

Request for Proposals (RFP)
Under
NATIONAL BIOPHARMA MISSION



for
Follow-on Funding for projects (Biotherapeutics and related infrastructure)
previously supported by BIRAC

Funded by
Department of Biotechnology, Ministry of Science & Technology, Government of India
Co-funded through World Bank Loan Assistance
(Innovate in India for Inclusiveness Project)

Through Implementing Agency
Biotechnology Industry Research Assistance Council (BIRAC)
(A Government of India Enterprises)



Section I - Program Overview - NBM

This is an Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - “Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation”, also referred to as National Biopharma Mission (NBM).

Funding agency

Department of Biotechnology (DBT) (Program co-funded by World Bank loan)

Implementing agency

Biotechnology Industry Research Assistance Council (BIRAC)

Background

According to the India Bioeconomy report 2022 by the department of biotechnology, by 2025 BioPharma sector is expected to grow nearly 1.4 times to nearly \$63 billion from \$45 billion in 2022. India-made biosimilars are getting accepted in developed markets like the USA. The report also said that there is immense opportunity in expanding the biosimilars space, as well as achieve discovery of newer molecules.

BIRAC has played a key role through its various schemes aimed in strengthening the biotherapeutic ecosystem. There are several products which have reached the market with BIRAC support. These include, Rasburicase to control Hyperuricemia under trade name TULY, a recombinant Uricase to control hyperuricemia in cancer patients by Virchow Biotech Pvt Ltd. First recombinant Follicle Stimulating Hormone (FSH) developed, manufactured, and sold by Bharat Serum and Vaccines Limited, India’s first urology cell therapy product (UREGROW®), an FDA approved therapy for the treatment of urethral stricture, developed by Regrow Biosciences Pvt Ltd.

In 2017, the Govt. of India launched the National Biopharma Mission (NBM), an Industry-Academia Collaborative Mission for accelerating discovery research to early development for Biopharmaceuticals, implemented by BIRAC. With stakeholder and expert’s consultations, opportunities and gaps were identified in Biotherapeutics product development, infrastructure, and raw materials requirement. Therefore, focused calls were launched under this Mission, in addition to the regular calls of BIRAC in the areas of Biosimilars, Shared Facilities, Novel Biologics, CAR-T Therapy, Raw Materials like Media, Resins and Single-Use Bioreactors.

Limited access for high-quality biologics due to high cost of treatment constitutes an unmet medical need all over the world. Biosimilars offer treatment options for diseases such as diabetes, and autoimmune disorders. One of the objectives of NBM is to promote 2-3 biosimilars (therapeutic proteins and/or monoclonal antibodies) and bring them closer to market. The purpose was to support development of Biosimilars 1) that are of high relevance for India, 2) for which innovator patents will expire by 2025 and 3) where there are very few or no Biosimilars in Indian market.

The supported Biosimilars which are now in advanced stage clinical trials include Liraglutide, Insulin Glargine, Aflibercept and Trastuzumab. In Novel Biologics, anti-Rabies monoclonal antibody, an anti-VGEF antibody for diabetic retinopathy, Antibody Drug Conjugate for cancer have shown encouraging data in preclinical studies.

Several other promising Biosimilar products which are supported under BIRAC are in various development stages include, Pertuzumab for breast cancer, Romiplastin for chronic immune thrombocytopenic purpura, Insulin Aspart for Diabetes, Bevacizumab, Ramcicirumab and CAR-T therapy for cancer, and recombinant Human Serum Albumin.

The projects funded for establishment of 'Shared Facilities' under NBM have started providing services to industry and academia. The regulatory-compliant, accessible facilities are catering to services for bio-analytical and functional testing, immunogenicity testing and cGMP manufacturing of clinical trial lots. The Clinical Trial Networks supported under NBM in the areas of oncology, diabetes, rheumatoid diseases, and ophthalmic diseases can provide ready access to patient population required by industry, academia and CROs for clinical trials.

To leverage on the supported ecosystem and strengthen the product pipeline in this sector, Follow-on funding call is proposed under the National Biopharma Mission, BIRAC with the following Aim:

- To boost already supported projects, either product, resources, shared facilities which have achieved the deliverables
- Accelerate past project outputs from NBM and other BIRAC schemes to reach advanced TRL levels
- Support academia projects or technologies with Proof of Concept Demonstrated, and need industry validation or scale-up to progress towards commercialization

Title: "Follow-on Funding for projects (Biotherapeutics and related infrastructure) previously supported by BIRAC"

Objective

To enhance the product pipeline of Biotherapeutics and provide **further support to already funded projects under BIRAC/NBM** to reach advanced TRL levels. Follow-on Funding call is proposed for:

1. Development of Biotherapeutics including Biosimilars, Novel Biologics, Cell and Gene therapy, Biologics Raw materials, IT Platforms for Quality Management Systems,

- Bioreactors, Platform Technologies, and any other technologies relevant to
Biotherapeutics
2. Strengthening of existing facilities

Scope

This call seeks proposals for development of projects supported under NBM and BIRAC schemes falling under:

1. Biosimilars
2. Bio-betters including antibodies and recombinant proteins
3. Novel antibody-based biotherapeutics including monoclonal antibody and antibody fragments (Fab, Fv, ScFv), Nanobodies, cell and gene therapy, antibody drug conjugates
4. Expansion of existing facilities without any civil/ construction work, to increase the service portfolio.
5. Platforms developed and requiring validation with industry
6. Validation and scale-up of Raw Materials

Expectation from Applicant

1. The applicant should be a BIRAC grantee and should have previous funded project ongoing/completed for which the follow-on funding is sought
2. The earlier project should have been successfully completed with clear achievements on deliverables
3. The proposal should be built up on the previous results and activities and have a clear development path
4. The proposal should show progress of at least 2 TRL levels beyond the current stage
5. The therapeutic candidate should have substantial improvement over marketed products. The areas of improvement could be improved specificity, efficacy, potency, half-life, immunogenicity, reduced toxicity and side effects, affordability as compared to existing therapeutics.
6. For shared facilities justification and need for expansion and support required should be elaborated. The current test services, comparative pricing compared to international agencies, pricing model for academia, start-ups, MSMEs, large Indian Companies International companies to be given in proposal. The extent of differential pricing based on BIRAC financial support to be mentioned

Intellectual Property

- The Applicant should have freedom to operate as related to IP, including consent from others where applicable.
- Intellectual Property developed under the BIRAC funding through this grant will be owned by and will be managed by the institution/company (unless stated otherwise).

Section II – Application Timelines, Process, Instructions, Applicant eligibility criteria and other processes for the RFP

1. Application Timelines

Key Dates

Call Opens	17th April 2023
Last Date of Submission	17th May 2023 (5:00 PM)

2. Application Guidelines and Process

The Proposals can be submitted online as per the required format.

2.1 Process for submitting the proposals online is detailed below:

- a. Go to BIRAC's website or Go the URL: <https://www.birac.nic.in/nbm/>
- b. Click on the RFP on NBM link under Programs and the active call would be highlighted.
- c. Click on the active call against which you wish to submit the proposal.
- d. Further details on 'How to Submit a Proposal' would be available in the User Guide available on the website.
- e. If you are a registered user, log-in using the credentials, else you need to register your company/organization by clicking on New User Registration.
- f. In case of new user registration, a computer-generated link will be sent to the email-id provided at the time of registration to generate a password.
- g. Once you login, you will be navigated to the proposal submission page under NBM link.

Instructions:

- a. Applicants are advised to fill-up and submit their applications early without waiting for the last date in order to avoid any last-minute contingencies. The system stops accepting applications automatically after **5:00 PM** of the last date of submission.
- b. Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review. Applicants are advised to provide self-contained proposals with essential supporting materials provided as uploads.
- c. Requests for changes in the proposal once submitted will not be entertained.
- d. Providing incorrect information intentionally is viewed adversely.
- e. Please read through this RFP in its entirety and ensure that your application, budget and organization are in compliance with the eligibility criteria provided. Proposals for projects that do not meet the eligibility criteria and/or do not directly respond to the call area will not be reviewed, regardless of their quality. You are strongly encouraged to contact BIRAC if you are unsure about the eligibility of your project.
- f. Proposed budget shall be made inclusive of all applicable taxes and shall be considered accordingly.
- g. Information on all relevant pre-existing agreements/ MoUs in connection to the proposed technology, background IP, collaborations, outsourcing, consultancy, joint ventures,

consortium partnerships, IP licensing, technology transfer, material transfer etc. should be provided at the time of proposal submission.

- h. Risk management proposal for the project should be submitted after scrutiny of the execution aspects of the project.

2.2 Eligibility Criteria

Who may apply?

The proposals can be submitted:

- The applicant should be a BIRAC grantee and should have previous funded project ongoing/completed for which the follow-on funding is sought
- Solely by Indian Company / LLP/ Non-profit organizations/ Society/ Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ which is a legal entity OR
- Jointly by Indian Companies/ Non-profit organizations / LLP/ Society/ Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ OR
- By an -academia consortium of Indian Company/ Non-profit organizations/ LLP/ Society/ Trusts/ Foundation/ Association/ Government entities/ Institutes/ R&D Organizations
- Indian Start-up companies in collaboration with Industry/Academia/research institutes/ are specially encouraged to apply.

2.3 Criteria Particulars for the Proponent entities

Indian companies

An Indian Company is defined as one which is registered under the Indian Companies Act, 2013 and a minimum of 51% of the shares of the Company should be held by Indian Citizens holding Indian passports [Indian Citizens do not include Persons of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders].

Non-profit organizations/ Government entities/ Institutes/ R&D Organizations

This will include Academic Research Institutes, Universities, Research Foundation, Medical Colleges, and Institutes – both public and private that are valid legal entities such as Trust, Society, or established under central or state statutes.

Limited Liability Partnership:

A limited liability partnership is defined as one which is incorporated under the Limited Liability Partnership Act 2008. Minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens. [Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders].

2.4 Relevant documents for submission in the application:

Companies: -

- a. Incorporation certificate
- b. Latest Share holding pattern as per BIRAC format only (For formats go to <https://www.birac.nic.in/nbm/cms/page/resources> and click Formats), certified by external CA with UDIN number and verified from MCA/ ROC records.

- c. Details regarding in-house R&D facility, if any, or Incubation agreement
- d. Audited financial details of last three financial years (i.e., 2020-2021, 2021-2022, 2022-2023), if applicable
- e. Copy of passports of the shareholders (in support of 51% eligibility criteria) or self-declaration of citizenship attested by a gazetted officer

Limited Liability Partnership: -

- a. Incorporation/Registration certificate.
- b. Partnership deed; or list of subscribers which states that minimum half of the partners are Indian citizens.
- c. Copy of passports of Indian partners/subscribers or self-declaration of citizenship attested by a gazetted officer.
- d. Research mandate/ details regarding in-house R&D facility, if any, or Incubation agreement.
- e. Audited financial details of last three financial years (2020-2021, 2021-2022, 2022-2023)

Indian institution/ universities/ public research organization/hospitals: -

- a. Affiliation/registration certificate or statute reference for establishment.
- b. Details regarding in-house R&D facility, if any, or Incubation agreement.
- c. If the institution/public research organization are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust.

Society/ Trust/ NGO/ Foundation/ Association: -

Society

- a. Society registration certificate.
- b. Details regarding in-house R&D facility, if any, or Incubation agreement.
- c. CA certificate (supporting the fact that half of the members of the society are Indian citizens)

Trust

- a. Trust deed.
- b. Details regarding in-house R&D facility, if any / Incubation agreement.
- c. CA certificate (supporting the fact that half of the members of the trustees are Indian citizens)

NGO/ Foundation/ Association

- a. Registration details/ certificate.
- b. Details regarding in-house R&D facility, if any / Incubation agreement.
- c. If the NGO/ Foundation/ Association are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/ Trust

3. Evaluation Methodology

- a. PMU-NBM, BIRAC will screen the proposals for eligibility to all the specified administrative and procedural provisions required in the RFP. If the application is found to be incomplete or not complying to the provisions described in the RFP, the application will be considered ineligible.
- b. Proposals that meet the eligibility criteria will be presented to the Scientific Advisory Group (SAG), Biotherapeutics of NBM. Eligible applicants will be invited for presentation to the Committee. The SAG will make its assessment and recommend shortlisted applications for further screening to the Technical Advisory Group of NBM. Proposals that do not meet the eligibility criteria will also be presented to the Scientific Advisory Committee by BIRAC.
- c. Written clarifications may be sought to ensure that any outstanding questions are resolved prior to concluding the full review.
- d. Financial due diligence and site visit of the applicant may be conducted by BIRAC if recommended by the SAG or BIRAC finance. The site visit Committee report will be communicated to the SAG Co-Chairs. If recommended by the SAG Co-Chairs, the proposal will then be presented to the Technical Advisory Group.
- e. A final decision on applications to be funded will be made by the Technical Advisory Group.

All personal data will be stored and used by or on behalf of DBT/BIRAC in accordance with the Acts and confidentiality norms.

DBT/BIRAC reserves the right to not to process your proposal should you be ineligible to be a proponent or should the subject of your proposal not fall within the RFPs' remit. Mere consideration of the Proposal in no way implies that sanction of Grant-in Aid will be forthcoming unless other legal requirements are fulfilled.

4. Evaluation and Decision-Making Criteria

a. Proposal Merit:

- Does the proposal's approach align with the objective of RFP?
- Does the proposal demonstrate previous work and results which will be useful for the proposed scope of work?
- Are the objectives, activities, and milestones well defined?

b. Team/Applicant:

- Is the Primary applicant competent to ensure effective conduct of the proposed work?
- Does the applicant team have relevant capabilities and appropriate experience for the same?
- Have the collaborations if any, have adequate technical expertise and background experience to achieve the objective of the RFP?
- Has the applicant provided letters of support/agreements with any third party they would like to engage with during the different stages of product development?

c. Implementation:

- Has the implementation methodology and work plan adequately detailed and realistic?
- Has the applicant provided clear metrics for monitoring project progress including milestones, and outputs expected timelines, budget and benchmarks? Do they seem feasible in the given time frame?
- Have the resources (technical and management people, equipment, collaboration, outsourcing needs etc.) required over the time frame been comprehensively mapped?
- Has the applicant anticipated difficulties/risks that may be encountered? Have alternative tactics and mitigation plans been considered in case of failure?

d. **Business Strategy:**

- Has the applicant provided any market surveillance for the said product?
- Has the applicant provided any details on cost effectiveness of the product?
- Has the applicant considered affordability on account of availing the Mission's funding?
- For shared Facilities support has the applicant given pricing model, facility governance model, differential pricing model?

e. **Budget Estimates:**

- Can the budget proposed be sanctioned as per BIRAC norms and mandates? Is the proposed budget reasonable considering the defined scope of work?
- Have reliable references been provided for justification?
- Is the resource allocation across various stages sufficient and appropriate?
- Is the proposed budget clearly demarcated under specific Heads of RFP?

5. Requisites for Funding

Decision to fund will be as per sanction of the competent authority. Successful proponents shall enter into necessary funding agreements. The fund disbursement will be subject to completion of required formalities. The disbursement will be by way of Grant-in-aid assistance. The fund recipient shall be accountable for fund utilization as per the sanction. Re-appropriation of funds can be undertaken only after prior approval of BIRAC, within the same Budget Head. Disbursement under budget sub-head is subject to specific utilization produced before and evaluated by BIRAC

In addition to signing of agreement between all the concerned parties, following requirements need to be completed before the first instalment can be released:

- a. A letter of authorization by the Head of the Academia and/or A Board Resolution from the Company Partner for acceptance of the Grant-in-Aid under NBM
- b. A No-Lien Account with a scheduled/nationalized Bank
- c. MoU with collaborator(s) (if applicable)/letter of support from contributors
- d. Commitment to comply with Clinical Research Validation and Management Framework (CRVMF) <https://www.birac.nic.in/nbm/uploads/2019/08/crvmf.pdf>
- e. Commitment to obtain all applicable environmental authorizations, prior to the commencement of product development activities

- f. Inclusion of qualified environmental / EHS engineer in the team for implementation of Environment and Health Risk Management Plan (EHRMP) and comply with Environmental Management Framework (EMF) requirements during all stages. Requirements on Environmental aspects may be found at <https://www.birac.nic.in/nbm/uploads/2019/08/emf.pdf>
- g. Adhere to the Project Risk Management Plan during all stages of execution
- h. Submission of documents related to conveyance of interests in the background technology/IP
- i. Any other additional document that may be sought by BIRAC

6. Funding Mechanisms

Project must be budgeted on a milestone basis. Applicants are encouraged to submit proposal for up to a duration of 24 months, however duration may change based on recommendation of the Advisory Groups. Fund disbursements will be subject to the project team attaining the proposed milestones. The primary applicant and the proposed collaborators should specify the funding requirement for their corresponding milestones. The funds will be disbursed to them separately, subject to the successful achievement of milestones and reporting of progress to BIRAC

a. *Allowable costs include*

- The expenses towards the project will be considered from the **project start date** which will be communicated to the applicant by email from BIRAC technical officer.
- *Personnel*: All personnel working on the development of the product *only* are allowed to claim costs. Researchers and PIs who receive a salary from the host institution as permanent or fixed term staff members may NOT claim salary reimbursement from BIRAC grants. Salaries for manpower may be charged who could technically contribute to the project provided the staff is drawing salary from a single source and contributing full time to the project.
- *Technology Consultants*: These may include both national and/or foreign consultants who provide a service and capability that is not available among the project partners. Preference should be given to national service providers.
- Supplies and consumables for the equipment required in the project
- Travel and accommodation: Travel for conferences, Conclaves, workshop, paper presentation, meetings must be directly related to the execution of the project or travel related to seeking technology transfer
- Institutional overheads (maximum 8% of recurring budget); may cover utilities, manpower, or unforeseen costs
- IP protection (Project related) – Upto Rs 2 Lakhs
- Conduct of pre-clinical/clinical studies, if provisions for which are currently not feasible in the country and need to be outsourced, appropriate justification for the need to be submitted

b. *Non-allowable costs include*

- Purchase or construction of a building/ space/ land
- Rental costs for space
- Refurbishment costs
- Recruitment costs for staff

- Legal fees
- Setting up large scale manufacturing facilities
- Commercialization
- Salaries for PI in government organizations and academic institutes
- Withdrawal of cash from no-lien account for petty expenses

7. Program Monitoring Mechanism

Project Monitoring Committee (PMC)

The projects shall also be monitored and mentored regularly by a Project Monitoring Committee (PMC) constituted by PMU-NBM, BIRAC for each project. The PMC is responsible to monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives contained in the Agreement.

Based on the foregoing, PMC will assess and recommend:

- Release of next instalment or part release thereof by BIRAC
- Revision of project duration
- Closing or dropping or modifying any of the components of the Project within the overall approved objectives, budget, and time-frame
- Mentor(s) to overcome any technological problem faced in the Project implementation
- To advise on issues related to securing of IPR
- To advise on any other matter as referred to it by BIRAC and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of proposed Scheme

8. Reporting of Progress

- On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format
- The MCR will be assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget will be released
- The Applicant will have to submit an audited and duly certified Utilization and Statement of Expenditure for every 30th September and 31st March.
- Format for MCR, Utilization Certificate and Statement of Expenditure will be made available as per requirement
- Compliance to the Project Risk Management plan

Note: We welcome potential applicants contacting the Mission before submitting applications to clarify any questions or discuss their ideas with us. Kindly submit the application at least a few days before the deadline to avoid technical difficulties at the last hour. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Contact Information

Further information can be obtained at BIRAC website. **BIRAC Website:** www.birac.nic.in

Contact Person:

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