

Guidelines for Mission program on Antimicrobial Resistance Call

Process Flow and Terms

DBT-BIRAC Joint Call

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Background

Antimicrobial resistance (AMR) is one of the major threats to human health in the 21st century, with some bacterial pathogens acquiring resistance to all clinically available antibiotics. Worldwide, infections caused by multi-drug resistant (MDR) bacteria are now a major cause of morbidity & mortality and have markedly enhanced healthcare costs. Considering AMR as a National priority, under National Action Plan endorsed by Govt. of India, the Department of Biotechnology has initiated a major **Mission program on Antimicrobial Resistance** with the vision to develop indigenous and cost-effective therapies against AMR; categorization of AMR-specific pathogen priority list of India; establishment of Bio-repository for AMR-specific pathogens; and development of rapid and cost-effective diagnostic kits to identify AMR-specific pathogens.

In a process to fulfil the ambition of this program, **Department of Biotechnology (DBT)** in collaboration with **Biotechnology Industry Research Assistance Council (BIRAC)** will invite pre-proposals in the area of development of new antibiotics and alternatives to antibiotics to counter AMR.

Objectives

With the aim to discover, develop and exploit new resources for antibiotics and alternatives to antibiotics, under this joint Call, the Department is seeking concept note/pre-proposals under following two categories:

- A. Development of new antibiotics
- B. Development of alternatives to antibiotics-
 - a. Therapeutic antibodies
 - b. Phage therapy and
 - c. Anti-biofilm products

From this joint Call, the Department seeks new innovative approaches that have the potential to transform public health action on a national or global scale by identifying and filling gaps in knowledge on the development of drugs to counter AMR. This Joint Call is aimed to support collaborative proposals that combine complementary and synergistic research strengths in any one of the aforementioned categories/sub-categories. The following pre-proposals would be encouraged for support:

1. Consortia-based concept notes/pre-proposals from academia (with/without industry) with already established/identified leads and explicitly outlined deliverables for further validation.
2. Innovative proposals with established proof-of concept.
3. Investigations based on, or involving, clinical trials.

Call/Advertisement

1. DBT will launch a national call for AMR MISSION Program. The Call for Proposals will be advertised on DBT website and in various leading Newspapers, & Scientific Journals.
2. The Call window inviting proposals is typically open for a period of one and half months.
3. The applicant needs to submit an online application for funding by registering and logging-on the DBT website www.dbtindia.nic.in. Please note that applications are accepted online only.
4. Applicants are advised to fill-up and submit their applications early honoring the established deadline, without waiting for the last date in order to avoid any last minute contingencies/clogging of website. The system stops accepting applications automatically at midnight of the last date of receipt of application.
5. Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review process. Applicants are advised to provide self-contained proposals with essential supporting materials

Expectation of the Call:

The call will cover research addressing the following topics:

1. Identification of new bacterial targets and/or therapeutic compounds.
2. Re-evaluation of existing anti-microbial compounds either alone or in combination with other drugs or immune-modulators.
3. Investigation on novel enzyme(s)/ targets/ mechanisms to overcome known antimicrobial resistance mechanisms and restore susceptibility to conventional antibiotics.
4. Investigation on alternative therapeutics that enhances immune pathogen elimination through therapeutic antibodies & phage therapy; and disrupts colonization & bio-film development through anti-biofilm products.

Not within the scope of the call:

1. Over-ambitious investigations encompassing both the categories/clubbing two or more sub-categories of alternatives to antibiotics.
2. Individual projects with limited R&D value.
3. Proposals focusing only on knowledge generation without a drug candidate/alternative candidate.
These may include:
 - a. Investigations addressing cross talk between the host and pathogen, as well as the relationship between microbes, environment and infection.
 - b. Assessing the role of commensal flora in homeostasis and microbe's pathogenicity, and elucidating how commensal organisms or pro-biotics can be used to prevent or treat infections.
 - c. Investigations on initial steps of the infection process.
4. Studies on bacteria not on the WHO Global priority list.
5. Investments in research infrastructures are not covered under this call.

