

**GOVERNMENT OF INDIA  
MINISTRY OF SCIENCE & TECHNOLOGY  
DEPARTMENT OF BIOTECHNOLOGY**

**LOK SABHA**

**UNSTARRED QUESTION NO. 3215  
ANSWERED ON 11.03.2026**

**BioE3 Policy**

**3215. Shri Vishaldada Prakashbapu Patil:**

Will the Minister of SCIENCE AND TECHNOLOGY

be pleased to state:

(a) the details of the overall value and impact of Government-backed initiatives such as the BioE3 policy and BIRAC on the growth and global competitiveness of India's biotech sector, especially in the context of R&D, local manufacturing, startup creation and scale-up to international standards,

(b) the details of the mechanisms for ensuring equitable access to public R&D funds including transparency in selection and monitoring of grants FDI recipients and the status of any public disclosure requirements and independent audit of these funds;

(c) the details of the strategies put in place to address major challenges for biotech startups such as access to late-stage capital regulatory approval delays and the geographic diversity of clinical trials; and

(d) whether the Government is tracking and publishing longitudinal data on job creation and startup survival rates in this sector and if so, the details thereof?

**ANSWER**

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE  
MINISTRY OF SCIENCE AND TECHNOLOGY & EARTH SCIENCES  
(DR. JITENDRA SINGH)

**(a)** The BioE3 Policy (Biotechnology for Environment, Economy & Employment), approved by the Cabinet, is being implemented jointly by the Department of Biotechnology (DBT) and its Public Sector Enterprise, the Biotechnology Industry Research Assistance Council (BIRAC) for fostering high-performance Biomanufacturing and enabling start-ups, SMEs, industries and academia with access to shared infrastructure/facilities and resources

for pilot & pre-commercial scale biomanufacturing of viable commercial bio-based products.

Bio-enablers (Biofoundries & Biomanufacturing Hubs and Bio-AI Hubs) augment discovery and translational research across the sectorial verticals:

- i. Bio-based chemicals, Bioplastics, Active Pharmaceutical Ingredients (APIs), and Enzymes
- ii. Functional Foods and Smart Proteins
- iii. Precision Biotherapeutics (monoclonal antibodies, mRNA therapeutics, cell & gene therapy)
- iv. Climate resilient agriculture (agribiologicals)
- v. Biofuels and Carbon capture
- vi. Futuristic marine and space research

DBT-BIRAC has launched India's first Biofoundry Network at 8 academic institutions, marking a landmark initiative aimed at transforming the country's biotechnology landscape and achieving a \$300 billion bioeconomy by 2030. The network serves as a national platform to support bioproduction scale-up at academia.

Further, 11 cutting-edge Biomanufacturing Platforms have been set up at industry across India, offering shared infrastructure to start-ups, SMEs, industries, and academic institutions. These centers are supporting pilot and pre-commercial scale up of technologies across diverse sectors, including microbial biomanufacturing, sustainable agriculture, smart proteins, functional foods, precision biotherapeutics, marine biotechnology, carbon capture, and next-generation cell and gene therapies.

The Biofoundry Network and Biomanufacturing platforms are expected to play a pivotal role in India's transition to clean and green technologies, reduce import dependence, and establish the country as a frontrunner in the global Bioeconomy impacting health, agriculture, food, energy, and environment.

***The details of the projects are at Annexure I.***

The BIRAC was set up by the DBT in 2012 and is playing a key role in strengthening R&D, startup creation, indigenous manufacturing, and providing global competitiveness to India's biotechnology sector. BIRAC provides a structured continuum of support from idea to commercialization. Details of various programs of BIRAC and their impact are as follows:

- i. Biotechnology Ignition Grant (BIG):** The Biotechnology Ignition Grant (BIG) is BIRAC's flagship early-stage funding programme which provides grant-in-aid support of up to ₹50 lakh for a period of 18 months to startups and innovators for establishing proof-of-concept of innovative ideas. The scheme is implemented through 8 partner incubators that provide end-to-end support including technical mentoring, IP facilitation, regulatory support, and market linkages, enabling translation of innovative ideas into scalable technologies.

  - Over the past 13 years, the BIG scheme has grown into one of India's most credible early-stage biotech funding mechanisms, providing not only financial support but also critical ecosystem access for innovators. Since inception, the programme has supported more than 1,000 high-potential projects, facilitated the development of 200+ products, enabled 800+ intellectual property assets, and supported startups in attracting over ₹3,500 crore in follow-on funding. Through these interventions, BIG has played a catalytic role in seeding science-led entrepreneurship and strengthening the early-stage biotech innovation ecosystem in the country.
- ii. Sustainable Entrepreneurship and Enterprise Development (SEED) Fund:** The SEED Fund provides first-equity-based financial support of up to ₹30 lakh per startup to facilitate transition from proof-of-concept to early-stage commercialization. This support enables startups to reach a stage where they can attract investments from angel investors or venture capitalists or access institutional financing.

