developed for detection and enumeration of circulating tumor cells in peripheral blood. This platform is designed for specific targeting, rapid isolation and imaging of cancer cells.
- ✓ **Nanoclean Global Pvt Ltd., New Delhi** has developed and commercialized Nasofilters: A Nano Respiratory Disposable Nasal Filter. Nasofilters, is the first ever non-inserted, hypoallergic and self-adhering nanotechnology based respiratory disposable nasal filters, which sticks to the user's nasal orifice, unlike traditional surgical masks which cover the half of the face and produces discomfort while wearing.
- ✓ **Aten Porus Lifesciences, Bengaluru** has developed ORX – 301: Treatment of Niemann-Pick Type C disorder. ORX-301 is a best-in-class treatment for the treatment of diseases caused by accumulation of lipids such as cholesterol in lysosomes. Demonstrates efficacy at 1/5 – 1/10th dose of treatment alternatives; currently being investigated in clinical trials. Can also be administered subcutaneously instead of intrathecally.
- ✓ **BeAble Health Pvt Ltd., Hyderabad** has commercialized ArmAble which is a game-based upper limb rehabilitation device
- ✓ **Pragmatech Healthcare Solutions Pvt Ltd., Vadodara** has developed and commercialized CERVICHECK™ Self Sampling Kit which is India's first clinically

validated and CDSCO approved at-home cervical self-sampling kit, which enables women to collect their own cervical samples in the privacy of their homes, or a place of their choice.

- ✓ **Flic Farm Pvt Ltd., Hyderabad** has developed and commercialized XMachines which is AI-powered electric autonomous robots for precision agriculture, helping farmers increase efficiency and reduce operational costs.
- ✓ **Primary Healthtech Pvt Ltd., Guwahati** has developed and commercialized Mobilab which is a portable point-of- care diagnostics in India with a unique device that delivers rapid results for 25 health parameters, including heart, kidney, liver, diabetes and anaemia
- ✓ **Janitri Innovations Pvt Ltd, Bengaluru** has developed Keyar Daksh which is an affordable & easy to use labor monitoring device KEYAR for early detection of fetal distress by monitoring Fetal-maternal heart rate & uterine contraction
- ✓ **Bionic Hope Pvt Ltd., Bareilly** has developed and commercialized Upper Limb Prosthesis which is an affordable upper limb prosthesis.
- ✓ **Cisgen Biotech Discoveries Pvt Ltd, Chennai** has commercialized CowVuw Device which is a Video assisted artificial insemination gun.

II.2.1.2. Biotechnology Industry Partnership Programme (BIPP)

Under the umbrella of i4 (Intensifying the Impact of Industrial Innovation) program, Biotechnology Industry Partnership Programme (BIPP) is BIRAC's Flagship "Late-stage funding" scheme. The Scheme was launched in January, 2009 and serves for scaling and commercializing high risk innovations through cost sharing between BIRAC and the industry. The expected TRL on the completion of a BIPP supported project is TRL 7 or higher.

Since its inception, BIPP scheme has played a significant role in shaping the current landscape of Indian Biotech industry. To its credit, BIPP scheme has provided support to 300+ beneficiaries, employing 2000+ skilled force resulting in filing of 40+ IPs and development/commercialization of 100+ products. The impact made by the Scheme is summarized below:

Impact of BIPP scheme

Further, BIPP scheme has a royalty clause as per which the company is required to pay royalty at 5% of the net sales of the product developed through BIRAC support. A royalty amount of more than Rs. 5.50 Cr has been booked under the scheme till date.

Some of the outstanding products developed and commercialized under BIPP are provided below:

- **Bharat Biotech International Limited, Hyderabad** developed and launched the Rotavirus Vaccine (ROTAVAC) in 2015.
- **Biological E Limited, Hyderabad** developed Inactivated Japanese Encephalitis Vaccine (JEEV) with partial support from BIRAC. The vaccine was launched in 2012
- **Serum Institute of India Ltd., Pune** launched CERVAVAC®, a gender-neutral qHPV vaccine for prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18; cervical, vulvar, vaginal, and anal precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18; and genital warts caused by HPV types 6 and 11.

- **Wockhardt, Mumbai** has commercialized MIQNAF (nafithromycin), a novel oral macrolide antibiotic discovered & developed in India. The drug offers a first-ever, "ultra-short course" once-daily, 3-day, safe, monotherapy for the treatment of community-acquired bacterial pneumonia (CABP).

- **Immuneel Therapeutics, Bengaluru** has commercialized Qartemi®, an anti-CD19 directed genetically modified autologous Chimeric Antigen Receptor T (CAR-T) cell therapy

- **ATGC Biotech Pvt. Ltd., Hyderabad** has developed and commercialized a Novel SPLAT technology for integrated pest management through mating disruption. The mating disruption products for control of pink bollworm (PBW), Brinjal Fruit and Shoot Borer (BFSB), Tuta Absoluta and many other lepidopteran pests are being approved as green label insect control products which will find its place in every organic grower practices.

- **Forus Health Pvt. Ltd., Bengaluru** has commercialized 3netra neo which is a Compact, portable and easy to use mydriatic digital wide field imaging system.

- **Eyestem Research Pvt. Ltd., Bengaluru** has developed and is validating Eyecyte-RPE, a patented suspension of Retinal Pigment Epithelium cells designed to treat moderate to severe dry age-related macular degeneration (DryAMD). The Company has completed phase 1 study for the investigational retinal pigment epithelium (RPE) cell therapy and submitted the results to CDSCO for permission to start phase 2 of the study.
- **Apramitha Innovations Pvt. Ltd., Hyderabad** has successfully validated Apremilast topical gel for the treatment of mild to moderate psoriasis. The Company is awaiting the Manufacturing License to initiate commercial activities.

- **PathShodh Healthcare Pvt. Ltd., Bengaluru** has commercialized anuPath nanoA1c, an IVD point of care device to measure blood glucose, haemoglobin and HbA1c in capillary finger prick samples

- **String Bio Pvt. Ltd., Bengaluru** has set up a pilot scale facility for scale up and validation of a gas-based fermentation process for conversion of methane to microbial protein. Technology involves production of single cell protein from methane. The proposed product will be used for animal feed. The product has been validated on aquatic and poultry species.

- **NovaLead Pharma Pvt. Ltd., Pune** has developed and validated Diulcus, a topical gel of Esmolol hydrochloride for the treatment of diabetic foot ulcers. The product has been out-licensed to Ipca Laboratories Ltd.

- **Piscium Health Sciences, Mumbai** has commercialized Piscium Alpha, Nano Engineered Dental Burs.
- **MJ Biopharm Pvt Ltd, Pune** has successfully completed clinical development and manufacturing scale-up of Insulin Glargine, an essential long-acting insulin analogue, The product is now ready for launch in India and will be made available to Government healthcare institutions.
- **Sensivision Health Technologies, Bengaluru** has launched REVIVE, a unique solution to address Birth Asphyxia complication in Newborns called Hypoxic Ischemic Encephalopathy (HIE).
- A commercially viable technology to produce 2 generation (Cellulosic) ethanol from rice straw has been established by **Kuantum Papers Limited.** The pilot plant can run continuously to produce 20 Kilolitres ethanol. The company is in the process of raising funds for the 100KL/day bio-refinery.
- **Himedia Laboratories Pvt Ltd., Mumbai** has commercialized CHOin1™ Serum Free CHO Medium and Feed, designed to support the proliferation, productivity of CHO clones. Suitable for research and routine large-scale GMP manufacturing and ideal for protein production using CHO-DG44, CHO-K1, CHO-S, and CHO-GS cell lines
- **Temperate Technologies Private Limited, Hyderabad,** has commercialized Coldeasy, a low-power and affordable cold storage solution that converts any room into a cold room, increases shelf-life of fruits and vegetables and enables multiple commodity storage in the same chamber

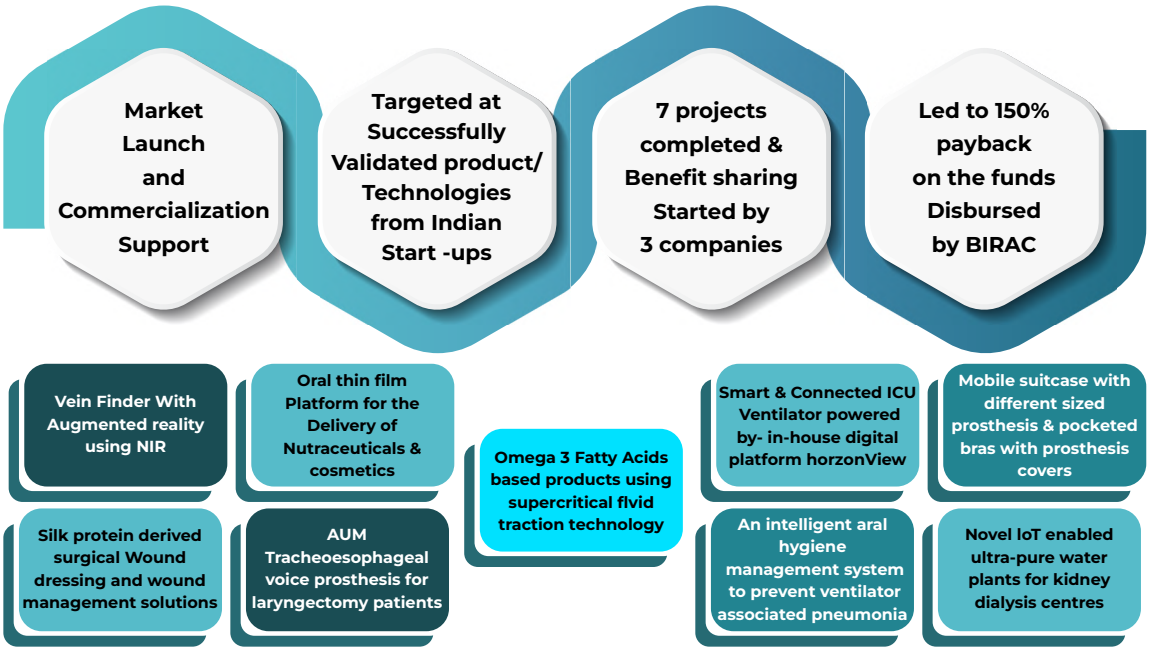
II.2.2. Product Commercialization Program (PCP) Fund

This initiative aims to fast-track the market launch and large-scale commercialization of products and technologies developed by Indian start-ups with commercial potential and societal impact. This program was launched in 2018. A benefit sharing clause associated with successful commercialization leading to payback of 150% of the fund (disbursed) to BIRAC within 8 years has been introduced in this program.

Eligible applicants include Indian start-ups that have received BIRAC support through funding schemes like BIG, SBIRI, BIPP, BioNEST incubation, or other recognized BIRAC initiatives. Start-ups supported by other funding agencies may also apply if their product or technology has achieved a Technology Readiness Level (TRL) of 7 or higher

according to BIRAC's scale, and is expected to be market-ready within 6 to 18 months.

To date, nine products and technologies have received funding through the PCP Fund. Seven projects have been completed and 3 companies have started benefit sharing resulting in approximately ₹74 lakhs revenue for BIRAC.



S. No	Company	Product/Technology
Benefit sharing companies		
1	Aspartika Biotech Pvt Ltd, Bengaluru	Production & Commercialization of Omega 3 Fatty Acids based products and nutraceuticals using Supercritical fluid extraction technology
2	Aarna Biomedicals, Delhi NCR	Deployment of physical trial based Sampoorti-Poorti System for post-surgical rehabilitation of mastectomees pan-India
3	Fibroheal Woundcare Private Limited, Bengaluru	Silk protein derived surgical wound dressings and other wound management solutions Completed Projects

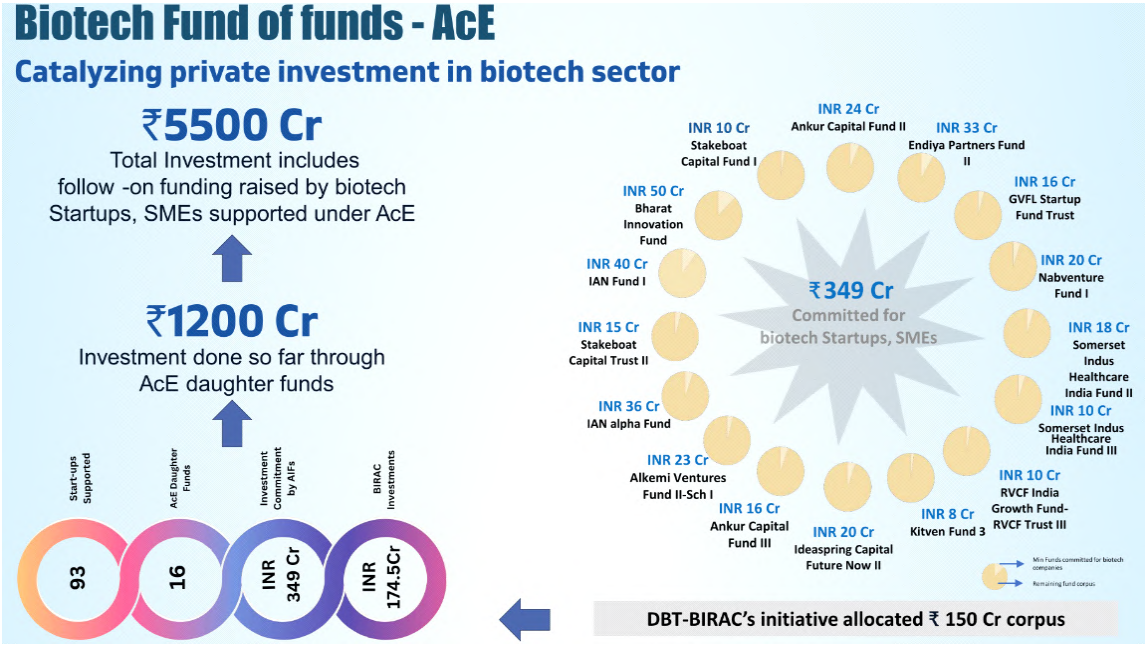
Completed Projects		
4	BonAyu Lifesciences Private Limited, Bengaluru	Oral thin film platform for the delivery of Nutraceuticals, as a better alternate to the conventional tablets, capsules, liquids and gels.
5	Innaumation Medical Devices Pvt. Ltd, Bengaluru	Tracheo-Esophageal Voice Prosthesis for Laryngectomy Patients
6	Medtra Innovative Technologies Pvt. Ltd., Kochi	Vein tracking/finder device with augmented reality using NIR
7	InnAccel Technologies Pvt. Ltd., Bengaluru	VAPCare: An intelligent secretions and oral hygiene management system to prevent a deadly infection called ventilator associated pneumonia, which is responsible for more than 250,000 deaths every year in India alone.
On Going projects		
8	Noccarc Robotics Pvt. Ltd., Pune	Noccarc V730i: Smart & connected ICU Ventilator powered by in-house developed digital platform HorizonView
9	Althion, Hyderabad	Ultra-pure water for kidney dialysis

II.2.3. Financial Assistance at different stages of product development cycle: BIOTECH INVESTMENTS

To foster R&D and innovation in Biotechnology by plugging the funding gap, the "Valley of Death" for early-stage start-ups, the following fund has been introduced

II.2.3.1 AcE (Accelerating Entrepreneurs) Fund

Biotech Fund of funds – AcE (Accelerating Entrepreneurs) is being promoted by DBT under the aegis of Make in India initiative, and implemented by BIRAC. Today, AcE fund supports 16 Alternate Investment Funds (AIF) daughter funds who have invested Venture capital of INR 1200+ Cr in 93 Start-ups, SMEs. These biotech companies have raised a follow-on funding of another INR 4300+ Cr. Put together, the pilot efforts of DBT-BIRAC have catalysed, so far, an infusion of INR 5500+ Cr into the biotech start-up ecosystem through PPP.



Scale of AcE fund is anticipated under Deep Tech RDIF and Bio-RIDE scheme.

II.2.3.2 Start-ups Follow-on funding: In addition, INR 1200+ Cr were raised by 46 biotech start-ups in the FY 2024-25 reflecting growing support from private, venture capital for the ecosystem. The following are the details of some of the start-ups:

- **Innovodigm, Kolkata**, raised ₹5.5 crore in a seed funding round led by the IAN Group.
- **Tan90 Thermal Solutions, Chennai**, raised ₹20 crore (USD2.4million) in a Series A funding round led by NABVENTURES, with participation from Blue Ashva Capital, Capital A, and 3i Partners.
- **GreenGrahi, New Delhi**, raised ₹32 crore (USD3.73million) in a seed round led by Avaana Capital.
- **InnerGize, New Delhi**, a mental health technology startup, raised ₹4.5 crore in its pre-seed round, led by Antler India.
- **Revelations Biotech, Hyderabad**, a company supported under BIRAC's BIPP scheme, received an investment of ₹1,360 crore (USD 163.86 million) through a partnership between Shaiva Group and Taranis Capital (UAE-based investors), in collaboration with the Government of Telangana under an MoU framework.

- **Janitri, Bengaluru** a startup supported by BIRAC through schemes including BIPP, SBIRI, AGC-janCARE, and SPARSH, raised approximately ₹12.04 crore (USD1.4million) in a pre-Series A round. The round was led by Ashish Kacholia and Prateek Maheshwari, along with institutional investors Tal64 Syndicate and O2 Angels Network.
- **Cureous Labs, Bengaluru** raised ₹1.25 crore (USD 150k) in a seed round led by Firstport Capital, along with angel investors.
- **Flixdrop, Noida** secured an undisclosed amount in a pre-Series A funding round from Caspian Equity. The investment was made through Caspian's agri-focused fund LeAF (Leap for Agri-Food), led by Emmanuel Murray.
- **Eyestem Research, Bengaluru** secured $ 10 million in a Series B funding round co-led by Mahyco and Alkem Laboratories.
- **Turtle Shell Technologies (Dozee), Bengaluru**, raised $ 10 million in debt funding from Stockhausen International Pte Ltd.
- **Cureous Labs, Bengaluru**, secured $ 0.18 million in a Seed Round from Inflection Point Ventures (IPV) and Anthill Ventures.
- **GoCarin Industries, Balasore**, raised $ 50,000 from Innosphere Ventures under Edge Alpha India 2025.
- **Inochi Care, New Delhi**, raised $ 50,000 from Innosphere Ventures under Edge Alpha India 2025.
- **Blackfrog Technologies, Noida**, secured a Pre-Series A investment of ₹14.88 crore from the Global Innovation Fund (GIF), with participation from Rainmatter by Zerodha, and the Manipal Education and Medical Group (MEMG).
- **Lamark Biotech, Ahmedabad**, raised ₹6.5 crore in a pre-Series A funding round led by IAN Group.
- **Loopworm, Bengaluru**, raised ₹28.41 crore Pre-Series A funding round led by WaterBridge Ventures and Enrission India Capital.

II.3 Incubation and Pre-Incubation Support

BIRAC strengthens the biotechnology innovation ecosystem by supporting incubation and pre-incubation programmes that nurture early-stage start-ups and entrepreneurial ideas.

Through a network of bio-incubators (BioNEST, E-Yuva, SPARSH centres), BIRAC provides access to mentorship, shared research infrastructure, technical guidance, and business development support, enabling innovators to translate ideas into viable biotech ventures.

II.3.1 BioNEST (Bioincubators Nurturing Entrepreneurship for Scaling Technologies)

The BioNEST scheme of BIRAC is a flagship initiative aimed at strengthening India's biotechnology innovation and entrepreneurship ecosystem by creating world-class bio-incubation infrastructure and enabling support systems for start-ups and innovators. The scheme facilitates the translation of research innovations into viable products and technologies by providing access to laboratory infrastructure, mentorship, funding linkages, and commercialization support within an enabling institutional environment.

Over the past 14 years, BIRAC has established a strong and geographically distributed network of bio-incubators across the country. These incubators are hosted within leading universities, national research institutes, medical and research hospitals, and also as independent stand-alone facilities to address regional innovation needs. The BioNEST network has expanded to 75 bio-incubators, collectively supporting more than 2,500 biotech start-ups and entrepreneurs working across diverse domains such as healthcare, diagnostics, medical devices, agriculture, industrial biotechnology, bioinformatics, and environmental biotechnology.

BioNEST incubators provide plug-and-play laboratory and office space, access to advanced instrumentation, shared core facilities, pilot-scale infrastructure, and specialized technical services that significantly reduce the entry barriers for early-stage biotech start-ups. By situating incubators within research-intensive institutions, the scheme promotes academia-industry convergence, facilitates access to scientific expertise and clinical validation environments, and accelerates technology development and commercialization.

In addition to physical infrastructure, BioNEST incubators offer comprehensive business and technical support services including intellectual property management, technology transfer, regulatory guidance, product validation, quality certifications, legal and contractual advisory, and market access facilitation. The incubators also act as nodes for networking, investor connect, industry partnerships, and capacity-building programs, thereby enabling start-ups to scale from proof-of-concept to market readiness.

Through the BioNEST scheme, BIRAC has created a nationally connected ecosystem that nurtures entrepreneurship, promotes indigenous innovation, and supports the growth of globally competitive biotech enterprises aligned with national priorities in health, agriculture, and sustainable development.

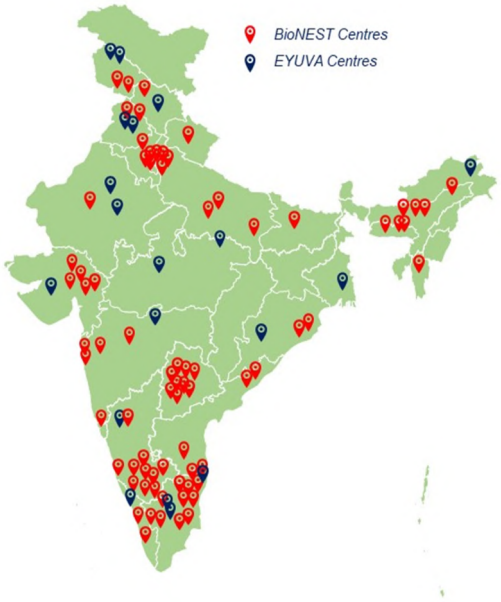
Objectives of the BioNEST Scheme:

- **Creation of world-class bio-incubation infrastructure:**
  Establish and strengthen bio-incubators equipped with high-quality laboratory space, shared facilities, and specialized equipment to support biotech start-ups.
- **Nurturing biotech start-ups and entrepreneurs:**
  Provide an enabling environment for innovators to develop, validate, and commercialize biotechnology products and technologies.
- **Strengthening academia–industry linkages:**
  Facilitate collaboration between academic institutions, research organizations, healthcare systems, and industry to accelerate translational research and innovation.
- **Mentorship and business support:**
  Offer structured technical, business, and regulatory mentorship through expert networks, industry leaders, and domain specialists.
- **Enabling services for commercialization:**
  Support start-ups in IP and technology management, legal and contractual processes, regulatory approvals, product validation, certifications, resource mobilization, and market access.
- **National networking platform:**
  Create a connected ecosystem of incubators, investors, industry partners, and policy stakeholders to promote collaboration, knowledge exchange, and scaling of innovations.

II.3.2 EYUVA (Empowering Youth for Undertaking Value Added Innovative Translational Research)

EYUVA scheme is an initiative of BIRAC aimed at fostering a culture of applied research and innovation among young students across India. The scheme supports and nurtures budding student innovators at undergraduate, postgraduate, and doctoral levels by providing mentorship, financial aid through fellowships & research grants, and access to incubation support.

Under E-YUVA, 19 dedicated E-YUVA Centres have been established at select academic and research institutions, which serve as hubs to identify and handhold promising student innovators. These Centres serve as hubs for ideation, problem-solving, and early-stage entrepreneurship, enabling students to translate innovative ideas into viable technologies or start-ups. E-YUVA also fosters skill development through hands-on training and exposure to real-world challenges in the biotech sector. Additionally, each E-YUVA Center partners with a BIRAC's BioNEST Centres (Knowledge Partner) to further enhance the entrepreneurial journey of the fellows. Since its inception, the scheme has played a pivotal role in building a pipeline of young innovators and catalysing grassroot-level biotech entrepreneurship.



94 Incubation Centres (BioNEST & EYUVA)

10,00,000+ sqft Incubation Space

3000+ Incubatees & students

1300+ IPs filed

800+ Products/Technologies in market

25000+ High skilled Jobs created

Covering **21** States & 4 UTs including Tier 2 & 3 cities

Bioincubation centres (BioNEST and EYUVA) supported across the country along with the impact created (Details can be found in Appendix I)

II.3.3. SPARSH (Social Innovation Programme for Products Affordable & Relevant to Societal Health)

SPARSH is a flagship initiative of BIRAC designed to catalyse the development of affordable, need-based biotechnology innovations that address pressing societal and public health challenges in India. Launched in 2013, the programme promotes socially relevant entrepreneurship by nurturing start-ups and innovators working at the intersection of biotechnology, public health, agriculture, nutrition, and environmental sustainability. SPARSH specifically focuses on enabling solutions that are accessible, scalable, and aligned with the needs of underserved and vulnerable populations.

The programme supports innovations across six priority thematic areas of national importance:

- Maternal and Child Health
- Ageing and Health
- Food and Nutrition
- Waste to Value
- Combating Environmental Pollution
- Agri-Tech (including reduction of post-harvest losses)

SPARSH is implemented through a networked model comprising SPARSH Centres hosted in academic, research, and clinical institutions, along with specialized Knowledge Partners that provide domain expertise and translational support. The programme has progressively scaled across three phases to expand geographic reach and thematic depth.

Programme Scale and Phases

- Phase I: Supported 8 SPARSH centres
- Phase II: Supported 14 SPARSH centres
- Phase III: Established 18 SPARSH Centres (including 3 collaborative centres) and 3 Knowledge Partners working under the thematic clusters of Public Health, Farm to Plate, and Climate Resilience, with a strong focus on translational deployment and regional outreach.

A distinctive feature of SPARSH is its fellowship-driven innovation model that engages students, young researchers, and grassroots innovators. Selected fellows receive a monthly fellowship of ₹60,000 along with a ₹10 lakh kick-start grant to develop proof-of-concept solutions. They also gain access to laboratory facilities, mentorship from technical and social domain experts, field immersion opportunities in real-world settings, and structured support for product development and commercialization pathways.

Through this integrated incubation-cum-fellowship approach, SPARSH bridges the gap between academic research, community needs, and market deployment, thereby enabling socially impactful biotech enterprises. To date, the programme has enabled over 100 social biotech start-ups and facilitated the creation of more than 65 intellectual property assets. Under Phase III, SPARSH aims to support an additional 270 start-ups, significantly expanding India's pipeline of affordable and inclusive biotechnology solutions. **(Details can be found in Appendix II)**

SPARSH impact

II.4. MENTORING SUPPORT

BIRAC provides structured mentoring support through Intellectual Property (IP) facilitation and the Regulatory and Policy Advisory Support Program (RAPA) to help innovators navigate complex regulatory and commercialization pathways.

These initiatives offer expert guidance on IP strategy, regulatory compliance, and policy frameworks, enabling start-ups to protect their innovations and accelerate the journey from lab to market.

II.4.1. IP & Technology Management Group

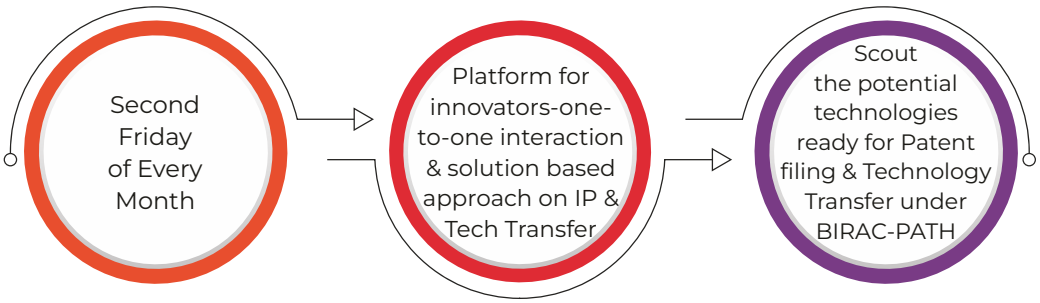
Since BIRAC inception, the BIRAC IP & Technology Management Division has played a

pivotal role in innovation management. The IP team at BIRAC actively conducts IP due diligence for proposals submitted under various BIRAC schemes, including comprehensive prior art searches. These efforts support external experts in making decisions on the technical merit and novelty of proposals. In addition, the division also evaluates the need for Technology Licensing Agreements and Material Transfer Agreements (MTA) for BIRAC supported applicants. These evaluations help to innovators to commercialize their products or technologies in the future.

Assessing intricacies of IP in Projects submitted to BIRAC under different programmes	**Patent due-diligence and Searches, opinions on license agreements, MoUs, MTA**
Mapping technologies emerging both Nationally, Internationally	**Patent Landscape and Analysis**
Sensitization & Capacity Building programmes on IP & Tech. Management	**Workshops & Webinars, Capacity Building Program**
Facilitating & handholding for securitization of new IPs & Tech Commercialization emerging in the projects	**BIRAC-PATH Program**
Advisory on IP and Tech Transfer & Commercialization	**IP & Tech Management Law Clinic Connect**

Activities of IP & Tech Management Group

The group also provides strategic IP advisory services to Start-ups, supporting them in building and strengthening their intellectual property portfolios. One such initiative is the BIRAC IP & Law Clinic Connect, a monthly program designed to guide Start-ups and researchers on intellectual property and technology transfer related matters. The program is virtually organized on the Second Friday of every month, the Clinic has completed 32 editions to date. In each session, more than five beneficiaries have received one-on-one guidance, with the program collectively mentored around 160 participants so far.



Advisory & Mentorship Program

BIRAC has organized around 40 IP & Technology Management awareness programs across different parts of India, to help entrepreneurs, innovators, researchers, start-ups to understand the importance of Intellectual Property Rights (IPR) in the product development life cycle. Further, the group had also conducted around 6 capacity building programs (Offline and online) for the stakeholders and recently, a Hands-on program focused on Patent Analytics and Freedom to Operate (FTO) was conducted.

The group also facilitates patent drafting, filing, prosecution and technology transfer & commercialization under the "BIRAC-PATH" program (Patenting & Technology Transfer for Harnessing Innovations). Under this program, BIRAC has supported around 42 patent applications, covering Indian patent filings, PCT filings, and National Phase Filings. This assistance helps innovators protect their inventions and move closer to bringing their technologies to market. To implement the program, BIRAC has empanelled technically proficient and experienced IP & Technology Transfer (TT) firms.

Additionally, the BIRAC team has successfully facilitated the transfer of five (5) technologies from academia to industry, for further development and commercialization.

White Rust Resistant Mustard Technology developed by University of Delhi

Transgenic cotton crop for resistance to lepidopteron pests developed by University of Delhi

Brucella abortus S19Δper vaccine developed by IVRI & supported by DBT

Preg-D Pregnancy diagnosis kit developed by CIRB & supported by DBT

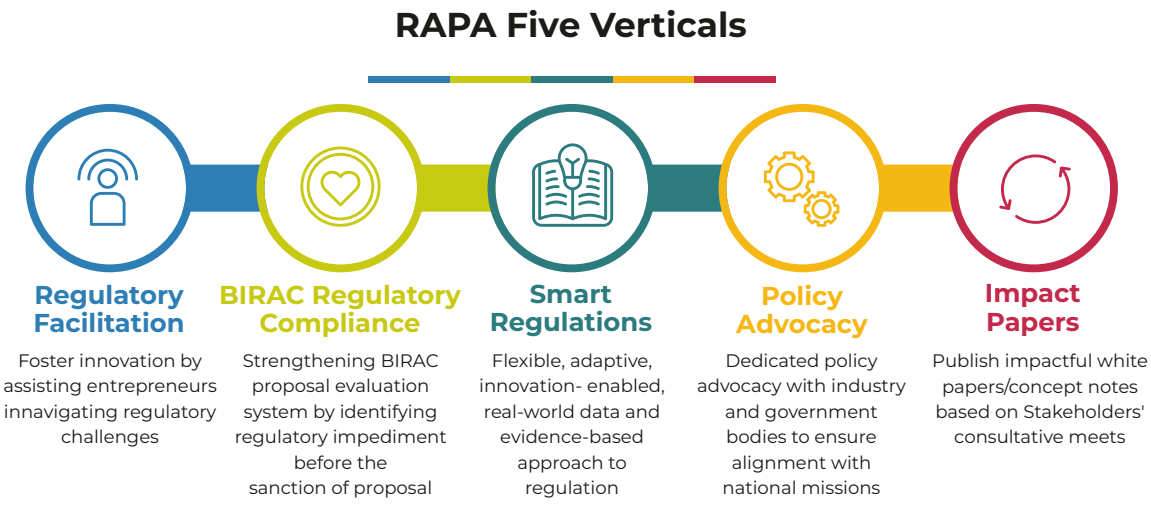
Recombinant Lactobacillus-based Probiotic for Poultry Feed developed by Sher-e-Kashmir University of Agriculture Sciences and Technology of Kashmir

II.4.2.Regulatory Affairs & Policy Advocacy (RAPA): Promoting Regulatory Compliant Innovations

With rapidly evolving policies and regulations, start-ups face challenges in keeping pace with the changing biotech ecosystem. To address this gap, BIRAC established the Regulatory Affairs & Policy Advocacy (RAPA) unit on 17th May 2024 to strengthen India's regulatory environment and support the smooth implementation of innovation-driven technologies. The main objectives of RAPA are:

1. Foster innovation by assisting entrepreneurs in navigating regulatory challenges
2. Dedicated policy advocacy with industry and government bodies to ensure alignment with national missions and the needs of innovators
3. Facilitate harmonisation of regulations at national and global levels
4. Publish impactful white papers/concept notes based on the Stakeholders' consultative meeting

To further strengthen its strategic direction, BIRAC convened a stakeholders' consultation meeting to develop a roadmap for **Regulatory and Policy Excellence**, involving consultants from various regulatory bodies. Based on the recommendations from this strategic meeting held in New Delhi, RAPA has established five key verticals.

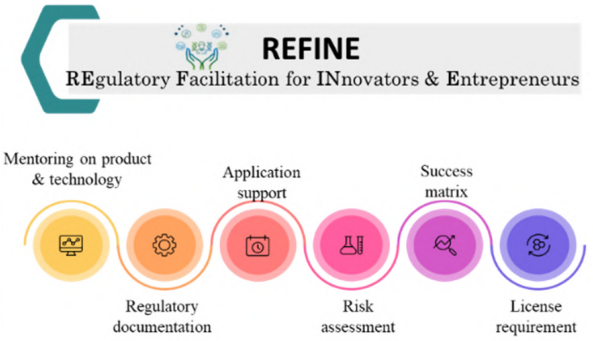


II.4.2.1. Regulatory Facilitation for Start-ups and Innovators

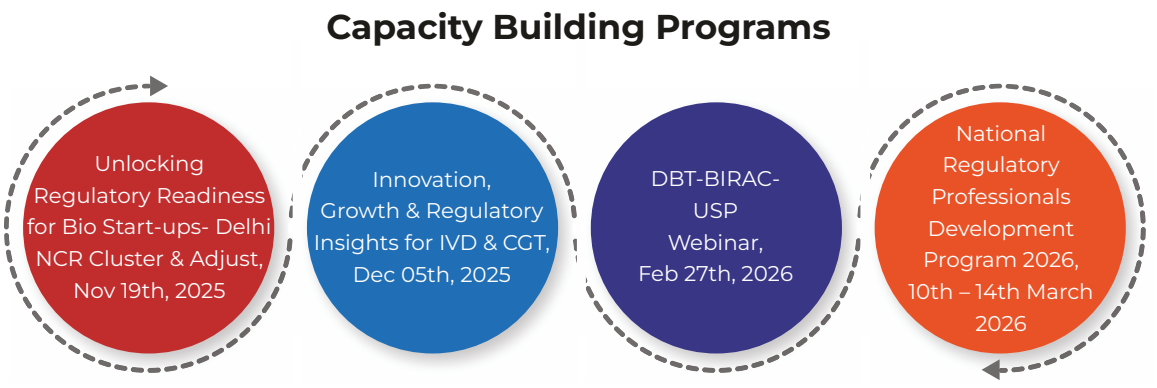
FIRST HUB: A Single Window Facilitation Platform for Innovators is designed to address the regulatory queries of innovators. Representatives from key organisations,

including CDSCO, ICMR, FSSAI, NIB, BIS, GeM, DBT, and BIRAC, assist innovators on the first Friday of every month. RAPA has successfully conducted over 85 First Hub meetings, addressing more than 1,100 queries of start-ups and innovators.

REgulatory Facilitation for INnovators and Entrepreneurs (REFINE): Customised facilitation to strengthen the regulatory framework, by providing product or technology-specific guidance on regulatory documentation, full application support, regulatory risk assessment, success metrics, and licensing requirements.



Capacity Building Programs: RAPA has undertaken several capacity-building initiatives through targeted workshops and webinars aimed at strengthening regulatory awareness among innovators and startups. These include:



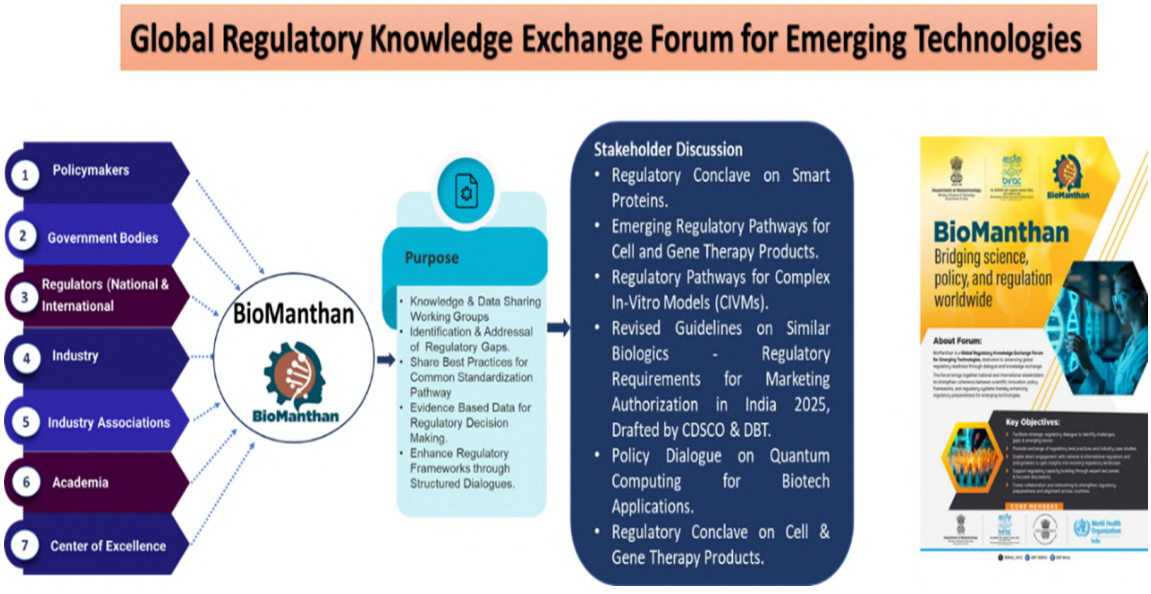
These programmes were designed to enhance regulatory preparedness, facilitate dialogue between regulators and innovators and support startups in navigating complex regulatory pathways in emerging domains.

Further strengthening capacity-building, RAPA is organising the National Regulatory Professionals Development Program, a first-of-its-kind, industry-led masterclass series designed to enhance regulatory, quality, and safety capabilities across the product lifecycle. This initiative directly supports India's vision of regulatory excellence, global competitiveness, and skilled workforce development in the biopharma and medical device sectors.

II.4.2.2. BioManthan, a Global Regulatory Knowledge Exchange Forum for Emerging Technologies, was conceptualised during Global Bio-India (GBI) 2024, as a collaborative platform where innovators, academia, regulatory agencies and industry stakeholders from national & international bodies collectively address regulatory gaps, share best practices and enhance regulatory frameworks for emerging technologies by structured dialogues.

RAPA has undertaken focused stakeholder consultations on Emerging Regulatory Pathways for Cell and Gene Therapy Products, Regulatory Pathways for Complex In-Vitro Models (CIVMs), Guidelines on Similar Biologics and Policy Dialogue on Quantum Computing in Biotechnology.

These multi-stakeholder deliberations led to the development of comprehensive white papers that identified key regulatory gaps, implementation challenges and strategic recommendations to strengthen the evolving regulatory ecosystem.



The Department of Biotechnology (DBT) and the Biotechnology Industry Research Assistance Council (BIRAC) organised a strategic consultation titled “Strengthening India's Clinical Trial Regulation: Lessons from Other Countries” on 5th February 2026 at the India International Centre, New Delhi.

The consultation was convened to facilitate structured dialogue on strengthening India's clinical trial regulatory ecosystem. It brought together global regulatory leaders, subject experts, clinicians, CROs, CDMOs, industry representatives, and policymakers to exchange best practices on the governance of clinical trials, including early-phase and first-in-human studies, as well as regulatory sandboxes for innovative and emerging therapies.

II.4.2.3. Compliance Support to BIRAC-supported proposals with National Guidelines:

BIRAC, being a PSU of DBT, it is of prime importance that the proposals supported by BIRAC comply with the national regulatory regime. RAPA has provided regulatory facilitation and mentored more than 400 BIRAC-supported projects to ensure compliance with national regulatory guidelines and standards.

II.4.2.4 . Smart regulations: Regulatory reforms through regulatory sandboxes

Smart regulations are required to enable responsible innovation by providing a safe, time-bound, and collaborative framework for early regulatory engagement, evidence generation, and compliance support, ultimately accelerating market access and global competitiveness.

BIRAC supports India's efforts to align its regulatory frameworks with internationally accepted standards while ensuring patient safety, scientific rigour, and regulatory efficiency.

A strategic consultation was organised to identify regulatory gaps and explore possible reforms to strengthen India's clinical trial regulatory framework, enable direct engagement among regulators, industry, and policy stakeholders, and promote the compliant and responsible translation of research into safe and effective products. The discussions highlighted benefits such as time-bound trials, limited roll-outs, regulatory data sharing, and continuous engagement with regulatory and enabling bodies, to improve regulatory clarity, reduce duplication, and accelerate patient access to innovative therapies.

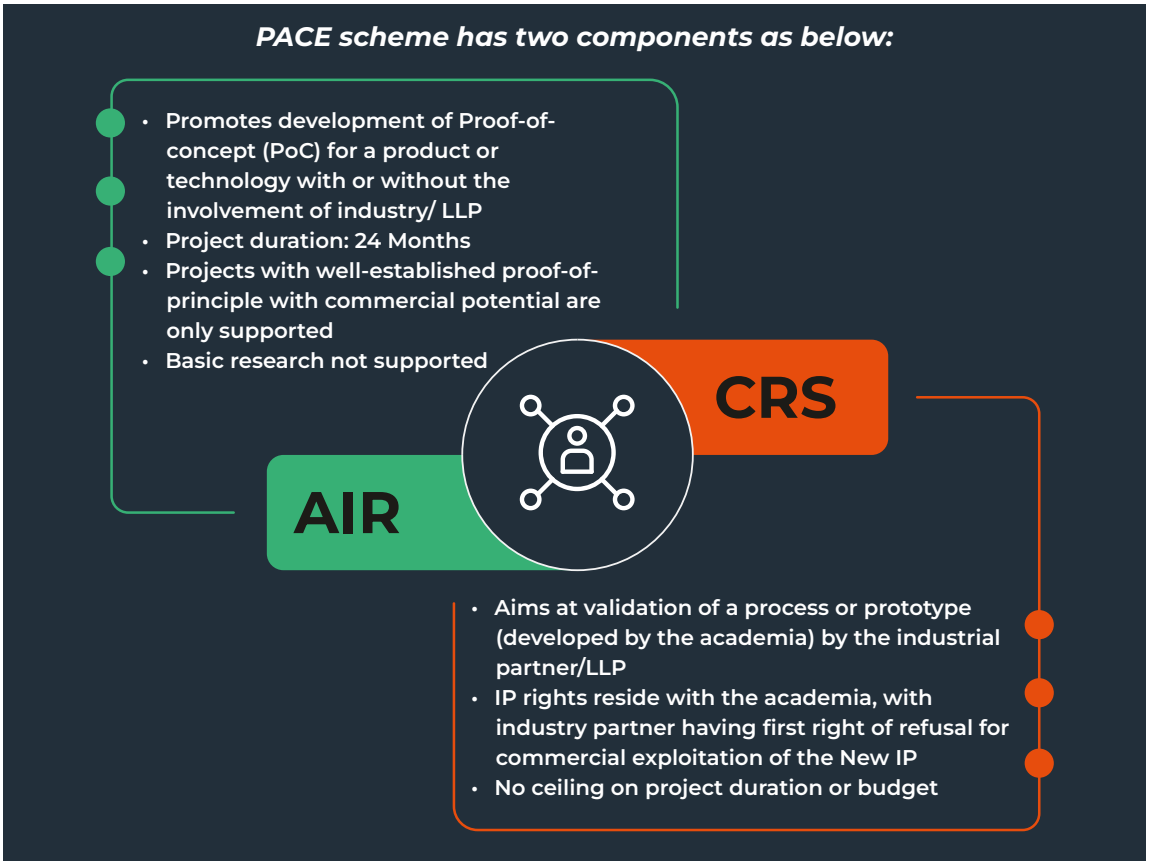
BIRAC presented the concept of a regulatory sandbox as a controlled and supervised environment that enables innovators to develop and validate new technologies under regulatory guidance, supporting evidence generation and early regulatory integration without undergoing the full approval process upfront. In the biotech sector, the sandbox can play a crucial role in balancing innovation with safety and compliance.

III. Academia - Industry Connect

As research by academia is not governed by commercial gains alone, the following schemes were introduced to encourage them to undertake research in upcoming and futuristic technologies and subsequently to realize market ready products.

III.1. Promoting Academic Research Conversion to Enterprise (PACE)

PACE (Promoting Academic Research Conversion to Enterprise) scheme was launched in 2017. Its purpose is to support academic institutions in translating innovative biotechnological ideas into validated proof-of-concept (PoC) and beyond, eventually enabling industry-led validation and commercialization.

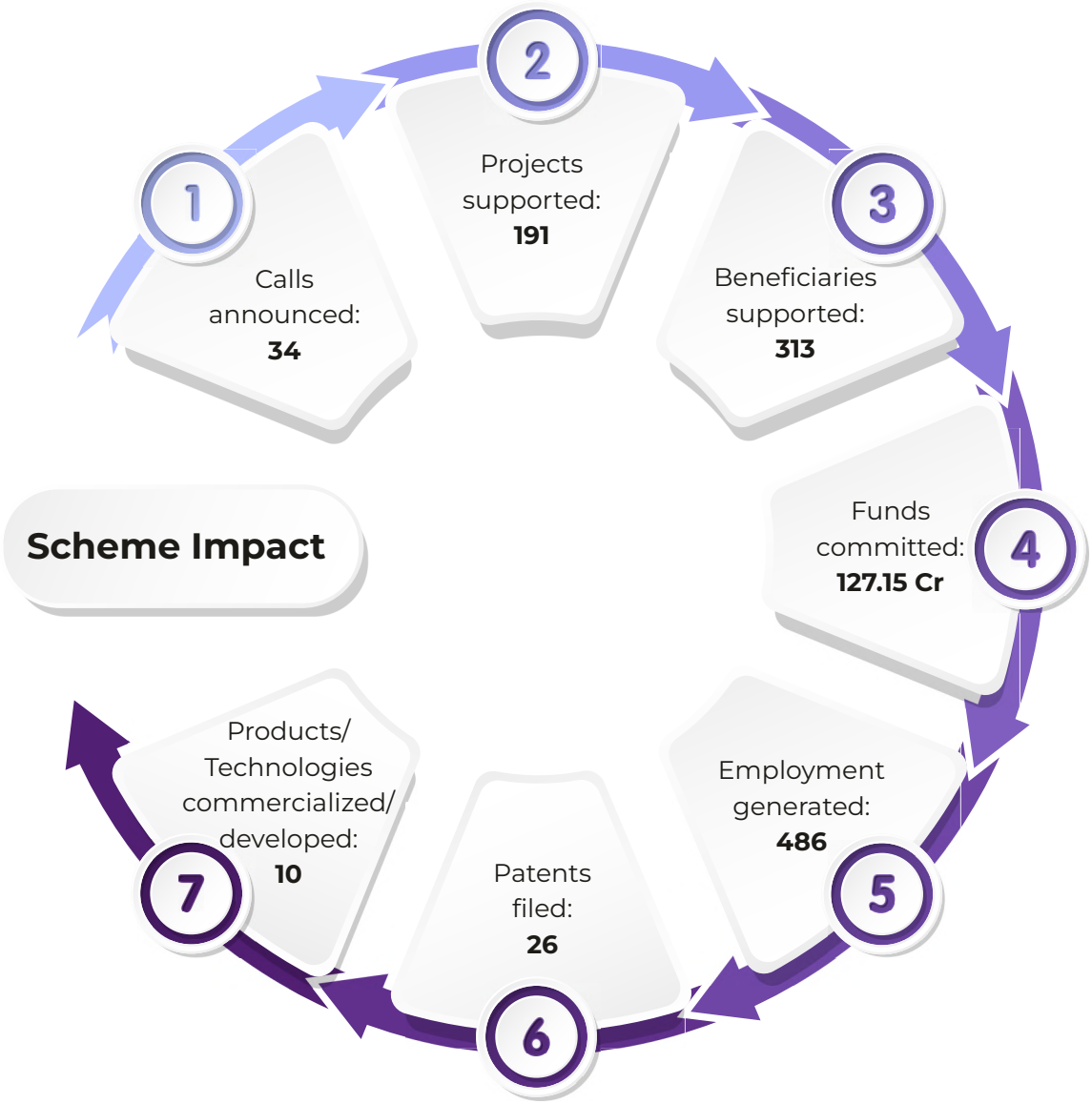


Contract Research Scheme (CRS) was launched by BIRAC in 2012 to bridge the gap between academia and industry. The scheme promotes validation of a product/technology (developed by academia) by an industry partner.

However, to further strengthen the scheme and support academia for PoC

development, BIRAC in 2017 launched Promoting Academic Research Conversion to Enterprise (PACE) to encourage/support academia to develop technology/product (up to Proof of Concepts [PoC] stage) of societal/ national importance and its subsequent validation by an industrial partner. AIR and CRS became the 2 components of this scheme.

Since inception, 191 projects have been supported under the scheme with 92 sole and 99 collaborative projects. 313 beneficiaries including 76 companies and 237 academic organizations have been supported resulting in filing of 26 patents and 10 products/technologies reaching TRL7-9.



Highlights of PACE scheme

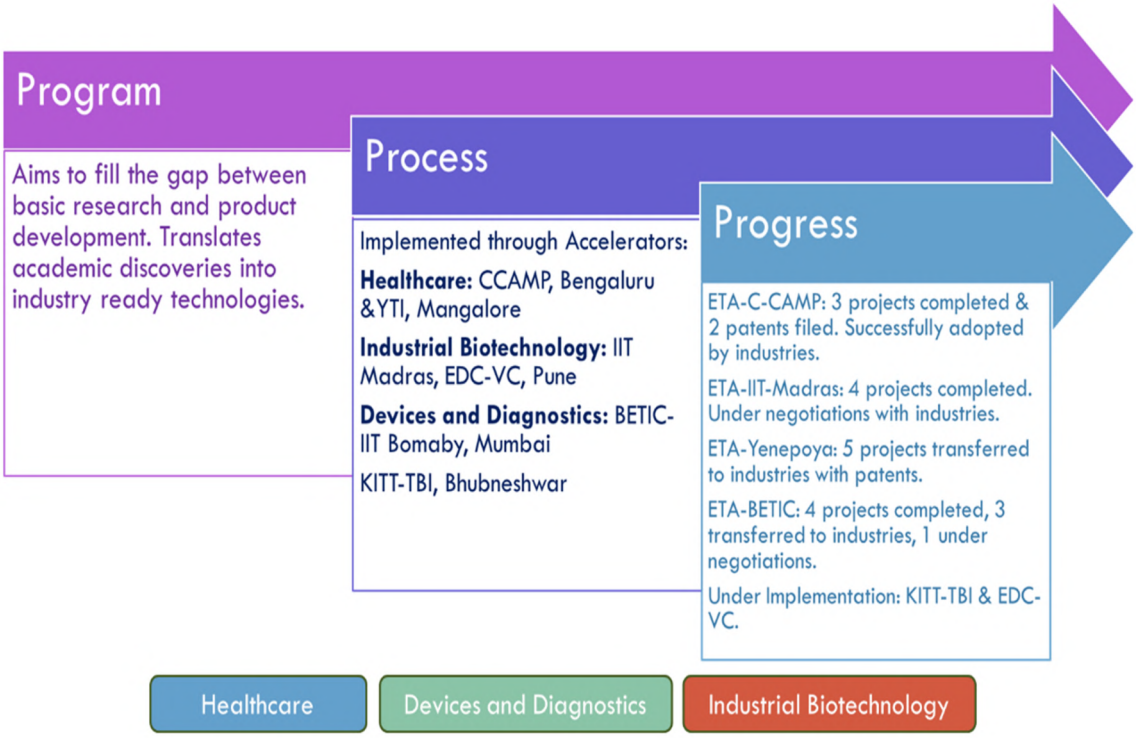
Some key achievements of projects funded under PACE scheme are provided below:

- ✓ **Amity University, Jaipur** in collaboration with **Genomix Molecular Diagnostics Pvt. Ltd, Hyderabad** has developed and commercialized Genomix Para tuberculosis Antibody ELISA Test Kit
- ✓ **NIPGR, New Delhi** has validated potential low glucosinolate transgenic event
- ✓ **Sri Sathya Sai Institute of Higher Learning, Andhra Pradesh** in collaboration with **M/s Tech Mahindra Limited, Mumbai** has developed and validated a Platform for developing a prediction model for determining probability of harbouring ESBL producing enterobacteriaceae in UTI
- ✓ **Amity University, Jaipur** in collaboration with **Genomix Molecular Diagnostics Pvt. Ltd, Hyderabad** has prepared killed vaccine using native isolate of MAP and subunit vaccine for paratuberculosis using specific immuno-dominant recombinant antigens
- ✓ **Indian Veterinary Research Institute, Bareilly (Collaborator: Institute of Animal Health & Veterinary Biologicals & Biovet Private Limited, Karnataka)** has developed Glycoprotein E, gE -deleted bovine herpesvirus-1 BoHV-1 as infectious bovine rhinotracheitis IBR marker vaccine candidate in cattle
- ✓ **IIT, Mumbai** in collaboration with **Dynasense Pvt. Ltd, Mumbai** has developed and validated a Diagnostic test kit for total cholesterol, HDL, LDL cholesterol and triglyceride in whole blood. The Manufacturing License is awaited from CDSCO for commercial launch
- ✓ **Tea Research Association, West Bengal** in collaboration with **Varsha Bioscience and Technology India Private Limited, Andhra Pradesh** has developed and commercialized VEERA: It is a forest tree seed-based oil used as a Bio stimulant for agricultural crops and RIA: The formulation contains Beauveria bassiana 5% AS and recommended for the control of Tea Mosquito Bug (Helopeltis theivora) in Tea.

III.2. Early Translation Accelerator (ETA)

Early Translation Accelerator (ETA) is a strategic initiative aimed at bridging the critical gap between laboratory discoveries and market-ready products by supporting early-stage translational research. Recognizing that many academic innovations fail to reach commercialization due to lack of validation and industry engagement, the ETA is designed to catalyze this transformation by fostering collaborations among academia and industry.

To date, seven* ETAs have been established. ETAs at C-CAMP and Yenepoya Foundation for Technology Incubation, established in the area of health care, IIT-Madras Bio incubator and EDC-VC are for Industrial Biotechnology whereas KITT-TBI and BETIC-IIT Bombay are for devices & Diagnostics. ETA at C-CAMP completed 3 projects and filed 2 patents. ETA-IB at IIT-Madras has also completed all the projects and they are in negotiation for technology transfer to suitable industries. Projects supported under Yenepoya and BETIC are completed and patents were filed. Projects are under implementation for other two ETAs i.e., KITT-TBI and EDC-VC



**BBB financial assistance is under process*

IV. Programs for Niche Areas and Supplementary Activities

BIRAC supports targeted initiatives in emerging and under-served biotechnology domains. These programs foster specialized capacity building, technology validation, and translational research through focused calls. They compliment core funding schemes by addressing strategic gaps and enabling innovations in niche and high-impact sectors.

IV.1. JanCARE

The जनCARE-Innovation Challenge has successfully driven health-tech innovations into low-resource healthcare settings across India, completing field validation studies for 14 grantees in 12 states. The initiative, launched in Dec 2020 by BIRAC and NASSCOM in collaboration with Grand Challenges India (GCI), was designed to discover, design, and scale innovative, affordable health-tech solutions for rural and semi-urban healthcare facilities such as PHCs, CHCs, and sub-centres.

Several innovations have already been adopted by government and industry stakeholders, demonstrating tangible improvements in areas such as cardiovascular care, maternal and child health, diabetes, COPD, and cancer management. Leading industry partners, including AstraZeneca, GE Healthcare, Siemens Healthineers, Medanta Hospitals, St John's Research Institute, Health Care Global Enterprises, and TATA AIG supported innovators with technical guidance, market access, and mentorship, ensuring sustained support through the pilot phase.

Out of 14 innovations supported, notable adoptions include:

- **Alveofit:** IoT-enabled handheld spirometers, facilitated by AstraZeneca, deployed in clinics and hospitals to enable point-of-care spirometry for better management of lung-related non-communicable diseases.

- **Savemom:** Introduced in Tamil Nadu and Maharashtra to reduce maternal and neonatal mortality, which was also featured as a case study at Harvard Business School.

Field deployment under the JanCARE program

Product – Keyar: Fetal Maternal Monitoring device
Company - Janitri Innovations Pvt. Ltd
Deployer State – Arunachal Pradesh and Punjab

Product – Alveofit: IoT enabled, Respiratory Healthcare digital platform
Company - Roundworks Technologies Private Limited
Deployer State – Tamil Nadu and Uttar Pradesh

Product – HaemurEx: Remote Health Monitoring System
Company - Arogyam Medisoft Solution Pvt. Ltd.
Deployer State – Arunachal Pradesh

Product - PreSco - AI/ML-based platform for Neonatal Sepsis Detection
Company - Avyantra Health Technologies Pvt. Ltd.
Deployer State – Telangana

Product – RespirAID: Portable Ventilator of Emergency Care and Transport Ventilation
Company - Biodesign Innovation Labs
Deployer State – Karnataka and Nagaland

Product - Gaze Pattern Based Screening for Early identification of Dyslexia in Children
Company - Giftolexia Solutions Private Limited
Deployer State – Maharashtra and Kerala

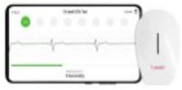
Product – Savemom: AI-driven end-to-end maternal care platform
Company - Olivewear Pvt. Ltd.
Deployer State – Andhra Pradesh,
Adoption State: Tamil Nadu and Maharashtra

Product - AarogyaAIÂ® Rapid Tuberculosis Drug Sensitivity Test
Company - AarogyaAI Innovations Pvt. Ltd.
Deployer State – Rajasthan

Product – EPICare: Technology program for effectively managing IMR & MMR
Company - Helyxon Healthcare Solutions Pvt. Ltd.
Deployer State – Tamil Nadu

Product –Healthcare Kiosk: Providing affordable healthcare services to India's most remote rural areas, where doctors are scarce
Company – Yuvitel Technologies Pvt. Ltd.
Deployer State – Madhya Pradesh

Product – CervAstra: Computational Pathology-based, affordable system for detection of Cervical Cancer
Company - Aindra Systems
Deployer State – Punjab



Product - Spandan: A Portable ECG Device
Company - Sunfox Technologies Pvt. Ltd.
Deployer State – Nagaland and Uttar Pradesh

Product - Onward Assist: Cancer analytics platform
Company – Inventigen Technologies Pvt. Ltd.
Deployer State – Andhra Pradesh

Product - Auticare: XR-AI based Assistive Technology Learning Platform
Company - Embright Infotech Pvt. Ltd.
Deployer State – Karnataka

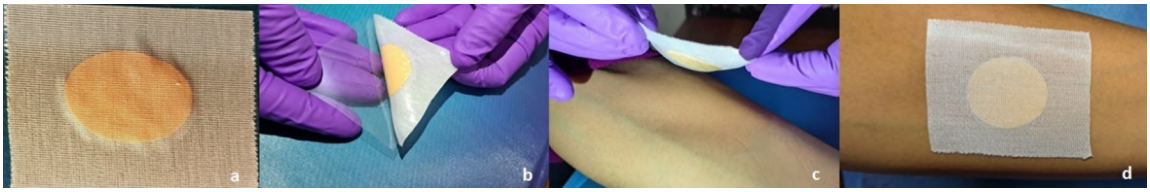
IV.2. Establishing preclinical models for Drug discovery

A focused call titled "Establishment of Preclinical Models for Drug Discovery" was launched tin 2023 to support the development of robust in vitro and in vivo preclinical models for screening new drugs, new chemical entities (NCEs), natural compounds, vaccines, and more. Projects have been funded to academic institutions, industries, as well as academia–industry collaborative initiatives. They cover a diverse range of model systems including organoid development, mouse models, organ-on-chip platforms and Drosophila models, targeting various disease areas such as cancer, rare diseases, neurodegenerative disorders, and metabolic conditions. The supported projects are in different stages of development at present.

IV.3. Program on Guar Gum

To promote development of this area, focused call for proposals was announced in 2019 and proposals were sanctioned for the development of novel products and technologies such as building material mixtures, sealants, bioplastics, biomedical patch and guar derivatives. Some of the products/technologies developed under this program include NUTRIFIBER (Nuevo Polymers Pvt. Ltd.); Indigenous biodegradable plastic (Ruhvenile Biomedical) and Indigenous Wall Putty (Shriram Institute for Industrial Research, Delhi).

Products/Technologies supported under Guar-Gum Program

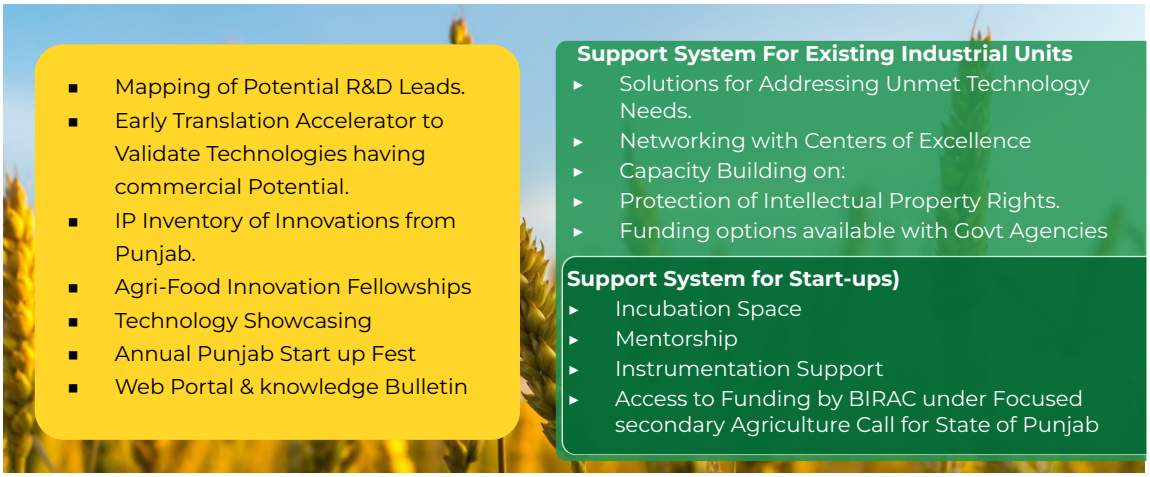


Guar-Gum Patch

BioPlaBean, a truly biodegradable material developed from completely natural sources like biopolymers.

IV.4. Secondary Agriculture Entrepreneurial Network (SAEN)

Network program supporting Punjab State Council for Science & Technology along with NABI, CIAB and BioNEST-PU was launched in 2018. SAEN is a strategic initiative for Early Translation Acceleration from Primary to Secondary Agriculture by supporting industry and promoting start-ups in agri-food sector in Punjab.



Key Features of the network

The following are some of the achievements, Tomato juice-based beverage has been licensed to an industry; Coloured wheat rich in anthocyanins, phenolics and minerals approved by FSSAI; BioNEST, Punjab University supported projects are focussing on the development of protein and fibre rich beverage, a device for the selection and segregation of normal functional seeds from diseased and broken seeds, etc.

IV.5. BIRAC-QUT, Australia- Bio-fortification & Disease resistance in Banana

BIRAC has supported a technology development and transfer program of bio-fortified and disease resistance banana from Queensland University of Technology (QUT), Australia which is being translated by the 5 identified Indian Research Institutes.

The project was started in 2012, with a two-pronged approach. One as a technology transfer agreement between QUT & DBT-BIRAC to execute and manage development and transfer of technology from Queensland University of technology, Australia to India for Bio fortification and Disease Resistance in Banana on behalf of DBT, BIRAC and second for BIRAC and five Indian Institutes for translation.

Initially transgenic banana plants with enhanced level of Provitamin A and Iron, and resistant to Focs and BBTV were developed using gene constructs provided by QUT to the Indian partners and were tested in greenhouses/net houses for detailed evaluation.

Currently promising transgenic banana events having high PVA and iron are been subjected to event selection trials. The data has been prepared for submission to RCGM.

Control: Grand Naine PVA (7.7 to 5.57 µg/g DW)

Gene construct: QUT-DC PVA (55.59 to 28.41 µg/g DW)

DXS PVA

Bio-fortified and disease resistance banana from Queensland University of Technology (QUT)

IV.6. BIRAC and USAID supported wheat project

On account of increase in population, deteriorating soil quality, continuously and unsustainably sinking water table coupled with the proportion of the population below the poverty line, food security in the Indo-Gangetic plains has become a major challenge.

To address some of these challenges, Govt. of India and USAID had envisaged a project whose overall objective was to develop high-yielding, heat-tolerant wheat cultivars for the Indo-Gangetic Plains. The project is entitled "Development of heat tolerant, high yielding and climate resilient wheat cultivars by utilizing genomics, molecular and physiological information and resources". The project was started in March 2017 in which the heat-tolerant varieties are being developed by building upon the available resources and breeding materials by utilizing information from model systems and currently available modern breeding, genetic, genomic, physiological, and biochemical tools.

In the process, genes/QTLs controlling heat tolerance are being identified, mapped and tagged; improved insight into physiological, genetic, biochemical, and molecular bases of the trait obtained.

Heat tolerant, high yielding and climate resilient wheat cultivars

IV.7. BIRAC – IKP Grand Challenges in Agri-technology Translation for Boosting Farmers' Income

BIRAC in partnership with IKP Knowledge Park has conducted a Grand Challenge in "Agri-technology Translation to Boost Farmers' Income" with the mandate to identify 'ready to deploy' and 'scalable innovations' in agriculture that will help in increasing the incomes of farming households.

It was started in March, 2022, the impact of the program was that a series of innovative technologies, practices, products, services, business model and/or integrated solutions that have been piloted at a small scale in India were identified, funded, monitored for field testing over a period of time through a 2-stage process in this program. The focus of the Challenge is that it will demonstrate how the farmers income can be increased through deployment of the selected technologies. In Stage-1 Ten start-ups were funded successfully. Five of the shortlisted ones were taken in the next round of funding which were jointly funded by BIRAC & IKP for validation and product development. The five shortlisted start-ups and their technologies are –

1. **Temperate Technologies Private Limited, Hyderabad** - Farm-level low-cost cold storage units to decrease post-harvest losses and boost farmer incomes

2. **Inventohack Innovations Pvt Ltd, Bhopal** - Providing Soil-Testing & Consultation using our patented sensor probe along with VLE network and Agritech to Farmers as Service.

3. **Capsber Global Agro Private Limited, Bengaluru** - Sustainable pest management in horticultural crops using innovative female fruit fly trap to boost farmers income

4. **F3 Biotechnology Private Limited, Dehradun** - Fabrication of novel micro-emulsion technology to promote high quality animal feed and lower feed cost to increase profitability for farmers and adequate animal growth

5. **BomLife Private Limited, Kolkata** - Validating standardization benchmarks and application protocols of IP protected bio-fertilizer & complete range of designer bio-organic inputs for chemical free agriculture achieving optimal yield at different geo climatic locations and assessing economic viability of the technology

Agri-technology Translation to Boost Farmers' Income

IV.8. Program on Synthetic Biology

Synthetic Biology Program was launched in 2018 to foster collaborative R&D and commercialization, and to coordinate a national mission aimed at advancing a bio-based economy. Two calls for proposals have been announced which led to supporting a total of 11 projects. These projects focus on developing products such as rose oxide, sandalwood sesquiterpenes and biobutanol production. The projects have resulted in development of PoC. Patents have been filed for a some of the technologies. Strategies for further supporting the developed outcomes as well as the promotion of research in this area is under process.

V. Sustainable Development

The Innovate for Sustainable Development Division at BIRAC promotes research and innovation that address key environmental challenges and focuses on emerging areas such as green hydrogen and waste management solutions developed in collaboration with municipal bodies. Through targeted funding programs and partnerships, the division supports technologies that convert waste into value, enable clean energy solutions, and develop bio-based alternatives. These efforts help align biotechnology innovation with sustainable development priorities while contributing to India's growing bioeconomy.

V.1 Innovation Clean Technology – scale up

In the year 2019, Department of Biotechnology was working on 100 days Agenda which involved Scale up/implementation of promising technologies in collaboration with Municipal Corporations/Local Bodies. Few potential technologies supported by DBT/BIRAC were identified and the implementation of these technologies was done in association with Municipal Corporations/Urban local bodies (ULBs) identified by the companies. Few potential technologies, that had achieved TRL 7, supported by DBT/BIRAC were shortlisted for consideration. Out of these, a total of 4 technologies are being implemented in association with the Municipality/ULB of Goa, Bangalore and Greater Mumbai. Two projects are ongoing which are being implemented in association with Municipality of Bhavnagar and Municipality of Srinagar.

Technologies developed by Flycatcher Technologies LLP, Goa, GPS Renewables, Mumbai and Openwater.in Pvt. Ltd., Bengaluru are being successfully deployed in association with municipalities.

Biodigestor using food waste installed at a site in Panaji (Flycatcher technologies, Goa)

2-ton-per-day plant using organic fraction of municipal solid waste for conversion to biogas installed at Haji Ali, Mumbai (GPS Renewables, Mumbai)

Membraneless, chemical free, wastewater treatment system (Openwater.in, Bengaluru)

V.2 Pilot production for Green Hydrogen

The National Green Hydrogen Mission (NGHM) was launched by Ministry of New and Renewable Energy (MNRE) on 4th January, 2023 with an outlay of INR 19,744 Crore with an aim to make India a Global Hub for production, usage and export of Green Hydrogen (GH2) and its derivatives.

MNRE has identified BIRAC as an Implementing Agency for Implementation of biomass-based and other innovative technology-based pilot projects under National Green Hydrogen Mission. A focussed call on “Implementation of pilot projects for production of Green Hydrogen from biomass-based & other innovative technology-based interventions” was launched in December 2025. A Financial assistance up to INR 25 crore per project is available for expenditure related to equipment/retrofitting for production of Green Hydrogen and its derivatives

VI. Fighting the Pandemic

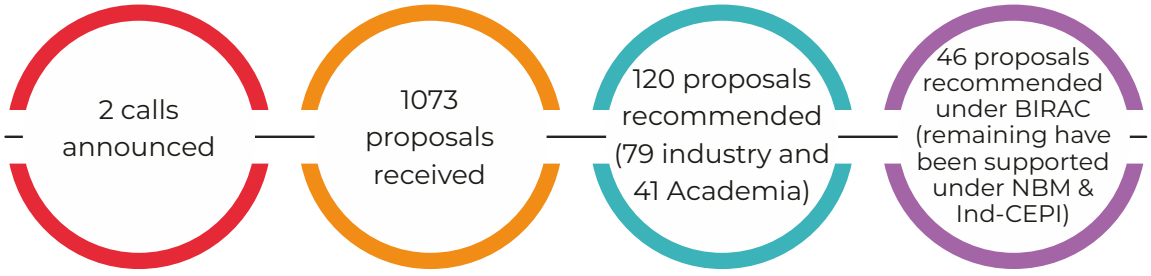
BIRAC played a pivotal role in mobilizing India's biotechnology ecosystem to rapidly respond to the COVID-19 pandemic by supporting the development of diagnostics, vaccines, therapeutics, and digital health solutions.

VI.1. Fast-tracked Review and Funding support under COVID-19 fund

The Fast-tracked Review and Funding support under COVID-19 fund initiative supported 21 start-ups in developing and scaling products with high social impact, addressing challenges arising from the COVID-19 pandemic. The support was extended through two key components: direct funding to start-ups, benefitting 7 start-ups, and co-funding partnerships with C-CAMP and IKP Knowledge Park, which jointly supported 14 start-ups under this provision

VI.2.COVID Research Consortium

To address the COVID-19 global health care crisis, DBT-BIRAC identified the Start-ups, Academic institutions and Companies that had potential solutions to address the challenges and worked with them to scale up their COVID-19 healthcare prevention and treatment solutions. For this, three calls for proposals were announced. Two calls to support Diagnostics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for control of COVID-19 and one call to support development of therapeutics. Out of 1073 proposals, a total of 120 proposals were recommended for funding out of which 46 proposals were recommended to be supported by BIRAC.



Proposals supported under Covid Research Consortium

VI.3. Mission COVID Suraksha

Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission, was announced as part of the third stimulus package, Atmanirbhar Bharat 3.0, for promoting research and development of Indian COVID-19 vaccines. Mission COVID Suraksha delivered four vaccines and augmented the manufacturing of Covaxin. The four vaccines are- "CORBEVAXTM", India's first protein subunit vaccine, developed by

Biological E. Limited, “ZyCoV-D” World's 1st and India's indigenously developed DNA Vaccine, developed by Zydus Lifesciences Pvt. Ltd., “GEMCOVAC™-19” World's 1st and India's indigenously developed mRNA vaccine developed by Gennova Biopharmaceuticals Ltd. and “iNCOVACC” World's 1st and India's indigenously developed intranasal COVID-19 Vaccine developed by Bharat Biotech.

Biological E Limited  	• COVID SURAKSHA provided funding to Biological E which enabled development of fully indigenous COVID19 vaccine based on adjuvanted protein-sub unit platform during the pandemic. • CORBEVAX selected for primary vaccination of children in the age group of 12-14 years and included in COWIN app pan India roll out began on 16th March ' 2022). CORBEVAX also added as heterologous "Precaution Dose" option in Cowin app. Pan India roll out started on 16th Aug' 2022 for adult population. CORBEVAX™ received WHO EUL on 15-January-2024.
Zydus Lifesciences Pvt. Ltd.  	• ZyCoV-D vaccine is the world’s first and India’s indigenously developed DNA based vaccine for COVID -19 for administration in humans including Children and adults 12 years and above. • ZyCoV-D is delivered by a needle free injector system known as PharmaJet®, which confers multiple advantages in terms of delivery of vaccine or in general for enhancing acceptance in children and adults who have fear of injections and thus enabling higher vaccination rates. • Vaccine received emergency use licensure in India as a 3-dose regimen on 20th August 2021 and as a two-dose regimen on 25th April 2022 for protection against COVID -19. Vaccine was also approved on 20th April 2023 as a heterologous booster dose against COVI D-19 in India.

Gennova Biopharmaceuticals Ltd. 	• Gennova has developed an mRNA-based vaccine against COVID-19, GEMCOVAC™-19, which overcomes the limitations associated with the currently approved mRNA vaccines.
Bharat Biotech 	• iNCOVACC is an intranasal COVID-19 vaccine candidate developed by Bharat Biotech • An adenovirus-vectored vaccine, administered through the nose rather than by injection

Further, a Call on "Integrated approach to address/support COVID-19 vaccine induced immunity, related processes and facilities" under Mission COVID Suraksha has been announced. A total of 56 proposals were received and 16 have been recommended for funding support.

VII. Program Management Units

BIRAC's dedicated Program Management Units have been established to ensure efficient implementation, monitoring, and coordination of large-scale biotechnology initiatives. PMUs provide technical oversight, facilitate stakeholder engagement, and streamline program delivery across academia, industry, and government partners. This structured approach enhances transparency, accountability, and the timely achievement of program outcome.

VII.1. National Biopharma Mission – Transforming India's Biopharma Landscape

India has long been celebrated as the Pharmacy of the World—a nation that ensured affordable medicines and vaccines reached millions across the globe. Yet, when the frontier shifted to biologics, monoclonal antibodies, and advanced cell therapies, our innovators faced structural barriers. The challenge was never talent or ideas—it was the absence of a connected ecosystem capable of translating discovery into delivery.

The National Biopharma Mission (NBM) was conceived to change that trajectory. Launched under the banner of "Innovate in India (i3)",. NBM focuses on industry–academia collaboration, empowering biotech entrepreneurs, build enabling ecosystem and accelerating inclusive innovation. With a sanctioned amount of ₹1500 Crore—equally supported by the Department of Biotechnology, Government of India and The World Bank—the Mission is implemented by BIRAC, which has become a trusted catalyst of transformative progress in India's biotech sector.

NBM is not just a program; it is part of a 10–15 year transformative initiative designed to build India's biopharma ecosystem from the ground up. In just over seven years, it has delivered strong outcomes—establishing shared facilities, de risking early stage development, and enabling startups and researchers to move beyond proof of concept to scalable, clinically validated products.

The Mission's impact is structural: it has shifted India's biopharma journey from fragmented efforts to an integrated, globally competitive ecosystem. The Bioeconomy Report reinforces this trajectory, projecting a rising biopharma share by 2030 and calling for expanded strategic focus and sustained investment.

NBM's legacy is clear:

- Shared infrastructure, shared risks, shared success.
- From generics to biosimilars to next generation biologics.
- Progression from participant to leadership in global health innovation.

NBM is ensuring that the future of healthcare is not just consumed in India—it is created in India, for the world.

Mission Objectives

This mission has been designed to give a boost to the 'Make in India' and 'Start-Up India' missions launched by the Government of India with the following objectives.

Specific Product
1
Support development of **vaccines, biotherapeutics, medical devices and diagnostics.**

Conducive Environment
2
Facilitate and nurture a conducive environment for **preparing India's technological and product development capabilities** in biopharmaceuticals.

Capacity Building
3
Establishing and strengthening shared infrastructure facilities **for product development and validation.**

Skill Development
4
Developing human capital by providing specific trainings to address the critical skills gap across the product development value chain.

Technology Transfer
5
Creating and enhancing technology transfer and intellectual property management capacities and capabilities.

Two-pronged approach was followed to enable accelerated Product Development with 9 Functional verticals

Components of National Biopharma Mission

1. Product Development	2. Ecosystem Strengthening
1.1 Vaccines 1.2 Biotherapeutics 1.3 Medical Device & Diagnostics 1.4 Antimicrobial Resistance	2.1 Shared Facilities 2.2 Scientific Research Consortia 2.3 Clinical Trial Networks 2.4 Skill Development 2.5 Technology Transfer Offices

NBM ACHIEVEMENT SNAPSHOT

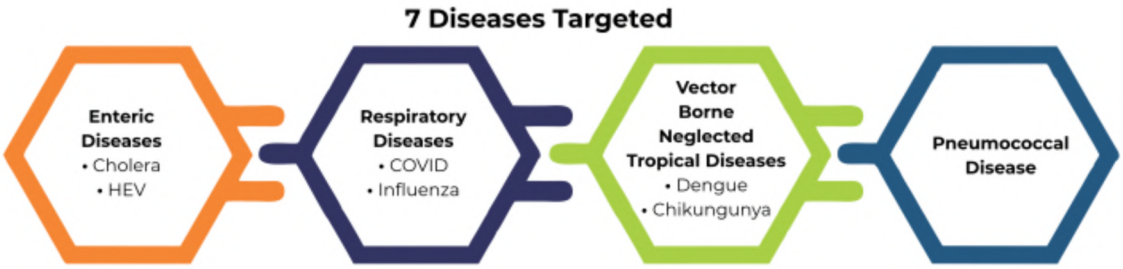
VII.1. 1. Product development Portfolio

Over the last 7 years, NBM has shown tremendous success with support for 238 grantees in 161 projects, of which 80 projects have been completed, and the rest of the projects are nearing completion. In the product development portfolio, projects supported can be

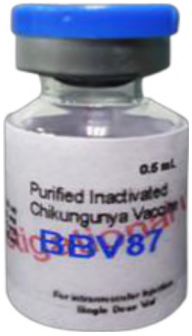
binned into 3 verticals, (i) Vaccines (ii) biotherapeutics, (iii) Medical devices and diagnostics.

VII.1.1.1 Vaccines development supported

In this vertical NBM supported 7 disease area as follows.



VACCINES – SUCCESS STORIES	
Zydus Lifesciences Limited, Ahmedabad 	**ZyCOV-D Covid Vaccine** • **World's 1st and India's indigenously developed plasmid DNA Vaccine** against SARS-CoV-2 • Two dose intradermal vaccine applied using the PharmaJet needle-free system, Tropis • **NBM Support:** Preclinical studies, Phase I and Phase II clinical trials. • **Current status: Marketed:** EUA received for age groups of 12 years and above.
Biological E Limited, Hyderabad 	**Corbevax™ COVID Vaccine** • **India's first indigenously developed protein subunit Covid-19 vaccine** • **India's first DCGI-approved heterologous** Covid-19 booster dose for adults • Two dose intramuscular vaccine • Launched in market at a price of Rs 800 (excluding GST) a dose for the private market, and at Rs 145 per dose. • Over 98.5 million doses sold in India • **NBM Support:** Preclinical studies and Phase I/II clinical trials. • **Current status: Marketed:** EUA received for age groups of 5 years and above

Bharat Biotech International Limited, Hyderabad 	**Chikungunya (CHIK) virus vaccine, BBV87** • 1. Vero cell-derived • Purified inactivated CHIKV antigen • Inactivated with beta-propiolactone (BPL) • Formulated with aluminium hydroxide • **NBM Support:** Phase II clinical trial of BBV87 in India. • **Current Status:** Phase II clinical trials completed in India, Latin America, and Thailand (12-65 years age group). SEC approval received for conducting the Phase III trial in India.
Zydus Lifesciences, Ahmadabad **with other consortium members** • **Jawaharlal Institute of Postgraduate Medical Education & Research** • **Sanjay Gandhi Postgraduate Institute of Medical Science** • **Shiv Nadar University** • **Indian Institute of Chemical Biology**	**Hepatitis E vaccines Phase II development supported by NBM** A recombinant subunit vaccine for hepatitis E, developed indigenously in India by Zydus Lifesciences with consortium • The vaccine was found to be stable up to 36 months at 2-8oC. • A randomized, placebo-controlled Phase II clinical trial demonstrated that it was safe and highly immunogenic. The vaccine was also found to induce antigen-specific CD4 and CD8 T cell proliferative responses, similar to those following natural infection, with induction of cytokine-producing cells
Indian Immunological Pvt. Ltd., Hyderabad 	**Dengue vaccine - Freeze-dried Live-attenuated Tetravalent vaccines by Indian Immunological Pvt. Ltd.** • Based on four live attenuated Dengue vaccine strains (Dengue serotype 1,2,3 and 4) received from NIH, USA • Potential to provide comprehensive protection against all four dengue serotypes • Single-dose regimen for effective immunization • **NBM Support:** Preclinical toxicity studies and Phase I clinical trials • **Current Status:** Phase I clinical trials have been completed and approved by the SEC-CDSCO. Material for Phase II trials has been manufactured approval from the Indian regulatory authorities is expected.
In addition, NBM has also supported the development of novel vaccines for Influenza and Malaria with high unmet need in India.	

VII.1.1.2. Biotherapeutics Development supported

NBM has supported a range of biosimilars and biotherapeutics. Supported affordable biosimilars for Diabetes, Rheumatology, Age related Macular Degeneration (AMD), as well as COVID-19 and Cancer treatments. NBM is supporting new age therapeutics such as CAR-T therapy for cancer.

In addition, development of Biosimilar clones, Novel Biotherapeutic platform and innovative manufacturing platforms, etc were also supported.

BIOTHERAPEUTICS – SUCCESS STORIES	
Levim Biotech Pvt. Ltd., Chennai 	India's 1st Liraglutide Biosimilar • Levim Biotech LLP has developed the biosimilar of Liraglutide injection after completing Phase-1 PK and Phase-3 efficacy & safety studies supported by NBM • Successful grant of US and European patent for process innovation • NBM Funding translated into a highly cost-effective product in the market - at a price of INR 1855 per PEN, Rs 100 for a standard daily dose of 1.2 mg compared to INR 5374 per PEN of Innovator Victoza, A cost savings of 65% over the originator
Zydus Lifesciences Ltd, Ahmedabad 	PEGYLATED INTERFERON ALPHA-2B Pegylated interferon 'Virafin' received EUA for treating the patients showing moderate COVID-19 funded by NBM
Lupin limited, Mumbai LUPIN	*Developing India's 1st Biosimilar of Aflibercept (Eyelea)* • Global market of Aflibercept: ~ 10 b USD (IMS Q4 2022) and Ranibizumab & Bevacizumab are the other competing products in market. However, Aflibercept has fared better than Ranibizumab in the market: 8 b USD VS 3 b USD • With NBM funding Lupin plans to launch it at a discount of about 40%. Reduction in price is likely to improve the accessibility and affordability of Aflibercept in India.

Tata Memorial Centre in collaboration with IIT- Mumbai / ImmunoACT, Mumbai	NBM has supported First-In-Human Clinical Trial using an indigenously developed CD-19 targeted CAR T cells NexCAR19 for relapsed/ refractory B-cell Acute Lymphoblastic Leukaemia (ALL) for paediatric patients. This project is led by Tata Memorial Centre in collaboration with IIT- Mumbai., This will greatly improve affordability and accessibility for relapsed/refractory B-ALL Paediatric with ~90% cheaper than in western countries.

VII.1.1. 3. Medical Devices and diagnostics supported

29 projects supported; 9 diagnostic kits launched; Indigenous MRI and Endoscopes launched, 4 products each for wound healing and Trauma and emergency supported, Video laryngoscope got ISO certification and clinical validation completed and ECG completed preclinical testing; Titanium heart valve clinical validation completed.

Medical Devices and Diagnostics – SUCCESS STORIES	
Voxelgrids Innovations Pvt. Ltd., Bengaluru 	India's first affordable MRI scanner in stationary and mobile configurations. Enhanced imaging capabilities - 1.5 Tesla superconducting magnet as well as well as a gradient amplifier, both built in India. Priced 40% lower cost in comparison to other MRI scanners. The 1st machine has initiated patient screening in a hospital setting.
Irillic Private Limited, Bangalore in Collaboration with CMR university, Bangalore 	**Fusion Imaging Endoscopy** for Minimally Invasive Laparoscopic surgeries by Irillic Private Limited, Bangalore in Collaboration with CMR university, Bangalore

MTM and NAF Kits- Huwel Lifesciences Pvt. Ltd.

RT-PCR Kit Huwel Lifesciences Pvt. Ltd.

RT-PCR Kit yaathum Biotech Pvt. Ltd.

Antigen Detection LFA- Ubio Systems Pvt. Ltd.

IgG/IgM Detection LFA- Ubio Systems Pvt. Ltd.

Patho Detect RT-PCR Kit MyLab Doscovery Pvt. Ltd.

Some of the marketed Diagnostic Kits supported by NBM, BiRAC

There are few more in pipeline getting ready for launch soon, as given below:

Candidate	Current Status
WCK 4282 by Wockhardt Limited, Aurangabad A novel antibiotic combination WCK 4282 (Cefepime-Tazobactam) for complicated UTI	Phase-2/3 trial completed. Launch expected in 2026
VLarynx -Video Laryngoscope by VPHORE Labs Private Limited, Bengaluru	Clinical trial in ~50 patients across 4 sites have completed, and submitting the report to CDSCO.
Protein A Resin for biologics purification	Industry validation ongoing
Real time High frequency ECGs by Carditek Medical Devices Pvt. Ltd., Bengaluru	Pilot Trials completed with prototype. Looking for marketing partner.
Smart eye endoscopic technology by Healthcare Technology Innovation Center (HTIC) IIT-Madras.	Submitting proposal to CDSCO to obtain approval on device manufacturing.

In addition to the above, some ancillary products were also supported to augment the product development in the above verticals. Some of the key products include:

OmniBRx Biotechnologies, Ahmadabad 	**1st single use 'CellBRx Bioreactor' System** for production of Vaccines, Biologics and Stem cell - Reduces overall cost by 90% & reduce time
	**India's 1st affordable Indigenous CHO GS serum-free**, chemically defined media (SFM007AP) developed and launched for biologics production. Currently there is no Indigenous culture media for CHO cells, commercial production costs 2000 -3000 INR/ Liter. A single 1 kL batch needs 30 Lacs INR med.
Lab Iconics Technologies LLP, Hyderabad 	Laboratory Information Management System (LIMS) with advanced features - Indigenous cloud-based laboratory informatics platform including Laboratory Information Management System, ELN (Electronic Lab Notebook), DMS (Document Management System), and QMS (Quality Management System). Onboarded 27 startups and SMEs with more than 1,500 active users, along with one academic institution comprising 200 users. Its growing adoption has contributed to revenue generation of ₹6.25 crores.

A total of 34 patents have been filed by NBM grantees from the projects funded and 56 articles have been published in peer reviewed indexed journals.

VII.1.1.4 Antimicrobial Resistance poses a global public health threat, with urgent need for new drugs to prevent and treat infections. In India, investments in AMR till 2023, had very little investments in the new drug development area. Realizing this gap, the National Biopharma Mission launched the call on AMR and supported 05 projects with ~30 Crores committed investment for the development of diagnostics, therapeutics, and possible sustainable solutions for AMR.

VII.1.2. Ecosystem Strengthening: Building India's Biopharma Foundations

At the heart of the National Biopharma Mission lies a long-term vision: to transform India's fragmented capabilities into a connected, world class ecosystem. The focus of this vertical was to—create multiple Centers of Excellence across the country to catalyze cutting edge research, innovation, and translation.

NBM invested in shared infrastructure that acts as national assets rather than isolated facilities. These include:

- Testing, prototyping and manufacturing facilities that meet global regulatory standards.
- Translational Research consortia linking academia, startups, and industry.
- Clinical trial networks to accelerate validation and patient access.
- Technology transfer offices to bridge discovery with commercialization.
- Skill development programs to train the next generation of scientists and innovators.

This ecosystem approach has unlocked collaboration, reduced duplication, and lowered barriers for innovators—especially women scientists and startups—who can now access advanced infrastructure without prohibitive capital costs.

By strengthening the foundations of India's biopharma sector, NBM has ensured that discoveries are not trapped in silos but can realistically progress from bench to bedside, from idea to impact.

"Shared facilities, shared risks, shared success—NBM has built the launchpads for India's leap from generics to global innovation."

VII.1.2.1. Shared facilities

A total of 25 projects were supported under this vertical by NBM, ranging from research innovation to pilot scale manufacturing covering all the vertical of Vaccines, Biotherapeutics and Medical devices and diagnosis.

Technical services facilitated: More than 500 users have availed services from these shared facilities supported under the Mission. These include 4 MedTech Prototyping facilities, 1 large animal facility for medical devices testing, 2 EMI/EMC facilities and 2 manufacturing facilities for Med tech domain and, 03 Biologics Analytical characterization facilities, 05 Biologics pilot to commercial scale manufacturing facilities, 01 facility for media, 02 immunogenicity testing for supporting the development of biologics. All of these facilities received quality accreditations under the Mission's support.

Shared Facilities IMPACT

- Differential service cost for academia, start-ups, SMEs
- Decrease in out licensing of tests and faster turn-around times

- First cGMP facility of CAR-T in hospital setting
- 4 more ISO 13485 certified medical device facilities in various regions of the country
- 05 GLP and GCLP facilities
- 150 personals employed
- Employment generation in rural, semi-urban areas, like Dharwad, Aurangabad, Mangalore


CAPS Syngene, Bangalore GLP

CBA, Venture Centre, Pune


CSIR IICT, Hyderabad


MJ Biopharma fill finish facility


cGMP CAR-T Manufacturing Centre and Tata Medical Centre, Kolkata


cGMP Manufacturing Shilpa Biologicals Pvt Ltd, Karnataka

Analytical testing and manufacturing facilities: Biotherapeutics

Immunogensity testing facility for vaccine trials- SUCCESS STORIES	
1. Viral Clinical Immunogenicity Lab, NIBEC, IRSHA, PUNE NIBEC National Immunogenicity & Biologics Evaluation Centre QUEST FOR QUALITY   	National Immunogenicity and Biologics Evaluation Center (NIBEC) was established jointly by Interactive Research School for Health Affairs IRSHA, Bharati Vidyapeeth University, Pune and the Department of Biotechnology, Government of India under BIRAC-National Biopharma Mission-Innovate in India (i3) program. **<u>Services Provided</u>** • 14 types of immunogenicity tests available • Dengue NS1/IgG ELISA • Dengue, Chikungunya, COVID • DENV/CHIKV/SARS -CoV-2-specific plaque reduction neutralization test (PRNT) studies • SARS-CoV-2 Microneutralization test

2. Central Research Laboratory (CRL) at Kempegowda Institute of Medical Sciences (KIMS), Bangalore Central Research Laboratory KIMS BENGALURU 	GCLP facility for clinical immunogenicity assessment for Pneumococcal and other bacterial vaccines **Services provided:** • Bacterial ID/AST & Serotyping • Determination of HL60 cell phenotype by FACS • ELISA and MOPA assay • Genetic characterization of Pneumococcal strains *S. pneumoniae* seed culture

Medical devices Prototyping facilities

C-CAMP, Bangalore C-CAMP MedTech Facility	**Rapid prototyping facility for microfluidic medical devices, ISO 13485 accredited Serviced more than 20 clients.**
Marathwada medtech Lab, Netra accelerator foundation, Aurangabad Marathwada MedTech Lab an MIT Initiative in collaboration with Netra Accelerator Foundation	**Facility for Rapid prototyping and testing of medical devices in a tiar 2 city. ISO 13485 accredited**
Yenepoya University, Mangalore Yenepoya Technology Incubator	**State-of-the-art infrastructure for prototyping and establishing proof of concept. ISO 13485 accredited. Serviced >20 users.**
IIT, Kanpur MedTech IIT KANPUR	**Facility for design and fabrication of medical devices and equipments, ISO 13485 accredited. Serviced 18 clients.**

Medical devices and Diagnostics Manufacturing facilities	
DBT-AMTZ National Command consortium, Vishakhapatnam  Diagnostic Kit Manufacturing Facility	Products during COVID-19 pandemic • Common Manufacturing Facility • 15,000 Ventilators • 130 million RT-PCR tests • 13 million viral transport medium • 30 K IR thermometers • Monile Diagnostic Laboratory-iLab
Huwel Lifesciences, Hyderabad 	Products during COVID19 pandemic – 298 lakhs Covid RT PCR kits, 21 lakh Molecular Transport Medium (MTM), 24 lakh Nucleic extraction kits, Fluorescents Probes for MDx kits

Large Animal Testing Facility	
Palamur Biosciences, Mehbubnagar 	**Medical Research Institute for device Assessment (MRIDA) is a Large animal testing facility for screening medical implants, devices and drug device combinations in large animals such as beagle dogs, swine and sheep.**

VII.1.2.2. Translational Research Consortia (TRC)

The Mission supported establishment of Translational Research Consortia to support and nurture the translational research ecosystem to stimulate, standardize, and provide support for advancing the development and evaluation of vaccines and monoclonal antibodies. Based on selected R&D areas, collaborative networks/ consortia were established for Dengue, Chikungunya, Hepatitis E virus and Malaria, with following outcomes:

- Candidate vaccine against Hepatitis E Virus has completed Phase-II trial – in academia -industry collaboration. The results were presented to the Indian regulatory authority and a Phase III licensure trial has been proposed. There is only one innovator vaccine available from China and this newly developed indigenous vaccine, once approved by regulatory bodies, will be a useful tool to prevent an important disease, for which no treatment is available.
- Chikungunya Translational Research Ecosystem: Capacity & Impact

A robust research ecosystem for Chikungunya has been built under TRC clinical cohorts, anchored by a serum biobank and multi-institutional collaborations. Manipal Academy of Higher Education (MAHE) led immune profiling and developed a cytokine-based multiplex immunoassay. International Centre for Genetic Engineering and Biotechnology (ICGEB) established a virus repository, while Institute of Life Sciences (ILS), Bhubaneswar created animal models. Clinical insights were driven by Topiwala National Medical College and Bai Yumnabai Laxman (TNMC & BYL) Nair Hospital (Mumbai), Post Graduate Institute of Medical Education & Research, (PGIMER) Chandigarh, and All India Institute Of Medical Sciences (AIIMS), Bhubaneswar, enabling cross-institutional translational outcomes.

Capacity Established:

Assays: Micro-neutralization and cell-free neutralization assays for CHIKV infection

Animal Models:

Acute and chronic models using reference strains (S27/DRDE-06) in adult C57BL/6 mice

- **Serum Biobank:**
  - 3,000 aliquots deposited
  - 185 paired acute/convalescent samples with isolated viruses
  - Ongoing recruitment from sentinel sites
- **Virus Repository:**
  - 24 CHIKV isolates sequenced and characterized
  - Viral subtype data correlated with immune status
  - Emerging as a critical epidemiological resource

Capacity Utilization:

- 13 collaborations for animal model services (7 academic)
- 2 peer-reviewed publications

Dengue Translational Research Ecosystem: Capacity & Impact

A multi-institutional dengue research ecosystem has been established, integrating clinical, immunological, and structural biology expertise. AIIMS Delhi, CMC Vellore, and MAHE served as clinical sites; International Centre for Genetic Engineering and Biotechnology (ICGEB) led B-cell isolation, mAb generation, and immunoassays; Translational Health Science and Technology Institute (THSTI) developed animal models and maintained the viral repository; National Institute of Immunology (NII) conducted follicular T-helper cell studies; IIT Delhi performed antigen-antibody structural characterization; and Clinical Development Services Agency (CDSA) managed the consortium.

Capacity Established:

- **Viral Repository**: 74 Indian dengue isolates sequenced and deposited to NCBI
- **Immunology Platforms:**
  - T follicular helper cell assay for durable immune response
  - HTS flow cytometry-based neutralization assays for vaccine evaluation
  - Dengue-specific T cell response assays
- **Serum Biobank:** 100 dengue-exposed patient samples archived

Animal Models:

- **AG129** (Type I/II IFN receptor-deficient) mouse model validated for antivirals, vaccines, and biotherapeutics
- **Human mAbs:** Indigenous monoclonal antibodies generated for therapeutic development

Capacity Utilization:

- 3 collaborative projects initiated; 2 MoUs signed for antiviral and mRNA vaccine efficacy studies
- Animal models offered on fee-for-service basis
- Industry MoUs with Indian Immunologicals, Panacea, Zydus, and Serum Institute
- 3 consortium publications
- The Malaria TRC, is developing a recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against Plasmodium falciparum which is useful in Preventing Plasmodium falciparum infection in humans and minimizing its community transmission as well. ICMR-Regional Medical Research Centre, Bhubaneshwar prepared and purified the recombinant antigens. National Institute of Immunology (NII), New Delhi has developed a dual transgenic parasite antigen expressing P. falciparum and demonstrated the efficacy. A successful proof-of-concept study demonstrated activity in in-vitro and in-vivo models. Candidate for Malaria nearing completion of preclinical studies.

VII.1.2.3. Clinical Trial Networks

The Mission has set up DBT's Resource for Indian Vaccine Epidemiology Network (DRIVEN) with 10 GCP-compliant Field Sites with more than 8,00,000 healthy population cohorts for vaccine clinical trials. The sites have completed serosurveys for COVID, Dengue, and Chikungunya at 05 DHS sites with ~ 1,00,000 population. The Acute Febrile Illness study at these sites for Dengue and Chikungunya has also been completed and sero-negative cohorts have been identified. The DRIVEN Network has also played a critical role in capacity building and community engagement. Community engagement, which was earlier informal and inadequately documented, was significantly strengthened through NBM support. The establishment of formal Community Advisory Boards enabled structured community participation in trial processes, thereby improving accessibility, recruitment, and participant retention. The network further supported the establishment of IT-enabled, paperless data management systems at Disease Surveillance sites, improving data quality and operational efficiency.

Impact

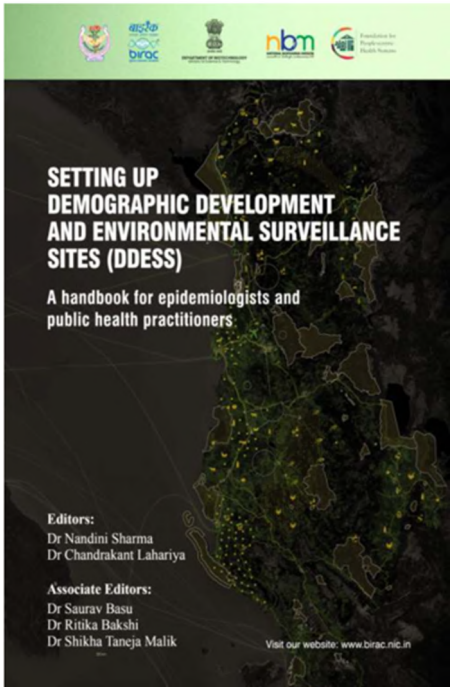
- 10 GCP-compliant and harmonised sites and study sites represent diverse geographic and socio-demographic settings, including urban, peri-urban, rural, and tribal-predominant regions, ensuring nationally representative data.
- Digital data capture was enabled using Android-based electronic questionnaires through SOMAARTH-1 and SOMAARTH-3, ensuring real-time, standardized, and high-quality data collection.
- GIS-enabled surveillance sites were established to support clinical trials and epidemiological research, enhancing spatial analysis and disease tracking.
- Over 500+ individuals were trained across sites, strengthening local research and operational capacity.
- Registry data made accessible to industry partners for clinical trial planning and feasibility assessments.
- Capacity building through skilled workforce development:

  63+ training programmes conducted

  2,590 personnel trained in GxPs, bioethics, and SOMAARTH platform usage
- 14 Publications & 22 Industry-Sponsored Clinical Trials completed/Ongoing across network

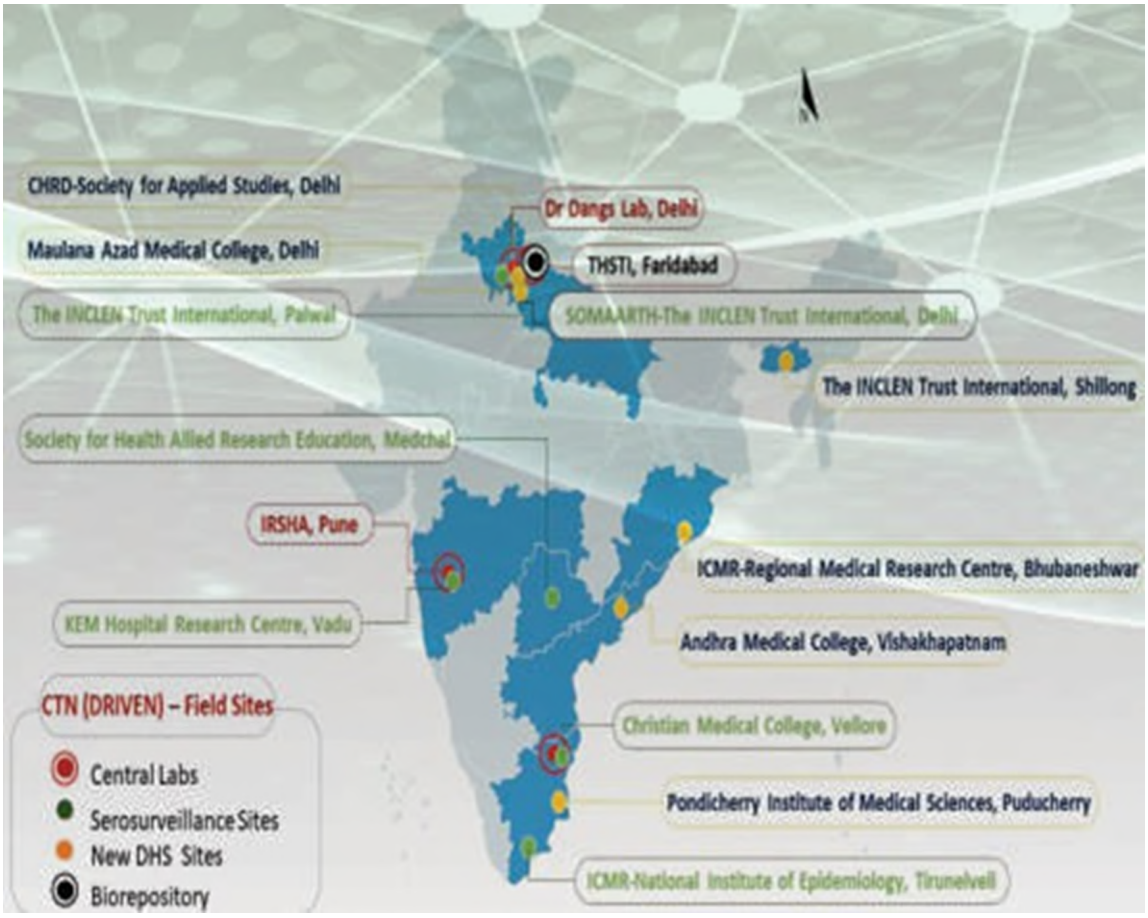
With the NBM support a Monograph on “Setting up Demographic Development and Environmental Surveillance Sites (DDESS)” was bulised as template for setting -up DDESS sites.

- It covers the entire spectrum of DDESS, from their design and establishment to the generation of actionable findings.
- Demographic, Health and Environmental features are geo-mapped at these sites.
- It shares the methodologies and various challenges faced during site development, including GIS mapping, ethical considerations, data collection methodologies, and ensuring the engagement and participation of local communities.



National Biopharma Mission's unique initiative, Network of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology, aims to strengthen the capacity to conduct clinical trials in India for products developed in these areas. It comprises of 5 networks of 36 organizations, comprising public and private hospitals, clinics, reputed academic institutions, spread across 18 states of India. These hospitals have established disease registries with data collected based on uniform protocol approved by Ethics Committee and on one common online platform for each network. More than 250 clinical trials are being supported in these sites.

- 53,700patients' data – Lung, Breast, Ovary, Gastric, Colon, Neuroendocrine Cancers
- 25,000 patient data of Type 1 diabetes and Type 2 diabetes.
- 11,800 patient data - 04 Ophthalmological indications
- 14,300 patient data - 09 Rheumatological indications



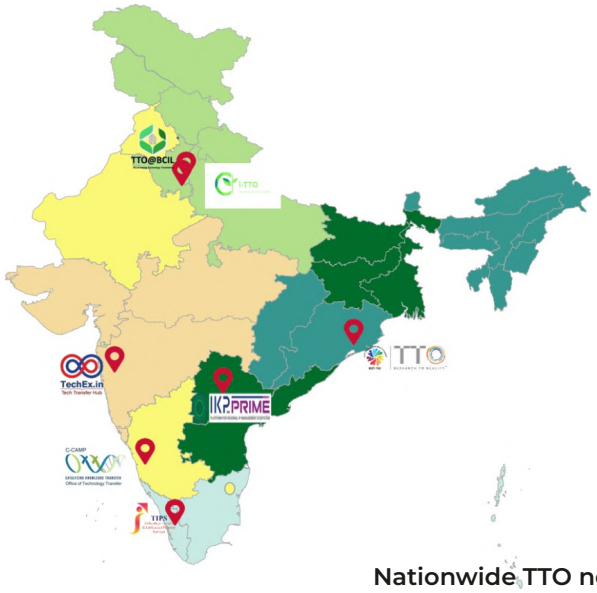
DRIVEN Network

Rheumatology
Ophthalmology
Oncology (TMC)
Diabetology
Oncology (JIPMER)

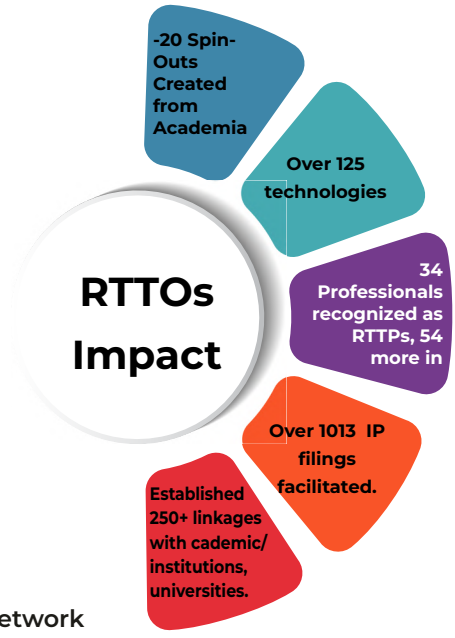
Clinical Trial Network of Hospitals

VII.1.2.4. The Technology Transfer Officers (TTOs)

The Technology Transfer Officers (TTOs) strategically located across 07 regions of the country established under the Mission, cover 1310 academic research institutions, incubators to facilitate technology assessment, transfer, patent filing, licensing and training. The Impact of these TTOs is given below.



Nationwide TTO network

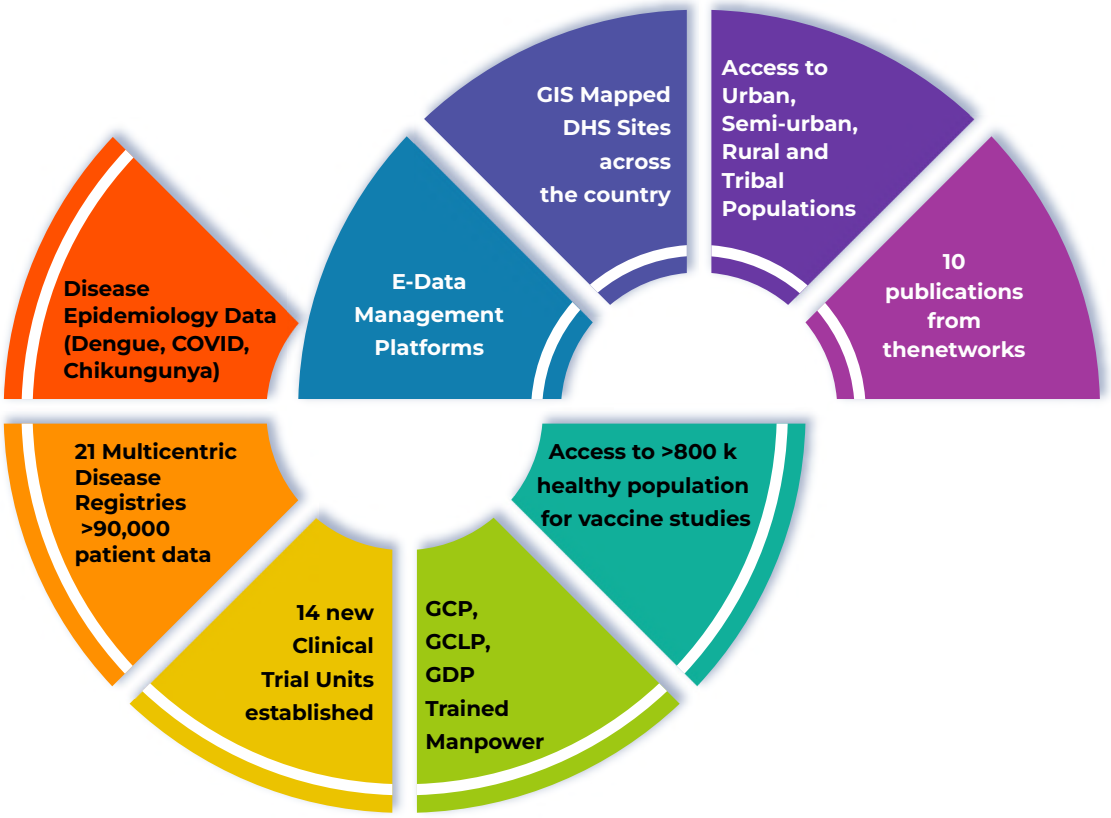


Structured Technology Licensing Showcase event with the Regional Tech Transfer Offices (RTTOs) : A New Era for India's Biopharma Innovation

One of its kind in India, the National Biopharma Mission (NBM) coordinated two landmark Technology Licensing Showcase events in partnership with the Regional Tech Transfer Offices (RTTOs) established under the Mission. Hosted at T-Hub Hyderabad and the Odisha State Convention Centre, these events created a unified national platform for IP-led commercialization—a first for India's biopharma sector.

The scale was unprecedented:

- **400+ participants** including innovators, investors, startups, MSMEs, and academia.
- **143 licensable technologies** pitched across both events.
- **Two health-tech licensing agreements** successfully concluded.
- Launch of comprehensive technology compendiums to guide future collaborations.



These showcases signalled a new era of structured tech transfer in India—strengthening IP culture, accelerating lab-to-market translation, and advancing collaborative, innovation-driven growth aligned with the BioE3 vision.

By convening diverse stakeholders under one roof, NBM demonstrated how coordinated platforms can unlock commercialization pathways, reduce fragmentation, and catalyse India's journey from discovery to delivery.

"From ideas to impact, from IP to industry—NBM is building India's innovation marketplace for the world."

NBM-RTTO's 1st National Technology Showcase Event at Hyderabad in Feb 2025.

Launch of Technology Showcase compendia at the NBM-RTTO's 2nd National Technology Showcase Event at Bhubaneswar, in November 2025.

Tech Transfer agreement at the NBM-RTTO's 2nd National Technology Showcase Event at Bhubaneswar.

VII.1.2.5. Skill Development Under NBM

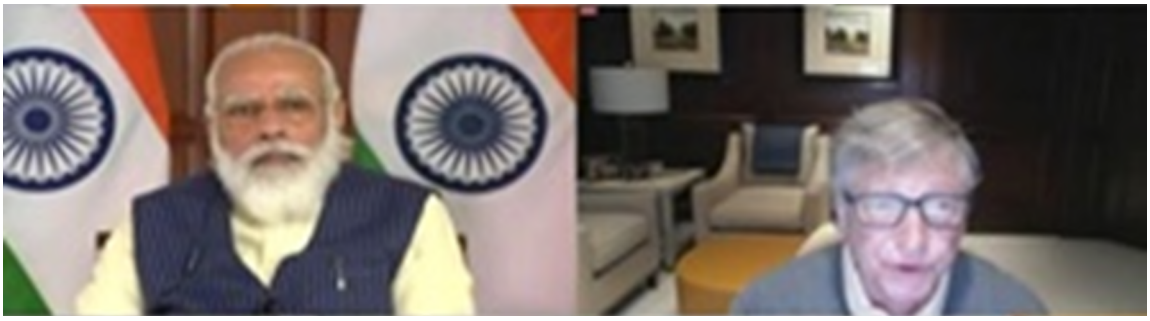
Over 7,500 S&T professionals have been trained through NBM's targeted skill development initiatives, covering biotherapeutics analytics, GCP, bioethics, medical device quality, environmental compliance, tech transfer, and regulatory frameworks. Recently, two expert-led, week-long hands-on training programs were launched on ISO 13485 and GCP-compliant clinical trial conduct. These are currently underway across four national hubs, engaging 100 researchers from academia and start-ups.

To commemorate the impact of the 6 years of National Biopharma Mission and to celebrate the achievements, a 1-day BioPharma Conclave was organised on 8th August 2024. On this occasion NATIONAL BIOPHARMA MISSION IMPACT BOOK was launched by Dr. Jitendra Singh the honourable Union Minister of State (Independent Charge) for Science & Technology and Earth Sciences, Minister of State in the Prime Minister's Office, Personnel, Public Grievances, Pensions, Atomic Energy, and Space.

Biopharma Conclave Organised by National Biopharma Mission

VII.2. Grand Challenges India (GCI) – PMU-BMGF

Grand Challenges India (GCI) was launched in 2012 from the understanding that partnerships are crucial for ensuring sustainability and progress. The collaboration between the Department of Biotechnology (DBT), Government of India, and the Bill & Melinda Gates Foundation was established to drive Indian innovation and research, with the goal of creating affordable, sustainable solutions to enhance health and well-being in India and beyond. The partnership is operated through the Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC) which jointly administers the program with DBT and the Foundation.



Grand challenges Annual Meeting 2020

GCI remains committed to nurturing both seasoned researchers and emerging entrepreneurs across academia and industry. GCI's mission is to expand the pipeline of groundbreaking ideas that fuel the development of new therapies, pilot cutting-edge technologies, and explore fresh approaches to address urgent public health challenges. Since inception, GCI has evolved alongside India's changing public health landscape. As we transitioned towards the Sustainable Development Goals (SDGs), the scope widened to address shifting research priorities. By 2025, GCI had supported over 247 projects, ranging from small pilot studies and intervention trials to large-scale validation studies and clinical trials. GCI's diverse portfolio spans areas including maternal and child health, nutrition-sensitive agriculture, sanitation, and infectious diseases.

1. One of GCI's proudest accomplishments was the indigenous development & successful inclusion of the HPV vaccine, funded and supported by GCI, into the National Immunization Program in 2023. Building on this success, GCI delivered an affordable HPV screening diagnostics in 2025 for improving women's health.

2. The MOMI (Multi-Omics for Mothers and Infants) program connects India's Garbh-Ini cohort with global partners to study how genetics, nutrition, and environment affect pregnancy and newborn outcomes. The program successes so far include identifying early biomarkers for conditions like preterm birth and gestational diabetes. The broader goal is developing predictive tools and context-specific strategies to improve maternal and child health.

3. Biorepository creation of repertoire of biospecimens (~10,50,000 biospecimens and ~5,50,000 USG images) at BRIC THSTI, led to several hypothesis driven sub-studies. The mission of the biorepository was to establish a high-quality reliable resource of a wide-range of biospecimen for regulated use in new technology/ product development in academia and industry to facilitate translational research in both clinical and basic sciences globally.

4. Women and Infants Integrated Growth Study (WINGS): WINGS Trial on 13500 women to have led to substantial reduction in the rate of low birth weight, small for age gestational babies and stunting at birth and at 24 months of age. Currently, Pilot Scale up Programme of WINGS interventions implemented in Five Blocks of District Una (Amb, Dhundla/Thanakalan, Gagret, Haroli & Una/Basdhera) of Himachal Pradesh.

5. Immediate Kangaroo Mother Care program: scaling up early skin-to-skin care for small and sick newborns, starting from hospitals and extending to community follow-up. Already launched at key Indian sites, it aims to improve survival rates and set a model for integrating Kangaroo Mother Care into national health systems.

6. Non-Hormonal Contraceptive Discovery program: Creating India's first large-scale genetic database on unexplained female infertility, screened over 1,018 women across 37 sites. By identifying new genetic targets, it seeks to develop safe, non-hormonal contraceptives, expanding choices for women worldwide.

7. Knowledge Integration & Translational Platform-KnIT Platform – Evidence generation on maternal health, nutrition and anemia prevalence at state-level. Engagement with state government for to inform research results. The research Findings are: 1. the analysis on Gestational Weight Gain (GWG) showed that improved GWG in line with the Institute of Medicine Standards has positive impact on growth status at birth and reduces prematurity 2. The analysis on Gestational Weight Gain (GWG) showed that improved GWG in line with the Institute of Medicine Standards has positive impact on growth status at birth and reduces prematurity.

8. Antimicrobial Resistance (AMR): Recognizing AMR as a critical national health threat, GCI is strengthening India's response through exploratory projects and a microbial genomics hub at CRL-KIMS, Bengaluru. Building on Phase I achievements, Phase II of program is expanding into a nationwide AMR surveillance ecosystem, while genomic mapping of Streptococcus pneumoniae and Group B Streptococcus is generating evidence to guide vaccine strategies and neonatal infection control.

9. Tuberculosis (TB) Control: GCI is advancing India's TB elimination goals by supporting low-cost, rapid diagnostics and simplified sample processing for community settings—innovations projected to reduce incidence and mortality. GCI also leading first-of-its-kind research program on the Cachexia in Tuberculosis to uncover disease mechanisms, develop novel interventions and patient-focused solutions and mapping the cachexia burden to strengthen patient care.

10. Artificial Intelligence (AI) in Health: Launched "Catalyzing Equitable AI Use to Improve Global Health" program to advance evidence-based, inclusive AI applications in diagnostics, population health, workflows, and communication, enabling LMICs and positioning India as a leader in equitable AI for healthcare.

11. Neglected Tropical Diseases – Lymphatic Filariasis (LF): Diagnostics for Lymphatic Filariasis (LF) to accelerate India's LF elimination by supporting development of affordable, field-ready diagnostics aligned with WHO targets and integrated into the National LF Elimination Programme.

12. Med Tech: Our efforts span the full spectrum of development, from pre-ideation and proof-of-concept under the Grand Challenges Exploration (GCE) – India program, to validation and large-scale implementation. In recent years, we launched several new initiatives, including the MedTech Challenge in 2019—a pioneering program in collaboration with DBT, the Bill & Melinda Gates Foundation, and the Wellcome Trust, aimed at equipping entrepreneurs with business acumen and facilitating market entry for their innovative products (JC Ortho Heal, Cureous Labs, Aindra systems, InnAccel Technologies).

13. In response to the COVID-19 pandemic, GCI introduced initiatives to support India's pandemic management efforts in 2020. Three Mobile diagnostic labs to support COVID testing and deployed in Kerala, Tamil Nadu, Assam.

14. Climate change on Health and Agriculture: In line with India's commitment to climate action, reaffirmed at COP28, GCI's program on the impact of climate change on Health and Agriculture is advancing locally-driven, sustainable and climate-resilient solutions addressing critical challenges such as early warning systems for climate-driven disease outbreaks, heat stress, air pollution to resilient healthcare systems and climate-smart agriculture. This initiative aimed at both adapting and mitigating the impacts of climate change.

Agriculture and Nutrition - Projects led to **'Doubling Farmer's Income'** and improved diet diversity in vulnerable population

15. capacity-building: GCI's capacity-building efforts extend through initiatives like Women in STEM and the PhD Immersion Program, designed to empower and cultivate the next generation of bioscience leaders.

Women Leader's in Global Health Meeting, December 2022, Delhi

VII.3. Ind-CEPI

About Ind-CEPI Program

The Ind-CEPI Program (India Coalition for Epidemic Preparedness Innovations) is a landmark initiative supported by the Department of Biotechnology (DBT) and implemented through a dedicated Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC), and the infrastructure coordinating unit at Translational Health Science and Technology Institute (THSTI, Faridabad). Ind-CEPI aims to enhance India's epidemic preparedness through rapid vaccine development and associated competencies/technologies for diseases of epidemic potential, as well as build coordinated preparedness in the Indian public health system and vaccine industry. In addition to vaccine development, the program focuses on supporting overall epidemic preparedness through capacity building, infrastructure strengthening and interministerial coordination for developing frameworks surveillance and logistics for use of new vaccines.

The **program functions in engagement with global CEPI, Coalition for Epidemic Preparedness Innovations** (a pioneering collaborative organization working towards global epidemic preparedness), aligning with its objectives. CEPI manages a portfolio of vaccines at various stages of development. CEPI provides technical expertise in vaccine research and development to Ind-CEPI under certain defined scope of an Engagement Strategy. A tripartite Engagement Strategy document was thus signed between CEPI, DBT and BIRAC in 2019, delineating shared objectives and joint technical activities which can be undertaken in the Ind-CEPI program.

Major accomplishments and actions undertaken in Ind-CEPI:

Vaccine Development: Program Ind-CEPI has taken decisive steps towards development of key vaccine candidates and supporting the same through clinical trials. In the endeavor to provide effective vaccines, the program has supported the development of two vaccines:

- COVID 19 mRNA vaccine (GEMCOVAC 19) is India's first mRNA vaccine and also world's first thermostable mRNA vaccine. The fund through Ind-CEPI supported pre-clinical toxicity and Phase-1 clinical trials of the vaccine by Gennova Biopharmaceuticals Ltd. Being thermostable, GEMCOVAC 19 can be transported at 2-8°C hence do not require expensive cold chain transportation. The vaccine has received Emergency use authorization (EUA).

- Chikungunya vaccine: As a part of Global Chikungunya Vaccine Clinical Development Program (GCCDP), Ind-CEPI has supported the development of world's first inactivated Chikungunya Vaccine developed in partnership of Bharat

Biotech International Limited (BBIL) and International Vaccine Institute (IVI). The program supported the set-up of GMP manufacturing facilities for the vaccine in India and subsequent manufacture of clinical trial materials along with Phase 1 clinical trials. The vaccine is currently under Phase 2/3 of clinical trials in Costa Rica and other countries.

S.No	Vaccine	Company	Support provided for	Current Status
1	**COVID-19 mRNA Vaccine, GEMOVAC-19**	Gennova Biopharmaceuticals Private Limited	Preclinical and Phase-1	**India's First mRNA vaccine; World's first Thermostable mRNA vaccine,** Received **Emergency use authorization**
2	**Chikungunya Vaccine (Inactivated)**	Bharat Biotech International Limited	Preclinical and Phase 1	Currently in Phase 2/3 of clinical trials

Overall societal impact:

- **Thermostable mRNA platform:** Gennova's mRNA vaccine platform has been a major breakthrough as was recognized as the world's first thermostable mRNA vaccine. As these vaccines do not require expensive cold chain transportation, they are relatively cheaper to manufacture and hence more accessible. Novel mRNA platforms have also been identified as a pivotal enabler of rapid response development of vaccines. The platforms are flexible to be adapted for developing new vaccine candidates and for clinical testing and subsequent scale-up during outbreaks. Thus, mRNA platforms are a vital tool that can help to create a library of vaccine candidates that could be used against Disease X that might emerge from high priority virus families. Based on this technology, regulators approved 2 Covid vaccines (GEMCOVAC 19 and GEMCOVAC OM (Omicron variant)), during COVID-19 pandemic.
- **Inactivated virions technology:** As a part of Global Chikungunya Clinical Development Program (GCCDP) of CEPI, Ind-CEPI has supported towards development of world's first inactivated Chikungunya vaccine, a debilitating illness that results in substantial health and economic consequences around the world, including in low- and middle-income countries (LMICs). Inactivated virions technology has a safety profile which potentially makes this vaccine accessible to special populations, such as the immunocompromised and pregnant women, that some other technologies cannot reach.

Infrastructure Strengthening for vaccine development

Consultancy support for establishing Quality Management System (QMS)

Through Ind-CEPI, BIRAC has also provided Consultancy support for establishing Quality Management System (QMS) for immunogenicity laboratories and animal challenge study facilities involved in vaccine development. Immunogenicity laboratories were supported for ISO/IEC 17025:2017 accreditation by NABL and Animal Challenge Study facilities were supported for GLP accreditation by NGCMA. Following 6 facilities were supported for QMS. Six facilities/ laboratories have been supported under this initiative:

Facility Supported	Type of facility	Consultancy support for
Institute of Life science, Bhubaneswar	Animal challenge study	GLP
Indian Institute of Science, Bengaluru	Animal challenge study	GLP
Translational Health Science and Technology Institute, Faridabad	Immunogenicity laboratory	ISO/IEC 17025:2017
THSTI- NCR biotech cluster, Delhi-NCR	Animal challenge study	GLP
Jawaharlal Nehru Centre for Advanced Scientific Research, Bengaluru	Immunogenicity laboratory	ISO/IEC 17025:2017
Institute for Stem Cell Biology and Regenerative Medicine, Bengaluru	Animal challenge study	GLP

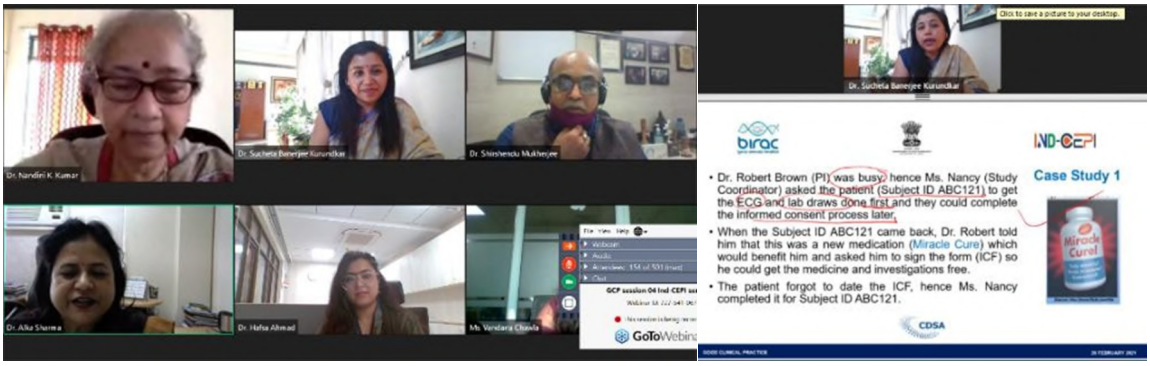
Capacity Building programs:

The program Ind-CEPI has made concerted efforts to promote capacity building, skill development and regional coordination. The PACT (Partnerships for Accelerating Clinical Trials) initiative was undertaken by BIRAC in collaboration with CDSA (Clinical Development Services Agency), under the aegis of the Ind-CEPI Program of DBT, to support researchers and investigator teams of neighbouring countries to enhance and strengthen their clinical trial capabilities.

In this direction, series of two consecutive e-Courses entitled “Strengthening Clinical Trial Research Capacity” in neighbouring and India Friendly countries respectively were organized. This training envisaged an in-depth coverage of various topics pertinent to following areas:

- Good Clinical Practice
- Ethical considerations in clinical research
- Good Clinical Laboratory Practice
- Novel vaccine development and immunization policy in a pandemic

With a total engagement of over 2500 participants from 13 countries including Afghanistan, Bangladesh, Bhutan, Maldives, Mauritius, Nepal, Sri-Lanka, Bahrain, Kenya, Myanmar, Oman, Somalia and Vietnam, the series was very well received and proved to be an important diplomacy initiative for regional networking and coordination with these countries.



Capacity Building program on Strengthening Clinical Trial Research

Strengthening internal inter-ministerial co-ordination for rapid vaccine development and testing to address known and unknown infectious disease threats

Ind-CEPI's participation in meetings and consultations with various inter-ministerial and global organizations like MOHFW, ICMR, CDSCO, DCGI, MOD and MEA and CEPI etc., aims to contribute towards establishing tools, networks, systems and resources that are required in advance to deal with EID outbreaks and for evaluating strategies for the rapid development and manufacturing of vaccines.

Ind-CEPI Mission has conducted collaborative discussions that has led to a coordinated response strategy during outbreaks especially during COVID -19. As a part of Bilateral Cooperation, dialogues were initiated with Myanmar and Bahrain as cooperation efforts with neighbouring countries in matters of COVID-19 vaccines, for joint production and distribution of COVID vaccines.

BIRAC's participation in The Nipah Diseases and Medical Countermeasures workshop, organized by CEPI, ICMR and ISARIC (The International Severe Acute Respiratory and emerging Infection Consortium) provided an overview of BIRAC's initiatives on One Health.

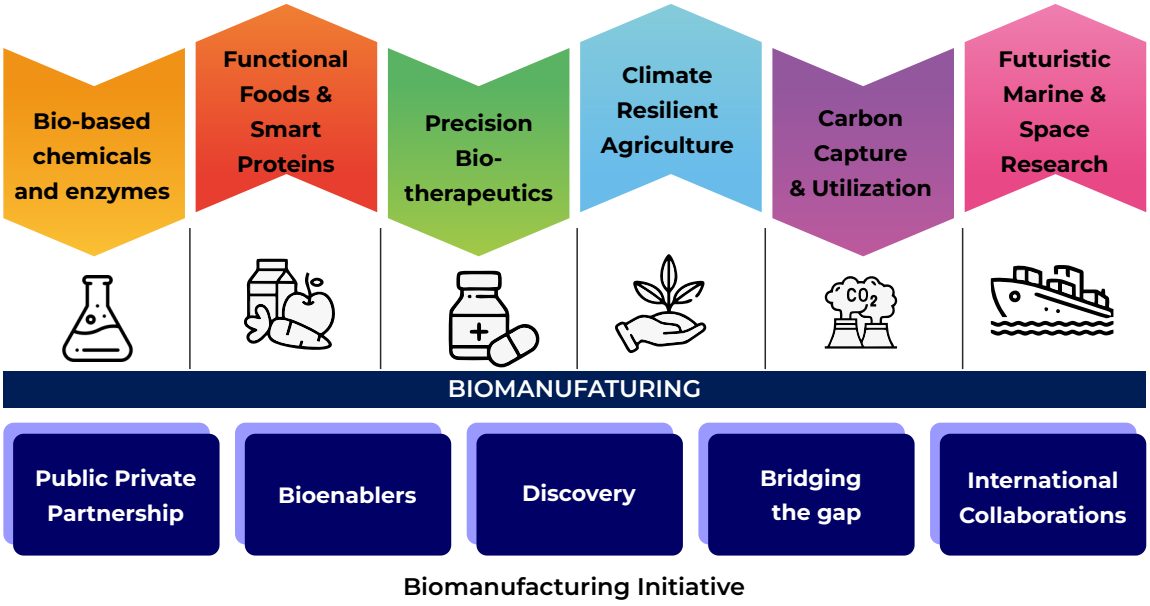
The H5N1 Vaccine Readiness Workshop organized by ICMR and CEPI in May 2025 BIRAC's participation in discussions highlighting organization role in enhancing the innovation ecosystem in India along with the contributions of BIRAC's mission programs Ind-CEPI and COVID Suraksha, in strengthening pandemic preparedness and developing new vaccine platform technologies.

VII.4. BioE3 Policy: Biomanufacturing Initiative

BioE3 Policy was launched in August 2024. Department of Biotechnology (DBT) has formulated an initiative for the implementation of BioE3 policy (Biotechnology for Environment, Economy & Employment) in August 2024 for fostering high performance biomanufacturing and to enable start-ups, SMEs, industries and academia with access to shared infrastructure/facilities and resources for pilot & precommercial scale biomanufacturing of viable commercial bio-based products.

BioE3 Policy for a green, clean, prosperous, and self-reliant India, will empower Indian institutions and industries to engage in transformative innovation through Public-Private Partnership (PPP) and international collaborations. Biomanufacturing leverages engineering microbial, plant, animal and human cells with increasing precision and control to produce commercially important products. In addition to enabling India's emissions reduction goals, Biomanufacturing will also have a transformative impact across diverse sectors of health, agriculture, food, pharmaceuticals, chemicals, materials, biofuels, etc. 'Fostering High Performance Biomanufacturing' stimulates and intensifies technology development.

The following are the verticals considered under this initiative a) Biobased chemicals and enzymes b) Functional foods and smart proteins c) Precision biotherapeutics d) Climate change and resilient agriculture e) Carbon capture and utilization f) Futuristic marine and space biomanufacturing g) Bio-enablers including Bio-artificial intelligence (AI) hubs and Bio-foundries/Biomanufacturing hubs i.e., High performance biomanufacturing platforms



Biomanufacturing Initiative

Bio-enablers consisting of sophisticated instrumentations, technology platforms such as data acquisition and analysis capabilities along with artificial intelligence (AI) and machine learning (ML), omics and biomaterial libraries translate knowledge into scaled up applications, and wide spread socio-economic impact. Further, they augment discovery and translational research across the six sectorial verticals selected under the program. The Bio-AI Hubs will enable discovery research across the sectors, while the Bio-foundries/Biomanufacturing Hubs will support facilities for pilot scale and pre-commercial scale research.

The following are the achievements so far,

Network of 21 Bio-enablers: 08 Bio-foundries and 13 Biomanufacturing Hubs has been created across the country catering to different thematic areas of biomanufacturing.

Webinar Series Launch: 16 webinars have been jointly conducted by DBT and BIRAC so far under different thematic verticals under biomanufacturing initiative.

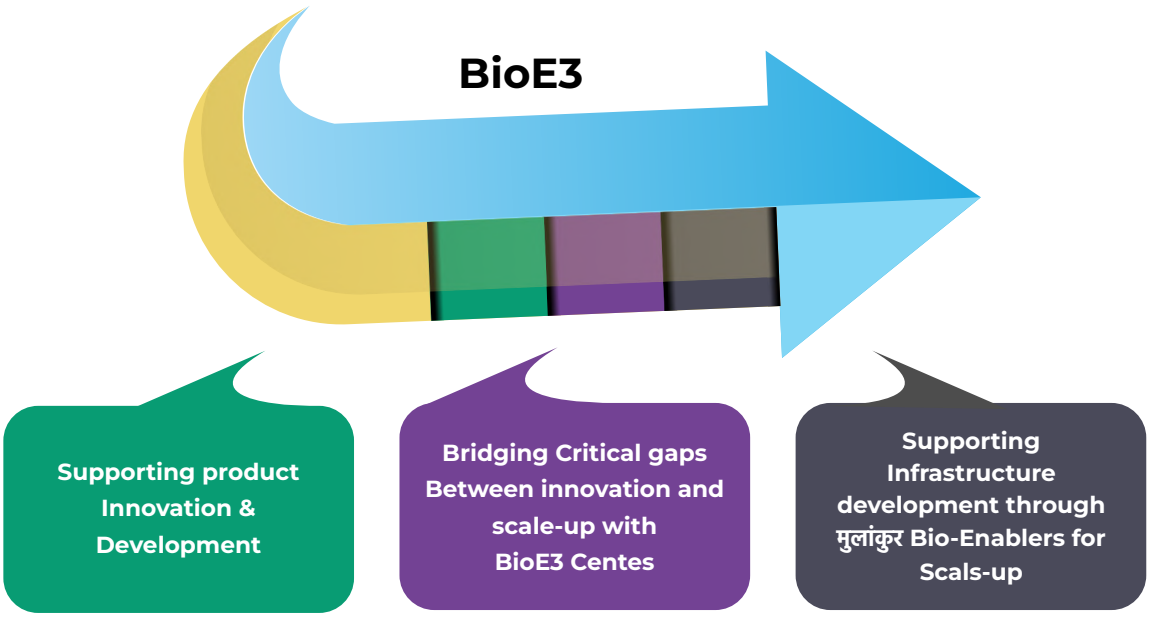
Launch of calls under thematic areas: The following Joint DBT-BIRAC Calls have been launched under the following categories viz. Discovery & Application-oriented Integrated Network Research; Bridging the Gaps for Scale-up

- Call I: "मूलांकुर" BioEnabler Hubs: Biofoundry & Biomanufacturing Hubs
- Precision Biotherapeutics: Cell & Gene Therapy
- Smart Proteins
- Carbon Capture & its Utilization
- Climate Resilient Agriculture
- Enzymes
- Precision Biotherapeutics- mRNA therapeutics
- Precision Biotherapeutics-monoclonal antibodies
- Bio-AI
- Call II: "मूलांकुर" Bioenablers: Biofoundries and Biomanufacturing hubs
- Functional Foods
- Bio-Based Chemicals, Biopolymers and Active Pharmaceutical Ingredients (APIs)
- Futuristic Marine research

Other initiatives under BioE3:

BioE3 Centres: A national stakeholder consultation organized by BIRAC in June 2025 identified critical gaps in India's biomanufacturing ecosystem, notably the lack of pilot-scale infrastructure, regulatory-grade facilities, skilled human resources, and integrated public–private partnership (PPP) models. The consultation strongly recommended the creation of BioE3 Centres—next-generation incubation and biomanufacturing hubs to bridge these gaps and accelerate innovation from lab to market.

WAY FORWARD



Implementation of Biomanufacturing through different verticals

VII.5. Biotechnology Industry Facilitation Cell – Program Management Unit (PMU) for Make in India

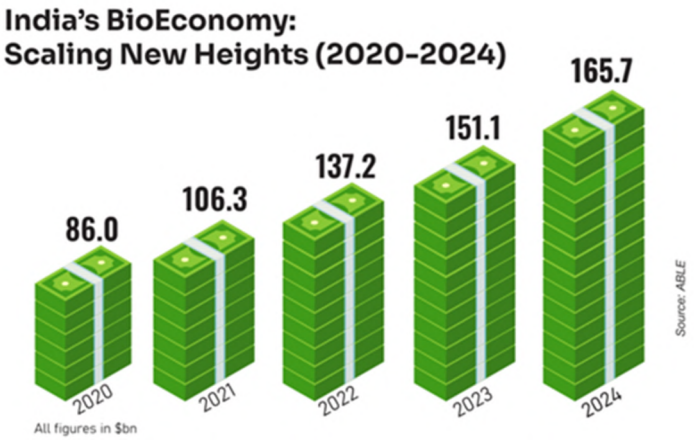
National Mission Program - Make in India (MII) for Biotech sector is led by DBT and supported by BIRAC since 2015, to strengthen the biotech innovation ecosystem in line with evolving national priorities and the global biotechnology sector landscape. The MII PMU undertakes policy advocacy, data research and analysis, stakeholders' consultations and provides strategic inputs. The PMU also works closely with Invest India, DBT and DPIIT for the growth of the Bioeconomy and Biotech Innovation ecosystem of the country. The PMU implements Biotech Fund of funds – AcE to promote private investment mobilization into the biotech innovation ecosystem. It undertakes annual monitoring of India's BioEconomy and undertakes detailed analysis to identify gaps and ground-level challenges faced by biotech Industry, Start-ups and entrepreneurs facilitating evidence-based recommendations.