Primary Applicant: The primary applicant for this call is mandatorily academia either alone or with industry.

Collaborations: Collaborative proposals would be encouraged. These may be:

1. Academia with academia
2. Academia with industry

Please note that even for collaborators, the basic eligibility criteria as below needs to be met.

Intellectual Property (IP):

Background IP rights and the new IP both generated during the project will rest with academia only. However, the industry partner will have the first right of refusal for commercial exploitation of the project development. Project development, shall mean the technology/know how, background IP, New IP, and anything that is capable of commercial exploitations that generated from the project.

Eligibility criteria:

Please note the following eligibility criteria carefully.

1. Eligible Organizations

- a. Central/State Govt. Institutions of Higher Education
- b. Private Institutions of Higher Education
- c. Research institutes, universities, medical schools, IIT's and other engineering institutions, other recognized research laboratories in the public sector and not for-profit institutions.
- d. The institution must be recognized by DSIR as a Scientific and Industrial Research Organization (SIRO), if outside public sector.

2. Required Registrations

Private institutions/Hospitals/ NGOs should be registered in Darpan Portal, Niti Aayog website.

3. Eligible Individuals-Principal Investigator(s)

Scientists working in established Universities/Academic Institutions/National Laboratories/Industries [Department of Scientific & Industrial Research (DSIR)-Recognized R&D Centre] & Non-Profit Organizations with necessary facilities and strong scientific background in the proposed area as the Principal Investigator(s) are invited to develop an application for support.

4. Eligible Industry (Companies)

An Indian company is defined as one which is registered under the Indian Companies Act, 2013 and minimum 51% of shares of the Company should be held by Indian citizens holding Indian passport. (Indian Citizens do not include Persons of Indian Origin (PIO) or Overseas Citizen of India (OCI) holders). The company should have its own in- house R & D facility that are functional and adequate to execute the proposed project components.

AMR cycle: 5 months from application stage to funding

Support Documents for AMR Application:

1. Letter of Agreement from key members of the technical team/engagement
2. Formal Agreement/MoU/Letter of support from academic partners
3. Formal Agreement or MoU with company
4. Letter indicating the TRL of the proposed study
5. Requisite regulatory approval for the study
6. Any other due diligence certificate requested by DBT

Call/Advertisement

1. A national call for proposal under the AMR Mission Program is to be launched on DBT website and in various leading Newspapers, & Scientific Journals.
2. The Call window inviting LOIs typically will be for a period of six weeks to two months.
3. LoIs will be submitted in the prescribed format **(Annexure-I)** through online: <http://dbtepromis.nic.in/pi/loi.aspx> and the proposal submission is in two phases:
Phase I: Letter of Intent (LOI) - In this phase, interested applicants may apply through a LoI to be submitted online on the link provided.
Phase II: Full proposal - successful LoIs will be invited to submit full proposals in this phase.
4. Applicants should fill-up and submit their applications early honoring the established deadline, without waiting for the last date in order to avoid any last minute contingencies/clogging of website. The system stops accepting applications automatically at midnight of the last date of receipt of application.
5. Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review process. Applicants are advised to provide self-contained proposals with essential supporting materials

6. Requests for changes in the LOIs once submitted will not be entertained.
7. Providing incorrect information or employing corrupt or fraudulent practices shall be viewed adversely.