  - The programme is implemented through 16 BioNEST incubators acting as SEED Fund partners, which identify and invest in promising startups through a structured selection process. To date, 153 biotech startups have been supported under the scheme, strengthening product validation, early market access, and domestic manufacturing capabilities. The portfolio has generated 300+ intellectual property assets, and 105 supported startups have collectively raised over ₹1,162 crore in follow-on funding, reflecting strong investor confidence and commercialization potential.
- iii. Launching Entrepreneurial Driven Affordable Products (LEAP) Fund:** The LEAP Fund is an equity-based programme aimed at accelerating commercialization and market entry of startups with validated technologies (above TRL-5). The scheme provides equity support of up to ₹100 lakh per startup to enable scale-up, regulatory advancement, manufacturing readiness, and product deployment.

- The programme is implemented through 6 designated BioNEST incubators serving as LEAP Fund partners, which invest in eligible startups through equity or equity-linked instruments. So far, 62 startups have been supported under this programme. These startups have generated 150+ intellectual property assets and collectively raised over ₹893 crore in follow-on funding, demonstrating successful scale-up and growing market traction.

Collectively, these initiatives strengthen India's biotechnology innovation ecosystem by promoting indigenous R&D, facilitating technology translation, enabling manufacturing scale-up to international standards, attracting private investment, and supporting the growth of globally competitive biotech startups.

- iv. Pre-incubation and Incubation Schemes:** BIRAC supports innovation, research translation, and startup creation through a network of incubation and pre-incubation programmes.

A total of 94 biotechnology incubation and pre-incubation centres have been set up by BIRAC across 25 states & UTs of the country under the following 2 schemes:

- I. **BioNEST (Bioincubators Nurturing Entrepreneurship for Scaling Technologies):** The scheme supports the establishment of bio-incubators across India to promote innovation and entrepreneurship in biotechnology.
- II. **E-YUVA (Empowering Youth for Undertaking Value Added Innovative Translational Research):** This initiative fosters a culture of applied research and innovation among students and young researchers by providing pre-incubation support.

These Bioincubators are located within Universities, Research Institutes, Research Hospitals, or as stand-alone centres and provide comprehensive support to entrepreneurs and startups across various life sciences domains, including healthcare, agriculture, and environmental solutions.

Through the BioNEST and E-YUVA schemes, BIRAC has supported around 3000 + startups, entrepreneurs and students.

- v. Public-private partnership (PPP) schemes:** BIRAC through its PPP schemes promote development of biotechnological interventions across the country by providing financial support for R&D, infrastructure and output of academic and institutional laboratories. The Schemes are as below:

- i. **Early Stage Validation funding scheme:** The Small Business Innovation Research Initiative (**SBIRI**) scheme provides financial support to Startups, LLPs and companies for advancing their established proof of concept

(PoCs) towards early-stage validation, thereby addressing a critical gap in the product development cycle. Since the inception of the scheme, a total of 350+ projects have been supported benefiting 450+ beneficiaries. Overall, 316.75 Cr has been committed to drive innovation and development efforts. The supported projects have generated 800+ employment opportunities, demonstrating a strong impact on job creation. In addition, the support has enabled 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.

**ii. Late Stage Validation and Pre-commercialization funding scheme:**

The Biotechnology Industry Partnership Program (**BIPP**) is BIRAC's Flagship Scheme that provides financial support for scaling and commercializing high risk innovations through cost sharing between BIRAC and the industry. 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.

**iii. Academia-Industry Research promoting funding scheme:** Promoting Academic Research Conversion to Enterprise (**PACE**) scheme, through its two components-Academia Innovation Research (AIR) and Contract Research Scheme (CRS), supports academic institutions in translating innovative biotechnological ideas into validated proof-of-concept (PoC) and beyond, eventually enabling industry-led validation and commercialization. Since inception, 191 projects have been supported under the scheme involving 313 beneficiaries including 76 companies and 237 academic organizations. The support has resulted in filing of 26 patents and 10 products/technologies reaching TRL7-9.

**vi. Biotechnology Innovation Fund - AcE (Accelerating Entrepreneurs)** is a Fund of funds being promoted by DBT under the aegis of Make in India initiative, implemented by BIRAC. It aims to foster R&D and innovation in Biotechnology domains by plugging the gap of the “**Valley of Death**”. The fund was launched in the FY 2017-18 with a total corpus of INR 150 Cr. BIRAC implements this fund through investment and partnership with SEBI-registered AIFs (i.e. Venture Funds and Angel Funds called daughter funds), that are professionally managed and

desirous of investing in Biotech start-ups & SMEs. From the respective total fund corpus, each daughter fund commits to invest 2x of BIRAC's committed investment in the Biotech start-ups & SMEs.

- After ploughing back INR 25 Cr returns from AcE fund, BIRAC has so far made investment commitment of INR 174.50 Cr in 16 Daughter Funds. Through these 16 Daughter funds, 106 biotech startups/SMEs have been supported so far with a combined investment of more than INR 1500 Cr and follow on investment raised by the startups/SMEs are more than INR 6000 Cr.

**(b)**

- Grant applications in DBT and BIRAC are invited through detailed Calls advertised widely and are submitted through online portal.
- All applications are reviewed through transparent, multi-tier grant evaluation mechanisms approved by the Department.
- Grant Review Committees comprise majorly external members and subject experts.
- The review committee also monitors the progress, if the project is sanctioned.
- The technically selected applications are submitted to Internal Financial Scrutiny in DBT and BIRAC. Additionally, BIRAC also conducts on-site visits for major industry programs for a thorough assessment of the industry's infrastructure.
- Following these processes, the grants are sanctioned through execution of MOU/GLA.
- All grantees are open to audit at institutional level and CAG Audits.

**(c)** To address funding gaps and commercialization challenges:

- **Biotechnology Ignition Grant (BIG)** de-risks early-stage innovation.
- **Sustainable Entrepreneurship and Enterprise Development (SEED) FUND** provides early equity support for validation and commercialization.
- **Launching Entrepreneurial Driven Affordable Products (LEAP) FUND** supports scale-up, regulatory preparedness, manufacturing readiness, and market deployment.

In addition, BIRAC facilitates investor connect platforms, industry linkages, regulatory guidance support, and incubation through BioNEST centres to improve access to capital, streamline regulatory pathways, and enhance market readiness.

- Product Commercialization Program Fund (PCP Fund) is to accelerate market launch, pilot-market validation, and largescale commercialization of biotechnology products/technologies developed by Indian startups.
- Regulatory Affairs & Policy Advocacy Division of BIRAC intends to drive innovation through navigation of regulatory complexities, harmonization of regulations & policies at both national and global levels, and fervently advocate for policies that catalyse the growth of start-ups, SMEs, and entrepreneurs in the dynamic landscape of regulatory and policy affairs.
- Clinical trial networks established through National Biopharma Mission (NBM), a PMU under BIRAC which accelerates Discovery Research to Early Development for Biopharmaceuticals address geographic diversity of clinical trials across the country

To strengthen India's regulatory and policy milieu, BIRAC has created a dedicated **Regulatory Affairs & Policy Advocacy (RAPA)** unit which drives innovation through navigation of regulatory complexities, harmonisation of global regulations, and advocates for policies that catalyse the growth of start-ups, SMEs, and entrepreneurs. Key initiatives undertaken by RAPA to address major challenges faced by biotech startups are as follows:

- **The First Hub** is a single window facilitation unit of BIRAC 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. To date, 1000+ queries have been addressed through the FIRST Hub portal.
- **Regulatory Facilitation for Innovators and Entrepreneurs (REFINE)** program was launched on 22 November 2024 for advanced regulatory facilitation by product- or technology-specific mentoring on regulatory documentation, application support, risk assessment, success metrics and licensing requirements.
- **Global Regulatory Knowledge Exchange Forum for Emerging Technologies** was conceptualised on 12 September 2024 for fostering policy dialogue and developing key strategies in the biomanufacturing sector. As part of this initiative, stakeholders' consultation meetings have been organised in emerging fields such as **smart protein, cell & gene therapy products, Biosimilars, Quantum Computing, Complex in-vitro models, etc.**
- A strategic consultation titled **“Strengthening India’s Clinical Trial Regulation: Lessons from Other Countries”** was convened on strengthening India’s clinical trial regulatory ecosystem. Which 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. The white paper was developed to capture the necessary regulatory reforms.

- **Capacity building:** Regulatory workshops and webinars were organised with IIT Delhi, RCB, USP to enhance innovators' understanding of approval pathways, clinical trial requirements, documentation standards, and international regulatory expectations, thereby improving compliance readiness and reducing avoidable delays. In addition, the National Regulatory Professionals Development program is being organised to build the capacity of regulatory mentors in the biopharma and medical devices sectors.

(d) The **Biotechnology Industry Research Assistance Council (BIRAC)** tracks programme-level outcomes to assess longitudinal impact, including employment generation, follow-on funding mobilization, intellectual property creation, valuation growth, and startup progression across funding stages.

