

BIRAC announces

Call for Proposals under PACE, SBIRI and BIPP

in

- ❖ **HEALTHCARE (including devices and diagnostics, drugs and drug delivery, biosimilars and regenerative medicine and vaccines and clinical trials)**
- ❖ **INDUSTRIAL BIOTECHNOLOGY (including Secondary Agriculture)**
- ❖ **AGRICULTURE (including Veterinary Sciences and Aquaculture)**

The current call of BIRAC under PACE, SBIRI and BIPP is focused on pre-identified priority areas under three sectors: Healthcare, Industrial Biotechnology and Agriculture which are of national, social or commercial importance.

PRIORITY AREAS FOR FUNDING

1. Healthcare (including devices and diagnostics, drugs and drug delivery, biosimilars and regenerative medicine and vaccines and clinical trials)

Medical Devices and Diagnostics represent a diverse field with several distinct types of devices and diagnostics. Medical devices sector in India has undergone a transformation from being a non-regulated sector to regulated one for 15 notified devices with a risk-based classification of devices as per the new Medical devices rules in 2017. There has been a lot of effort in boosting domestic manufacturing of medical devices in the country by promoting state-level policies and through establishment of dedicated Medical device parks across India. There has been a positive wave of development in devices and diagnostics sector with lot of young entrepreneurs venturing into this sector. Currently, the focus is on medical devices that improve diagnostic, interventional and therapeutic treatments focusing on applied research and the development of new medical devices or instrumentation. Advances in medical devices, diagnostic testing and imaging are expected to continue apace enabling more care to be delivered closer to home. Intelligent devices and enhanced diagnostics could radically alter the way conditions are detected and treated, improving clinical outcomes and quality of life for the whole population.

The current call of BIRAC invites proposal focused on the development of Quantitative/semi-quantitative point of care diagnostics. Proposals based on development of high end medical devices (class 3 & 4) are also encouraged.

Under **Drugs and Drug delivery**, funding is focused on development and validation of affordable technologies and products with a view to reduce their cost, increase their availability and accessibility to the society. BIRAC has identified two priority diseases under this area: diabetes and respiratory diseases. Proposals based on the development of drugs or drug delivery systems targeting diabetes and respiratory areas are invited under the current call.

The primary motive of supporting the area of **Biosimilars and Regenerative medicine** is to make critical innovator biological drugs and cell based therapies affordable within the country. Many biological originator products are going off- patent in coming years, which provides a huge opportunity for India to capture the global market of Biosimilars. Also with its innovative capacity along with established facilities in stem cells, cord blood banking, tissue engineering, biomaterials and gene therapy and with regulatory guidelines in place, India is ready for investing in advance research for commercialization of regenerative medicine. The current call invites the proposals from academia and industry for developing technologies and products in the area of immunotherapy, reproductive disorders and regenerative medicine.

Vaccines are a smart investment for not only saving lives through immunization, but also preventing the devastating cost of hospitalization for treatment, thus contributing to global health economy. As a nation, it is critical that we continue to invest in programs that support our populations' wellbeing. Realizing the importance of vaccines, BIRAC invites proposals based on different aspects of vaccine development such as vaccine delivery, stability and use of adjuvants. Proposals based on development of oral vaccines, personalized vaccines and their modes of storage are also invited. Proposals on the clinical trial of developed vaccines are also encouraged.

2. Industrial Biotechnology (including Secondary Agriculture)

Industrial biotechnology encompass the area which consists of development of technologies focusing on creation of new products useful to the industry, modifying or developing processes using enzymes, finding alternative technologies to replace petroleum based products and environmental remediation. This area has the potential to develop processes with reduced water and energy consumption. Under **Secondary Agriculture**, projects focusing on value added products in the Agri-food sector are supported. The major driver for the growth of this sector is the large number of initiatives undertaken by governments for environment protection and pollution control. However, the area is marred by a number of challenges such as:

- Lack of potential disruptive technologies (scalable, low on cost, less GHG, time to market)
- High investment and production costs
- Limited availability of raw material
- High investment in R&D and process development and massive investments to build new production facilities
- Complex innovation processes as well as absence of critical regulations
- The technology transfer gap between basic R&D and the commercialization
- The combination of “technology push” and “market pull” along the value chain is necessary

To overcome the concern areas, BIRAC has decided to invite focused proposals based on priority areas having commercial potential to boost the industries working in those areas encompassing strain engineering, biomass conversion and food processing technologies.

3. Agriculture (including Veterinary Sciences and Aquaculture)

Agriculture is a potent resource for promoting sustainable development and reducing poverty in the current scenario. However, it requires a widening and perpetually changing array of knowledge and innovation to meet diverse needs of the world's growing population and to resist or mitigate the effects of climate change. The forces that generate knowledge and drive innovation in agriculture will also continue to change. Under the current call proposals are invited from academia and industry for the development of value added products including functional food, nutraceuticals and micronutrient fortification. Proposals are also invited on development of tools and technologies for preventing post-harvest losses and Information and Communications Technology (ICT) based applications in agriculture

Veterinary Science deals with diagnosis, cure and prevention of disorders, diseases and wounds for animals excluding human beings. It also deals with pests that may cause diseases, vaccines that can prevent the seasonal diseases and therapeutic solutions that involve medicines. Nowadays, focus is laid on the strategies to increase the productive longevity of ruminant animals through nutritional and therapeutic interventions which results in enhanced productivity and better health of animals.

Academia and Industry is invited to submit proposals based on gene mediated production of therapeutic proteins and multicomponent vaccines, biotechnological applications for feed digestion and better utilization. For animal vaccines, projects based on development of adjuvant and vaccine delivery systems are invited.

Aquaculture denotes harvesting of plants and animals in variety of water sources ranging from small lakes, tanks, and ponds to rivers and the Oceans. They are inclusive of rearing both fresh and salt water plants and animals including fish, crustaceans, mollusks and aquatic plants including micro and macro algae. Under the current call, projects based on production of probiotics, prebiotics, and synbiotics for aquaculture and development of pharmaceuticals/nutraceuticals from marine products would be screened for further processing.

SCOPE OF THE CALL

Under the present call, proposals are invited **ONLY** in the following areas:

- Healthcare (including devices and diagnostics, drugs and drug delivery, biosimilars and regenerative medicine and vaccines and clinical trials)
- Industrial Biotechnology (including Secondary Agriculture)
- Agriculture (including Veterinary Sciences and Aquaculture)

Products, Processes and Technologies with established Proof of Principle (for AIR/SBIRI)/ Proof of Concept (for CRS/BIPP) that can be developed to a commercial product will only be considered.

AREAS FOR SUPPORT

1. Healthcare

Devices and Diagnostics

- Quantitative/semi-quantitative point of care diagnostics
- High end medical devices (class 3 & 4)

Drugs and Drug Delivery

- Diabetes
- Respiratory diseases

Biosimilars and Regenerative Medicine

- Immunotherapy
- Reproductive disorders
- Regenerative medicine

Vaccines and Clinical Trials

- Vaccine delivery, stability, adjuvants,
- oral vaccines
- personalized vaccines and storage

2. Industrial Biotechnology (including Secondary Agriculture)

- Strain engineering and process development for production of Industrial enzymes (nitralase, esterase, asparaginase, specialty enzymes for orphan diseases, therapeutic enzymes, pharma products, Lignin valorization, enzymes for flavor and fragrances, protease) (scale of operation may be decided internally in accordance to the scheme)
- Biomass conversion to high value products (non-ethanol)
 - Rare sugars
 - Amino acids (Lysine, methionine, arginine)
 - Nutraceuticals
 - Isolation of protein and fibre
 - Protein supplement
 - Bioplastic
- Food processing technologies

3. Agriculture (including Veterinary Sciences and Aquaculture)

Agriculture

- Value added product development in Agriculture (including functional food, nutraceuticals and micronutrient fortification)
- Development of tools and technologies for preventing post-harvest losses
- Information and Communications Technology (ICT) based applications in agriculture

Veterinary Sciences

- Gene mediated production of therapeutic proteins and multicomponent vaccines
- Biotechnological application for feed digestion and better utilization
- Development of adjuvant and vaccine delivery systems

Aquaculture

- Production of probiotics, prebiotics, and synbiotics for aquaculture
- Development of pharmaceuticals/nutraceuticals from marine products

TYPES OF PROJECTS SUPPORTED

What is supported?