ARP shortlisting & full proposal shortlisting

The Area Review Panel (ARP) will consist of eminent domain experts which is constituted with the requisite approval. The experts have to sign a no conflict of interest and confidentiality agreement after the proposals are assigned to them. In Phase I, only LoIs will be accepted through the online system. These will be evaluated by an experts committee and successful LoIs will be invited to submit full proposals. The full proposals will be evaluated by AMR Screening Committee and shortlisted for further screening

The evaluation process by AMR screening committee will be based on the below factors:

Evaluation criteria:

1. Scientific merit
2. Clarity of hypothesis
3. Relevance and ability to implement approaches
4. Background of the investigator
5. Feasibility of conducting the research in the present settings

The AMR expert committee panel consisting of eminent domain experts may call for proponent's presentation or may recommend site visit of shortlisted proposals. The final recommendations will be processed for approval of the competent authority.

Financial concurrence and release of Governing Agreement by DBT/BIRAC

Subsequent to DBT APEX recommendation, financial concurrence will be taken for company component by BIRAC followed by approval of MD- BIRAC and Chairperson BIRAC. The amount concurred for the company will be communicated to DBT.

Sanction Order will be issued by DBT to all parties with final milestones and budget. Further DBT will process MOA to Academia. BIRAC will process a separate GLA with company .MOU between funds recipient will be furnished before sanction order is issued by DBT which will be independent of any of the funders to reflect the mutual agreement aspects of the fund recipients, specifically roles and responsibilities, IP ownership for academia, first right of refusal to company, dispute resolution etc.

Funding

The funding support offered will be in the form of grant-in-aid. There is no cap on funding but will commensurate with activities.

No funds will be allocated under Nonrecurring head for the company. The fund disbursement will be milestone based i.e. 4 installments for 12 months project and 5 installments for ≥ 18 month's project. The fund disbursement by BIRAC to industry will be milestone based and will be released in 4 installments in case of 12 months project and 5 installments in case of ≥ 18 month's project. First installment (30%) on sanction of the project & last installment on completion of the project and submission of the project report (~ 10%). The remaining installment with 20%+ 20%+20% or 30%+30% release depending on the duration of project. PI will define the budget heads with due diligence and justification. The releases will be done based on recommendation of project monitoring committee from DBT BIRAC and UC- SOE submitted by Industry.

Post Funding

The releases will be based on milestone based achievement which will be monitored by project monitoring committee. The fund recipient shall submit technical milestone attainment report periodically.

Acknowledgement

The funding support by DBT/BIRAC shall be duly acknowledge when publishing/showcasing/or presenting project particulars or outcomes.

Other Formalities

Fund releases for the project will be subject to fulfilment of certain formalities such as opening of no lien account by the company, submission of Board resolution by the company, submission of letter of authorisation by the academia etc.

For Further details

Contact:

DBT:

BIRAC:

Indicative timelines

<u>Activity(ies)</u>	<u>Time line(in days)</u>
Call Launch for LOI	Day 0
Call for LOI closes	Day 15
LOI selection by Expert committee	Day 30
Full Proposal Submission opens	Day 60
Full proposal review meeting by expert selection Committee	Day 103
Presentation by Applicants	Day 133
Apex meeting	Day 150
Sanction Order, Agreement, Fund disbursal	Day 165

**Proforma for submission of Pre-Proposal on Innovative
Approaches to address Antimicrobial resistance**

Annexure-I

(Maximum five single space printed A4 pages)

1. Title of the Concept note/Pre-Proposal:

2. Coordinator/Principal Investigators/Co-investigators:

Name:

Address:

Telephone:

Email:

3. Background of work:

a) Category under which proposals to be submitted (Please note that you can only apply under any one of the following categories):

- New antibiotics
- Therapeutic antibodies
- Phage therapy and
- Anti-biofilm products

b) What is the primary aim of your proposal?

c) What is the novelty and relevance of your approach to address the problem?

d) What is the preliminary work done? Please include details and data on the same.

e) What are the Primary Objectives of the present proposal?

- f) What is the workplan for achieving the stated primary objectives?

- g) What is the team competence and infrastructure availability for doing the study in your present institution/workplace/collaborations?

- h) Best 3 publications in the last 3 years in relevant areas:

- i) Brief CV of the investigators/collaborative partners: