

Request for Proposals (RFP)

for

Development of candidate therapeutics, or any other novel approaches, and countermeasures to combat Anti-Microbial Resistance

Under

NATIONAL BIOPHARMA MISSION



Funded by

Department of Biotechnology (DBT), 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

Antimicrobial resistance (AMR) is a growing pandemic and a potential threat to public health in the 21st century. Based on estimates from 204 countries and territories, the Global Research on Antimicrobial Resistance (GRAM) report published in the Lancet on 19th January 2022, mentions that in the year 2019 4.95 million deaths may be associated with drug-resistant infection and at least 1.27 million people died as a direct result of antibiotic-resistant bacterial infections India has some of the highest antibiotic resistance rates among bacteria that commonly cause infections in the community and healthcare facilities

([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/)).

As per the analysis published in Antimicrobial Agents and Chemotherapy in March 2022, 76 antibacterial agents are currently in clinical development, 41 of them targeted toward WHO priority pathogens (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8923189/>). Globally, the focus is now on developing combination drugs for aiming at multiple targets and decreasing the need for high dosages, and the development of resistance. In a review published in Nature Reviews Microbiology in 2019 out of 407 antibacterial projects under development, half are novel approaches like repurposed drugs, engineered phages, microbiome-modifying strategies, vaccines, or ant virulence agents (<https://www.nature.com/articles/s41579-019-0288-0>).

Considering AMR as a National priority, under the National Action Plan endorsed by Govt. of India, the Department of Biotechnology initiated a major Mission program on Antimicrobial Resistance with the vision to develop indigenous and cost-effective therapies against AMR. In the recent past few companies from India have been able to seek international grants like CARB-X, and BIRAC and UK partnership-based innovation foundation-Nesta grant in this area. Based on the critical need to tackle AMR and efforts being undertaken to develop innovative interventions towards this Mission, the BIRAC, under the aegis of the National Biopharma Mission aims to support the development of scientifically appropriate products being developed in India under the below objective.

**Antimicrobial resistance is a global priority to save lives.
India urgently needs effective therapeutics to solve this
problem. The BIRAC initiative aims to catalyse India made
solutions**

Objective

Development of new antibiotics, therapeutics, or any other novel approaches to combat Anti-Microbial Resistance

This program is to seek Request for Proposals (RFP) for supporting –

Development of products active against sensitive and drug resistant microbial pathogens mentioned in the Indian Priority Pathogen list (mainly, *E. coli*, *Klebsiella Pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, carbapenem resistant *Enterobacteriaceae* (CRE). The products should have established proof of principle including but not limited to the following -:

- *New Chemical Entities or antibiotics from a new class with a novel mechanism of action (first in class), or pre-existing class of drugs (best in class), Repurposed Drugs, Combination with existing drugs*
- *Therapeutics which may be broad-spectrum or pathogen-specific antimicrobial Peptides, genetically-engineered antibodies, Immunomodulators, molecules that modulate virulence or pathogenicity, Microbiome modulating agents, bacteriophage therapies*

Scope of the Call:

- The product should address the bacterial pathogens and the resistances identified in the Global priority list of antibiotic-resistant bacteria published by the WHO; and conforms to the Indian Priority Pathogen List developed by WHO India, in collaboration with the Department of Biotechnology, Govt. of India
- The molecule should have at least established proof of principle (Completed TRL-2* stage as per BIRAC TRL (https://www.birac.nic.in/desc_new.php?id=44) TRL is Technology Readiness Level.
- The product should have a progress plan for at least 2 TRL levels from the current TRL level under this call, e.g, proposals starting from TRL-2 should reach at least TRL-4 at the end of the project duration.
- The following proposals would be encouraged:
 - Collaborative or Consortia-based proposals from academia and industry (academia with/without industry). The support from non-academic partner should be in the form of commitment of one or more resources including, but not limited to: product/prototype development support/guidance, personnel, in kind contributions of materials and/or reagents [i.e., chemical libraries, innovative biotechnology platforms, scale up or production, provision of animal or other laboratory models for evaluation, data management resources or regulatory support].
 - Industry with already established/identified leads and explicitly outlined deliverables for further validation.
- In-licensing of molecules for further development in country may be considered with appropriate justification provided for in-licensing, and a plan to introduce the product in public and private market in India.
- This call will not support:
 - Proposals without Established Proof of Principle
 - Activities related to commercialization
 - Fundamental/basic research

Expectations from the Applicants:

1. Proposals should be supported with clear product modality, target pathogen (s) and rationale for targeted pathogen (s)
2. Applicant should have accessibility to AMR samples, library or repository of clinical samples or plan for sourcing the same
3. Proposal to be supported with clearly defined product development plan with details of proposed activities, milestones which are quantifiable, timelines and the budget estimates, and aspects as applicable to TRL levels. The non-recurring budget component if any, should be not more than 10% of the total budget and supported with strong justification
4. Should have strategies to address impediments and failure of candidate in preclinical stages
5. Clear demonstration Freedom to Operate and licensing ownership by an Indian entity as applicable.
6. Details of partnerships, collaborations, consultations with global or national experts, regulatory agencies that will be established for ensuring conduct of proposed activities should be included in proposal.
7. Proposal should indicate the feasibility of advancing the candidate from current readiness state of technology (stage of development) by providing clear understanding and articulation of risks and rationale of proposed solutions to these risks (most significant technical, regulatory and IP risks)
8. The data generated as an outcome of this grant should comply with ICH guidelines and suitable for submission to DCGI for seeking relevant approvals

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

1. Application Timelines

Key Dates

Call Opens	10th March 2023
Last Date of Submission	24th April 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:

- 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 Industry-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.,2018-19, 2019--20, 2020-2021), 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 (2018-19, 2019-20, 2020-21)

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 submitted for peer-review by national and/or international reviewers to assess the proposal merit by online review, constituting Area Review panel (ARP). Reviewers will be checked for conflicts of interest and will sign confidentiality agreements. Information may also be shared with selected third parties for the purposes of independent audit, evaluation and assessment of activities.
- c. The Scientific Advisory Group will collate the results of the reviews, make their own assessments and recommend shortlisted applications for further screening to the Technical Advisory Group.
- d. Grantees may also be invited for interaction or sought written clarifications when it is felt beneficial to ensure that any outstanding questions are resolved prior to concluding the full review.
- e. Technical and financial due diligence process (site visits) of the shortlisted applications would be carried out by PMU-NBM, BIRAC as part of the review process before presenting the proposal to Technical Advisory Group.
- f. 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. 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. Opening up 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

5. 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:

- a. Release of next instalment or part release thereof by BIRAC
- b. Revision of project duration
- c. Closing or dropping or modifying any of the components of the Project within the overall approved objectives, budget and time-frame
- d. Mentor(s) to overcome any technological problem faced in the Project implementation
- e. To advise on issues related to securing of IPR
- f. 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

6. Reporting of Progress

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

7. Funding Mechanisms

Project must be budgeted on a milestone basis. Funding will be awarded for maximum up-to 30 months depending on the objectives. 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***

- *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. Lateral hiring process is strictly not allowed.
- *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 & 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
- Attendance at conferences
- Legal fees
- Setting up large scale manufacturing facilities
- Commercialization
- Salaries for available manpower and staff

8. Intellectual Property

- The applicant team 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 the responsibility of the applicant (unless stated otherwise).

9. Evaluation and Decision-Making Criteria

a. **Proposal Merit:**

- Does the proposal's approach align with the objective of RFP?
- Does the proposal demonstrate preliminary work of the identified product which will be useful for the proposed scope of work?

- Are the objectives, activities and milestones well defined?
- Does the proposal identify project objectives with the AMR Mission?

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?
- Does the applicant qualify the basic eligibility criteria mentioned in the guideline?

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?

e. Budget Estimates:

- Can the budget proposed be sanctioned as per BIRAC norms and mandates? Is the proposed budget reasonable in light of 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?

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

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