- Proposals with established Proof-of-Principle (PACE-AIR) and Proof-of-Concept (PACE-CRS, SBIRI, BIPP)
- Projects that propose a process/product innovation with significant potential impact or commercial potential
- Developed process should be sustainable from an economic and environmental point of view
- Should be scalable
- The Technology Readiness Level (TRL) at the end of the project should be:
 - 3 (Proof of concept established): PACE-AIR
 - 6-7 (Early and Late stage validation): SBIRI & CRS
 - 7 and above (Late stage validation upto pre commercialization): BIPP

What is not supported?

- Concepts/exploratory research ideas without proper Proof-of-Principle (PACE-AIR and SBIRI,) and Proof-of-Concept (PACE-CRS, BIPP)
- Proposals without preliminary data and potential for product/technology development
- Funding cannot be used to support PhD student research or any other academic research.
- The grant is not a research fellowship

WHO CAN APPLY?

Eligibility:

PACE-AIR:

1. Under the scheme, academia (Public or Private Institute, University, NGO, or Research Foundation) having a well-established support system for research shall be the primary applicant.

It can apply either:

- (1). Individually, or
- (2). Jointly with academic* and/or industrial** partner

**For Public or Private Institute, University, NGO, or Research Foundation, proper registration/accreditation from a government body is mandatory*

***Participating company (if any) should be registered under the Indian Companies Act, 2013 with at least 51% Indian shareholding i.e., shares of the Company should be held by Indian Citizens holding Indian passport (Indian citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders).*

2. The applicant Company should have adequate in-house facility to address the project implementation or incubated with any of the recognized incubation facility.

PACE-CRS:

1. Academia* has to be the Primary Applicant with one or more partners of which atleast one is a company**

**For Public or Private Institute, University, NGO, or Research Foundation, proper registration/accreditation from a government body is mandatory*

***Participating company should be registered under the Indian Companies Act, 2013 with at least 51% Indian shareholding i.e., shares of the Company should be held by Indian Citizens holding Indian passport (Indian citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders).*

2. The applicant Company should have adequate in-house facility to address the project implementation (which shall be evaluated during the site visit) or incubated with any of the recognized incubation facility.

SBIRI:

1. The proposals can be submitted
 - a. solely by a Company* incorporated under the Companies Act, 2013 or Limited Liability Partnership (LLP)** incorporated under the Limited Liability Partnership Act, 2008 or Joint Ventures either in the form of Company/ LLP
 - b. by any of the above entities jointly with other private or public partner(s) (Universities or Institutes).

**Minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport (Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders)*

***Minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens.*

2. The Applicant Company/LLP should either:-

- a) Have adequate in-house facility to address the project implementation (which shall be evaluated during the site visit) or
- b) Incubated with any of the recognized Incubation Facility

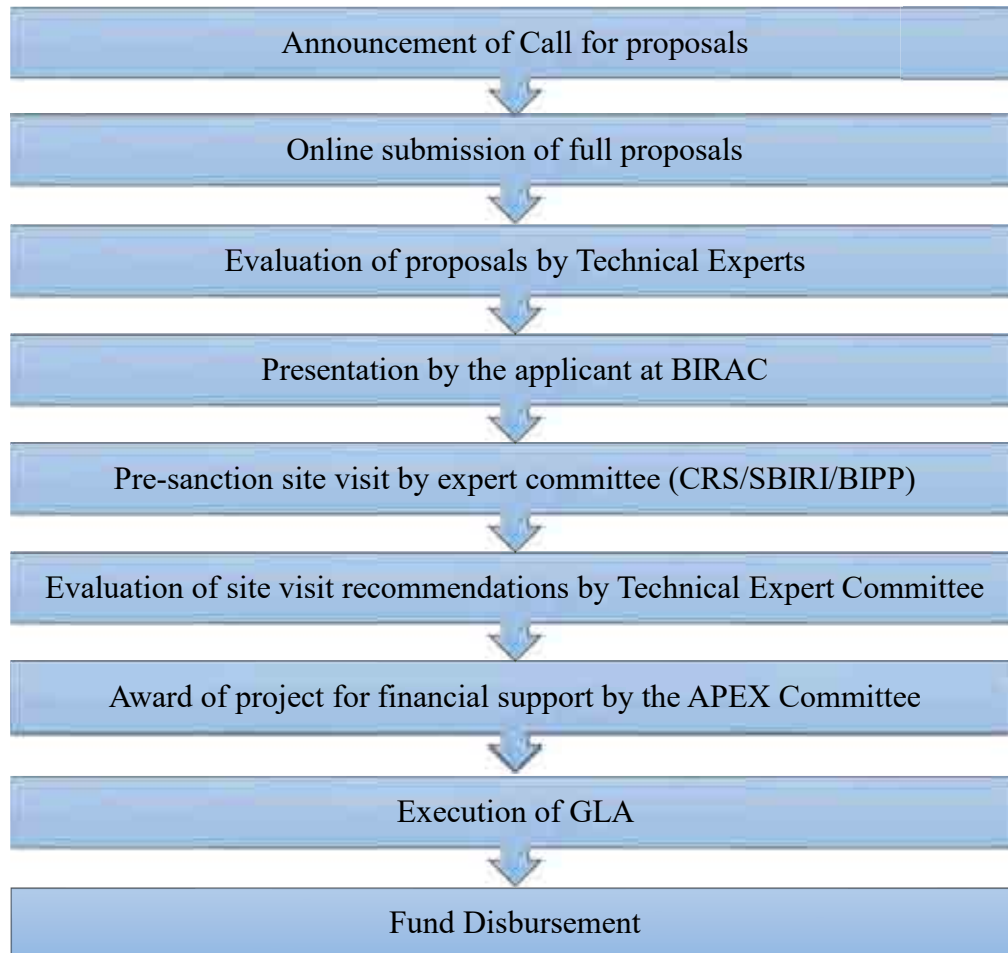
BIPP:

1. Single or consortia of Indian Company (ies) - Small, Medium or Large. An Indian Company is defined as one which is registered under the Indian Companies Act, 2013 and Minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport (Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders) The proposals can be submitted:
 - o Solely by an Indian Company; or
 - o Jointly by an Indian Company and National R&D Organizations and Institutions; or
 - o By a group of Indian Companies along with National Research Organizations etc.
2. The applicant Company should either :-i) Have adequate in-house facility to address the project implementation (which shall be evaluated during the site visit) or ii) Incubation with any of the recognized Incubation Facility.

DURATION OF PROJECT

Up to 18 months for proposal submitted under PACE-AIR. No specific duration has been fixed for PACE-CRS, SBIRI and BIPP schemes.

EVALUATION PROCESS



FUNDING

Funding support will be in the form of Grant-in-Aid and is scheme specific. Kindly refer to the guidelines of respective schemes for more details by visiting <http://www.birac.nic.in>

Fund Disbursement Policy

The fund disbursement is milestone based and will be released in 4-5 instalments as per the timeline of the project.

Instalment No.	When	Amount (for proposal more than 12 month)	Amount (for proposal less than 12 month)
1	Signing of Contract	30% of project cost	30% of project cost
2	Completion of 1st Milestone	20% of project cost	30% of project cost
3	Completion of 2nd Milestone	20% of project cost	30% of project cost
4	Completion of 3rd Milestone	20% of project cost	NA
5 (Final) *	Completion of project and submission of final report	10% of project cost	10% of project cost

**Since the last instalment is released after conclusion of the project, its nature would be reimbursement.*

DATE OF CALL FOR PROPOSALS

The call would open on 15th February, 2019 and shall close on 31st March, 2019.

CONTACT

For details related to TRL definitions, schemes and submission of proposals, please log on to <http://www.birac.nic.in>

For additional information/clarification, please contact:

Head-Investment (investment.birac@gov.in)

Biotechnology Industry Research Assistance Council (BIRAC)

1st Floor, MTNL Building,

9, CGO Complex,

Lodhi Road, New Delhi –110 003

Phone: 011 -24389600