- I. The **Biotechnology Ignition Grant (BIG)** scheme provides grant-in-aid support of up to ₹50 lakh for 18 months to early-stage innovators to establish proof-of-concept and develop prototypes. This funding enables startups to hire scientific, and technical personnel during the formative phase, build core R&D teams, and de-risk technology development. As a result, over 1000 BIG-supported startups have generated approximately 3,000 jobs while strengthening their survival prospects through structured milestone-based monitoring and incubation support.
- II. The **Sustainable Entrepreneurship and Enterprise Development (SEED) Fund** provides first-equity support of up to ₹30 lakh to post-proof-of-concept startups to facilitate product refinement, validation, and early commercialization. By enabling pilot deployment, regulatory preparedness, and market entry, the scheme improves revenue potential and investor confidence. The 153 supported startups have collectively attracted over ₹1,162 crore in follow-on funding and generated around 3,000 employment opportunities, reflecting sustained growth and improved business viability.
- III. Similarly, the **Launching Entrepreneurial Driven Affordable Products (LEAP) Fund** extends equity support of up to ₹100 lakh to startups with validated technologies for scale-up, regulatory advancement, manufacturing readiness, and commercialization. This late-stage support helps enterprises expand production

capacity, enter new markets, and attract private capital. The 62 supported startups have raised over ₹893 crore in follow-on funding and generated nearly 1,300 employment opportunities, demonstrating strengthened market traction and long-term sustainability.

- IV. The **Make in India (MII)** Programme Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC) publishes a comprehensive landscaping report of India's biotechnology sector titled the **India BioEconomy Report (IBER)**.

As per the India BioEconomy Report 2025 (IBER 2025), the biotechnology sector in India has generated approximately 3.5 million jobs and has over 10,000 cumulative biotechnology startups in the country. The report also tracks the growth trajectory of the sector over time, thereby providing longitudinal insights into the expansion of the biotech startup ecosystem.

**DBT-BIRAC Biofoundries Programs**

1. Microbial Biofoundry for yeast and bacterial engineering at International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi.
2. Precision Biotherapeutics for scale up of Monoclonal Antibodies (mAb) and Live Biotherapeutics at Translational Health Science and Technology Institute (THSTI), Faridabad
3. Agri-food product at BRIC- National Agri-Food and Biomanufacturing Institute, Mohali
4. Pilot Scale Production of Biopesticides at Institute of Pesticide Formulation Technology (IPFT), Gurgaon
5. Bioengineering Research Center for development of Indigenous microbial chassis for Bioproduction at BRIC- NCCS, Pune
6. Cancer Cell Therapy Biomanufacturing Hub at ACTREC, Tata Memorial Center, Mumbai.
7. National Institute of Animal Biotechnology (NIAB) with HiMedia Laboratories Pvt. Ltd, Hyderabad-Nation's First Animal Stem cell repository
8. IIT-Madras with TICEL Bio Park Ltd, Chennai-Development and scale-up of products used in cosmetics, food, pharma and Bioplastic Industry.

**DBT-BIRAC Biomanufacturing Platforms**

1. Foundation for Science Innovation and Development (FSID), Bangalore with Tata Chemicals Limited- Pilot Scale Facility (100 L) to Scale up Specialty Chemicals and Enzymes.
2. Immunoadoptive Cell Therapy Private Limited, Mumbai-GMP grade facility for Gene Delivery vector.
3. Hi Tech Biosciences India Ltd, Pune- Fermentation facility (at a scale of 10 KL) to Produce drug Intermediates and Bio-energy Starter Cultures at Commercial Scale.
4. Embio Ltd, Mumbai- Pilot scale and large scale fermenters for Pre-commercial production of APIs.
5. Laurus Bio, Visakhapatnam- Fermentation Facility for Functional Foods, Smart Proteins, Bio-based Chemicals, Enzymes and Precision Biotherapeutics.
6. Virchow Biotech Private Limited, Hyderabad- Commercial Production of Monoclonal Antibodies and Biosimilars.
7. Agilent Bioplus LLP- scale up the production of gluconates.
8. Revelations Biotech Pvt. Ltd- commercial production of Fructo-oligo saccharides (FOS).
9. HiMedia Laboratories, Mumbai-1 KL scale for food based products, food additives, probiotics and cell growth stimulators.
10. Sundyota Numandis Probiocentials Private Limited, Ahmedabad- QMS compliant facility for commercial production of probiotics and smart proteins.
11. Jindal Steel, Angul- Facility for sequestration of CO<sub>2</sub> and its utilization for growing engineered microalgal strains.

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