The MII cell was instrumental in creating and steering Global Bio-India (GBI) – an international biotech congregation which has now evolved as the renowned platform to see the largest congregation of bio-based deep tech innovations in the country as an annual biotech showcase event. The PMU has also supported DBT core group for the Biofoundry/ Biomanufacturing initiative and BioE3 policy initiative. It undertakes initiatives to support the existing ecosystem of large and medium-scale biotech

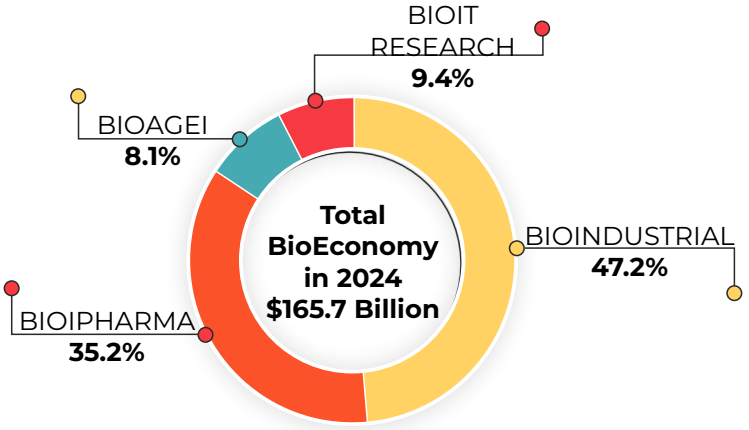
companies (under Make In India national mission), as well as new emerging Start-ups (under Start-up India national mission).

VII.5.1. BioEconomy

India's BioEconomy crossed the $150 billion USD mark in calendar year 2023. This was a major milestone. At a 9.7% growth, India's BioEconomy increased to $165.7 billion USD in 2024 contributing about 4.25% to the overall GDP of India. The Report was released by Dr. Jitendra Singh, Hon'ble Union Minister (I/C), Ministry of Science & Technology during BIRAC's 13th foundation day celebrations on 21st March 2025



- The total number of Indian biotech start-ups reached a milestone of 10,075 in 2024.
- Four key segments contribute to the India BioEconomy i.e., BioIndustrial at 47.2%, followed by BioPharma at 35.2%, Bio Services at 9.4% and BioAgri at 8.1%.



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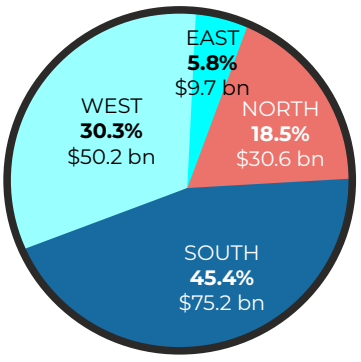
*Totals may not sum to 100% due to rounding to the nearest decimal



REGIONAL BIOECONOMY DISTRIBUTION

India's BioEconomy growth exhibits distinct regional patterns indicating opportunity to promote ecosystem to foster further growth across the nation.

G20 summit under Brazil and South Africa has recognized BioEconomy as a new chapter of Global sustainable driver.

VII.5.2. Policy Advocacy and Strategic Facilitation

As part of its mandate, Make In India PMU undertakes stakeholder consultations, industry feedback analysis, and evidence-based policy inputs to support DBT and relevant ministries in addressing ecosystem bottlenecks and improving ease of doing business in the biotechnology sector. These inputs are provided through structured consultations and inter-agency engagements.

The PMU has provided consultative and analytical inputs to national policy discussions related to bio-manufacturing capacity enhancement, innovation infrastructure, start-up ecosystem strengthening, and regulatory facilitation. This includes support through stakeholder engagement and background inputs resulting in policy level impact including the following:

- BioE3 Policy & Bio-RIDE Scheme to support Bio-innovation and Bio-manufacturing under PPP mode
- Abolition of Angel Tax for Startups (Union Budget 2024)
- Custom Duty Rollback on Biotech Reagents (HS 9802)
- Enhancement of Startup Age Limit to 20 years for deep-tech startups with turn over limit to INR 300 Cr under DPIIT (Deep Tech Focus)
- Revised DSIR Recognition Norms for tax benefit for startups

These policy outcomes are the result of inter-ministerial and multi-stakeholder processes led by the Government of India, with the MII-PMU BIRAC contributing as a supporting technical and ecosystem interface.

VII.5.3. Project Development Cell (PDC)

In order to boost FDI, manufacturing and attract investments in the biotech sector, the PDC incorporation at the departments have been recommended by the Department for Promotion of Industry and Internal Trade (DPIIT). Infrastructure and Investment Initiatives: This initiative through DBT would draw in Investments, create jobs while driving high impact innovations. MII PMU hosts PDC activities for the biotech sector as per DBT's mandate.

VIII. Bringing Together the Biotech Community Stakeholders

- BIRAC spearheads regular national and international events that bring together stakeholders to showcase India's growing strength in the sector and create opportunities for connection, co-development, co- creation, and co-scaling. These events emphasize peer-to-peer learning, identifying gaps and opportunities, networking, and showcasing innovations.

- Global Bio-India (GBI) is a mega international event led by the Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC) to showcase India's potential and growth opportunities to the international world. GBI offers a platform to biotechnology stakeholders, including international bodies, regulatory bodies, Central and State Ministries, SMEs, large industries, bio clusters, research institutes, investors, and the start-up ecosystem to meet and interact. Other notable events hosted by BIRAC in the past include Biotech Start-Up Expo 2022 and the S22tart-up Conclave event at the India International Science Festival (IISF 2022).

- Launch of BioSaarthi Global Mentorship Program (March 2025) to facilitate product development & scale up mentorship for international market access, regulatory readiness, and global partnerships.

- BIRAC has established national-level annual events like the Innovators Meet and Foundation Day for Start- Ups and Entrepreneurs. These events bring together technical experts, business leaders, innovators, and entrepreneurs on a common platform for showcasing and interaction.

- For operational purposes, BIRAC has developed the 3i Portal, a well-established online platform for application submission, screening, and post-grant monitoring. The BIRAC 3i Portal offers a user-friendly, bilingual, and convenient solution for managing various funding schemes effectively. It provides single-window access to information and services delivered electronically to its users.

- The Technology Portal of BIRAC is an online platform designed to connect innovators, researchers, start-ups, industry, and other stakeholders in the biotechnology ecosystem. It serves as a one-stop interface for technology sourcing, showcasing, and partnerships. 200+ connects have been provided so far to technology seekers.

- Biotech Innovation Showcase e-portal features 850+ products/technologies from BIRAC supported Start-Ups and companies that is accessible in public domain.

- BIRAC's facility network e-Portal provides a comprehensive list of equipment available at all BioNEST Incubation Centres. The portal provides information on equipment specifications, user charges, and other related details, which can be accessed through the portal. Start-ups can avail these facilities by directly reaching out to the respective Incubation Centres.

Appendix I

Table: List of 94 Bioincubation centres (BioNEST and EYUVA)

S. No	Incubation Centre	City	State
1	BioNEST Andhra Pradesh MedTech Zone (AMTZ)	Visakhapatnam	Andhra Pradesh
2	BioNEST Sri Padmavati Mahila Visvavidyalayam (SPMVV) -Society For Innovation Incubation Entrprenuership (SIIE)	Tirupati	Andhra Pradesh
3	BioNEST Translational Oncology Council, Vyas Cancer Research Private Limited	Visakhapatnam	Andhra Pradesh
4	E-YUVA College of Horticulture and Forestry, Central Agricultural University Pasighat	Pasighat	Arunachal Pradesh
5	BioNEST Council of Scientific & Industrial Research-North East Institute of Science and Technolog (NEIST)	Jorhat	Assam
6	BioNEST Indian Institute of Technology Guwahati-Technology Innovation and Development Foundation	Guwahati	Assam
7	BioNEST Institute of Advanced Study in Science & Technology (IASST)	Guwahati	Assam
8	BioNEST National Institute of Pharmaceutical Education and Research- Guwahati	Guwahati	Assam
9	Incubation Centre Indian Institute of Technology (IIT) Patna Campus	Patna	Bihar
10	BioNEST Panjab University	Chandigarh	Chandigarh
11	E-YUVA Panjab University	Chandigarh	Chandigarh
12	BioNEST Birla Institute of Technology and Science Pilani	Sancoale	Goa
13	BioNEST Ahmedabad University	Ahmedabad	Gujarat
14	BioNEST Gujarat State Biotechnology Mission, (GSBTM)	Savli, Vadodra	Gujarat
15	BioNEST National Institute of Pharmaceutical Education And Research NIPER - Ahmedabad	Ahmedabad	Gujarat

16	BioNEST B. V. PATEL PERD (Pharmaceutical Education & Research Development) Centre	Ahmedabad	Gujarat
17	BioNEST Sanctuary of Innovation, Incubation and Entrepreneurship - SRISTI	Ahmedabad	Gujarat
18	E-YUVA Atmiya University	Rajkot	Gujarat
19	BioNEST RCB (Regional Centre for Biotechnology)	Faridabad	Haryana
20	BioNEST Indian Institute of Technology (IIT) Mandi Catalyst	Mandi	Himachal Pradesh
21	E-YUVA Shoolini University of Biotechnology & Management Sciences	Solan	Himachal Pradesh
22	BioNEST Indian Institute of Integrative Medicine Technology Business Incubator	Jammu	Jammu & Kashmir
23	BioNEST Industrial Park- Indian Institute of Integrative Medicine Technology Business Incubator	Kathua	Jammu & Kashmir
24	E-YUVA University of Kashmir	Srinagar	Jammu & Kashmir
25	E-YUVA Sher-e-Kashmir University of Agricultural Sciences and Technology	Kashmir	Jammu & Kashmir
26	BioNEST Bangalore Bioinnovation Centre (BBC)	Bangalore	Karnataka
27	BioNEST C-CAMP (Centre for Cellular and Molecular Platforms)	Bangalore	Karnataka
28	BioNEST Indian Council of Agricultural Research-Indian Institute of Horticultural Research	Bangalore	Karnataka
29	BioNEST IKP- Engineering Design And Entrepreneurship Network	Bangalore	Karnataka
30	BioNEST Manipal University Technology Business Incubator Society	Manipal	Karnataka
31	BioNEST Mazumdar Shaw Medical Foundation (MSMF)	Bangalore	Karnataka
32	BioNEST University of Agricultural Sciences-Gandhi Krishi Vigyana Kendra (GKVK)	Bangalore	Karnataka

33	BioNEST Council of Scientific & Industrial Research-Central Food Technological Research Institute (CFTRI)	Mysuru	Karnataka
34	BioNEST Dayananda Sagar Entrepreneurship Research and Business Incubation Foundation (DERBI)	Bangalore	Karnataka
35	BioNEST Dharwad Research and Technology Incubator Foundation (DhaRTI) at Indian Institute of Technology Dharwad	Dharwad	Karnataka
36	E-YUVA University of Agricultural Sciences (UAS)	Dharwad	Karnataka
37	BioNEST Amal Jyothi Rural Technologies Business Incubator	Kottayam	Kerala
38	BioNEST Mindriot Research and Innovation Foundation, Dr Moopen's Medical college	Wayanad	Kerala
39	E-YUVA Kannur University	Kannur	Kerala
40	E-YUVA Career College	Bhopal	Madhya Pradesh
41	E-YUVA Amicable Knowledge Solution (AKS) University	Satna	Madhya Pradesh
42	BioNEST Entrepreneurship Development Centre (EDC), Venture Center	Pune	Maharashtra
43	BioNEST RiiDL Research Innovation Incubation Design Laboratory Foundation	Mumbai	Maharashtra
44	BioNEST Society for Innovation and Entrepreneurship (SINE), Indian Institute of Technology Bombay	Mumbai	Maharashtra
45	BioNEST Innovation Technology Entrepreneurship (ITE) Research Foundation, Datta Meghe Institute of Higher Education & Research	Wardha	Maharashtra
46	E-YUVA Punyashlok Ahilyadevi Holkar Solapur University	Solapur	Maharashtra
47	BioNEST Bio-resources Development Centre, Upper Shillong (BRDC)	Shillong	Meghalaya

48	BioNEST Institute of Bioresources and Sustainable Development	Shillong	Meghalaya
49	BioNEST North Eastern Hill University, Tura Campus	Tura	Meghalaya
50	BioNEST Mizoram University	Aizawl	Mizoram
51	BioNEST Clean Energy International Incubation Center	New Delhi	Delhi
52	BioNEST Centre for Medical Innovation & Entrepreneurship" (CMIE) at All India Institute of Medical Sciences	New Delhi	Delhi
53	BioNEST Delhi Pharmaceutical Science Research University (DPSRU) Innovation & Incubation Foundation	New Delhi	Delhi
54	BioNEST Foundation for Innovation and Technology Transfer (FIIT), Indian Institute of Technology Delhi	New Delhi	Delhi
55	BioNEST Zonal Technology Management - Business Planning and Development Unit-Indian Agricultural Research Institute	New Delhi	Delhi
56	BioNEST Indigram Labs Foundation	New Delhi	Delhi
57	BioNEST University of Delhi South Campus	New Delhi	Delhi
58	BioNEST Institute of Life Sciences	Bhubaneswar	Odisha
59	BioNEST Kalinga Institute of Industrial Technology-Technology Business Incubator (TBI)	Bhubaneswar	Odisha
60	E-YUVA Gandhi Institute of Engineering and Technology (GIET) University	Gunupur	Odisha
61	BioNEST National Agri Food Biotechnology Institute (NABI)	Mohali	Punjab
62	E-YUVA Central University of Punjab	Bathinda	Punjab
63	BioNEST Indian Institute of Technology Jodhpur - Technology Innovation and Start-Up Center (TISC)	Jodhpur	Rajasthan
64	E-YUVA University of Rajasthan	Jaipur	Rajasthan

65	E-YUVA Central University of Rajasthan	Ajmer	Rajasthan
66	BioNEST Association For Bio-inspired Leaders and Entrepreneurs (ABLEST) at Shanmugha Arts, Science, Technology & Research Academy (SASTRA) Technology Business Incubator	Thanjavur	Tamil Nadu
67	BioNEST Crescent Innovation & Incubation Council	Chennai	Tamil Nadu
68	BioNEST Golden Jubilee Women Biotech Park	Chennai	Tamil Nadu
69	BioNEST Healthcare Technology Innovation Centre (HTIC) MedTech Incubator, Indian Institute of Technology Madras	Chennai	Tamil Nadu
70	BioNEST Indian Institute of Technology Madras Research Park	Chennai	Tamil Nadu
71	BioNEST Peelamedu Samanaidu Govindasamy (PSG)-Science & Technology Entrepreneurial Park (STEP)	Coimbatore	Tamil Nadu
72	BioNEST Sri Ramachandra BIRAC-BioNEST Bioincubator at Sri Ramachandra Institute for Higher Education and Research (SRIHER)	Chennai	Tamil Nadu
73	BioNEST Veterinary Incubation Foundation at Tamilnadu Veterinary And Animal Sciences University (TANUVAS)	Chennai	Tamil Nadu
74	BioNEST Vellore Institute of Technology-Technology Business Incubator (VITTBI)	Vellore	Tamil Nadu
75	BioNEST SRM (Sri Ramaswamy Memorial) - Medical College Hospital and Research Centre	Chennai	Tamil Nadu
76	E-YUVA Anna University	Chennai	Tamil Nadu
77	E-YUVA Peelamedu Sengunthar Gounder Rangaswamy (PSGR) Krishnammal College for Women	Coimbatore	Tamil Nadu
78	E-YUVA Tamil Nadu Agricultural University (TNAU)	Chennai	Tamil Nadu
79	BioNEST A-IDEA, National Academy of Agricultural Research Management Technology Business Incubator (NAARM-TBI)	Hyderabad	Telangana

80	BioNEST Avishkaran-Foundation For Pharma Innovation, National Institute of Pharmaceutical Education and Research	Hyderabad	Telangana
81	BioNEST Hyderabad Eye Institute (Laxmi Vara Prasad)	Hyderabad	Telangana
82	BioNEST International Institute of Information Technology Hyderabad	Hyderabad	Telangana
83	BioNEST IKP Knowledge Park	Hyderabad	Telangana
84	BioNEST International Crops Research Institute for the Semi-Arid Tropics ICRISAT	Hyderabad	Telangana
85	BioNEST Society for Biotechnology Incubation Centre (SBTIC)	Hyderabad	Telangana
86	BioNEST ASPIRE (Association for Scientific Pursuits for Innovative Research Enterprises), University of Hyderabad	Hyderabad	Telangana
87	BioNEST Foundation for Center for Healthcare Entrepreneurship (CfHE), Indian Institute of Technology Hyderabad	Hyderabad	Telangana
88	BioNEST Innorestech Foundation, Banaras Hindu University (BHU)	Varanasi	Uttar Pradesh
89	BioNEST Council of Scientific & Industrial Research - Indian Institute of Toxicology Research	Lucknow	Uttar Pradesh
90	BioNEST SIDBI(S)IIC (Small Industries Development Bank of India-Innovation & Incubation Centre) at Institute of Technology Kanpur	Kanpur	Uttar Pradesh
91	BioNEST Research Innovation Development and Entrepreneurship Society (RIDES), Jaypee Institute of Information Technology	Noida	Uttar Pradesh
92	BioNEST JSS (Jagadguru Sri Shivarathreeshwara) Academy of Technical Education STEP (science & technology entrepreneurs park)	Noida	Uttar Pradesh
93	BioNEST Technology Incubation and Entrepreneurship Development Society (TIEDS), Indian Institute of Technology Roorkee	Roorkee	Uttarakhand
94	E-YUVA Adamas University	Kolkata	West Bengal

Appendix II

Table: List of the newly selected SPARSH centres under Phase 3

S. No.	Name of the Institute hosting SPARSH centre	City	State
1.	PSG-STEP, Coimbatore	Coimbatore	Tamil Nadu
2.	Foundation for Innovation and Technology Transfer	New Delhi	Delhi
3.	SCTIMST-TIMED in collaboration with IIITM-K (Maker Village)	Thiruvananthapuram	Kerala
4.	Atal Incubation Centre - Centre for Cellular and Molecular Biology	Hyderabad	Telangana
5.	Yenepoya Foundation for Technology Incubation, Karnataka	Mangalore	Karnataka
6.	KIIT Technology Business Incubator in collaboration with Bhubaneswar City Knowledge Innovation Cluster Foundation (BCKIC)	Bhubaneswar	Odisha
7.	Bio-resources Development Centre, Upper Shillong in collaboration with IIT Guwahati Technology Innovation and Development Foundation	Shillong	Meghalaya
8.	Society for Technology Business Incubator, IISER Mohali, Punjab	Mohali	Punjab
9.	Golden Jubilee Biotech Park for Women, Chennai	Kanchipuram	Tamil Nadu
10.	Birla Institute of Technology and Science Pilani, Rajasthan	Pilani	Rajasthan
11.	Parul University, Gujarat	Vadodara	Gujarat
12.	Padmashree Institute of Management and Sciences	Bangalore	Karnataka
13.	University of Petroleum and Energy Studies	Dehradun	Uttarakhand
14.	TIDES, IIT Roorkee	Roorkee	Uttarakhand
15.	Association for Bio-inspired Leaders and Entrepreneurs at SASTRA TBI, Tamil Nadu	Chennai	Tamil Nadu

16.	TISS Incube Foundation	Pune	Maharashtra
17.	IIT Madras - Gopalakrishnan Deshpande Centre for Innovation and Entrepreneurship	Chennai	Tamil Nadu
18.	Association of Biotechnology Led Enterprises	Bangalore	Karnataka

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