

**Biotechnology Industry Research Assistance Council
(BIRAC)
A Government of India Enterprise**

Request for Proposal (RFP)
Grand Challenges India Funding Opportunity
On

Antimicrobial Resistance (AMR)

Jointly funded by

**Department of Biotechnology (DBT)
Ministry of Science and Technology
Government of India**

&

Bill & Melinda Gates Foundation (BMGF)

1. Introduction

Grand Challenges India

In 2012, the Department of Biotechnology, Government of India, and the Bill & Melinda Gates Foundation signed a Memorandum of Understanding (MoU), where both parties agreed to collaborate on scientific and technological research to alleviate some of the world's most critical global health and development issues, for the benefit of the people of India and other developing countries.

This partnership seeks to identify opportunities to initiate and promote scientific and technological research in the country, to provide India-specific solutions for the country, which can then be adapted for use in other developing countries. Specifically, the partnership focuses on encouraging research and exploring avenues to reduce maternal and child mortality and morbidity; developing scientific and technical solutions for infectious diseases; strengthening India's scientific translation capacity; developing scientific and technical advances related to agriculture, food and nutrition, among others

Grand Challenges initiatives follow these core principles:

1. Strategic and well-articulated grand challenges serve both to focus research efforts and capture the imagination and engage the world's best researchers.
2. Projects are selected based on national and societal need and transparent calls for proposals seeking the best ideas.
3. Funders, investigators and other stakeholders actively collaborate to accelerate progress and integrate advances to ensure these advanced technologies reach to developing countries masses
4. Projects are selected not only for scientific excellence, but also for their likelihood to achieve the desired impact, and they are milestone-driven and actively managed to that end.
5. Projects and investigators will have to follow global access commitments to ensure the fruits of their research are available to those most in need.

Here we announce a call on 'Antimicrobial Resistance', a program directed at addressing challenges that we face in tackling antimicrobial resistance in India and in comparable geographies.

This call is part of a global call on antimicrobial resistance, where Grand Challenges partners from Brazil, South Africa, Africa and India have come together and announced a call for proposals. Each country partner will be running the call in their country.

Given the international nature of this call, there is scope for international collaborations across partner countries.

This Request for Proposals (RFP) is specific to Indian researchers. We encourage partnerships with researchers in other countries, especially where the opportunity exists to build on established collaborations.

2. Program Details

This program aims at encouraging innovation in tackling AMR under three specific categories: solutions for better use of surveillance data to achieve actionable results, innovations in products and technologies to break infection cycles in healthcare settings and to remove antibiotics from effluents.

Background

Antimicrobial resistance is a growing threat to public health, and in the last few years has begun receiving attention from the research and medical communities with increased thrust and funding being made available for R&D in this space. However, AMR is a broad umbrella term and comprises of several aspects across different disciplines such as drug discovery, diagnostics, surveillance, antimicrobial stewardship in humans and animals, antibiotics in the environment among others. Therefore, tackling AMR requires efforts across themes and disciplines.

The Government of India with its associated bodies has undertaken several programs to fund R&D such as through the Indian Council of Medical Research, the Department of Biotechnology among others in a variety of fields, including research in drug discovery, diagnostics development, repurposing of old drugs and setting up surveillance networks. However, there are still areas that will benefit from targeted funding, such as surveillance, prevention of infections and environmental AMR.

Fulfilling an unmet need

While there are efforts to develop surveillance networks in India through government agencies such as the Indian Council of Medical Research, there is much that still needs to be understood regarding resistance patterns, and its epidemiology. There is a need to explore new data sources, analytical techniques and biomarkers, that may allow us to gather better and more accurate data about how resistance develops and moves in the community. This kind of data will be particularly useful for establishing algorithms that can predict trends in resistance development and its associated factors so that appropriate interventions could be planned.

Another area where research is particularly important, especially for India, given its high rates of infectious disease, is innovative low-cost products and technologies that can be used to break the cycle of infections especially in healthcare settings. Since the drug development pipeline takes a very long time, another alternative to tackle resistance is to break the chain of transmission of these resistant microbes.

The effect of antibiotics in the environment is still not well understood, but what is known is that there is a large outflow of antibiotics/antimicrobials from various sources such as industries that produce APIs for antimicrobials, the community, farms, industrial agricultural set ups among others. It is therefore important to arrest this flow of antibiotics into the environment through new technologies and products.

a. Programme objective

Therefore, this call seeks proposals that are exploratory or seek to develop proof of concept in three areas, specifically solutions for surveillance, low-cost technologies and products that will improve infection prevention in healthcare settings and technologies that will remove antibiotics/antimicrobials from effluents.

b. What we are looking for

Proposals must provide a strong rationale for the work proposed, demonstrating a clear understanding of India's context and needs, and present a defined hypothesis and associated plan for how the idea would be tested or validated.

Surveillance Solutions

We seek new approaches that have the potential to transform public health action on a regional or global scale by identifying and filling gaps in knowledge on antimicrobial resistance burden encompassing antibacterial, antifungal, and antiparasitic agents – we are not seeking incremental improvements in typical disease surveillance solutions. Specifically, we seek projects that propose innovation in the following areas:

- **Biomarkers:** Pilot tests of new biomarkers or combinations of biomarkers that could lead to new understanding of the actionable implications of antimicrobial resistance surveillance data, including biomarkers that ultimately might be the basis for point-of-care diagnostic tests
- **Data sources:** Pilot tests of new sources of data, particular those that would bring together different research communities for new perspectives on the problem
- **Analytical methods:** Pilot tests of bioinformatics approaches, including those that combine or connect existing databases in novel ways.

Technologies/products that target improved infection prevention

- **Low-cost technologies/products:** exploratory work in developing novel products and/or technologies that specifically target improved infection prevention and control in healthcare settings as well as technologies to remove antibiotics from effluents.

Technologies/products that target improved effluent treatment to remove antibiotic load

- **Low-cost technologies/products:** exploratory work in developing novel products and/or technologies that specifically target removal of antibiotics from effluents. This may be a proof of concept study or developing an efficient and affordable technology which can be readily applied to antibiotics from various sewage disposal units/factory outlets/livestock effluents which contain antimicrobials going into the waste system.

We will give highest priority to those projects that:

- Pilot test approaches that could be added to existing surveillance platforms, since we are not seeking to create new surveillance platforms.
- Pilot test approaches to **improve** products/technologies that are already in use to break infection patterns and remove antibiotics from effluents.
- Incorporate combination of the areas of innovation listed above
- Could contribute to a portfolio of funded projects that addresses a country's regional diversity and the diversity of vulnerable populations
- Explain how proposed approaches will be tested so that they have the highest likelihood of being relevant for implementation in the country's public health system

Examples of what we are looking for

- Provides an ecological perspective, such as a One Health perspective integrating antimicrobial use in livestock or perspectives that can integrate environmental monitoring in the community setting with medical monitoring in the hospital setting
- Addresses the diversity of vulnerable populations and the different aspects of the AMR burden that might be reflected in urban versus rural settings
- Includes data sources ranging from the level of the individual (e.g., microbiome across body sites) to the community (e.g., public toilets and sanitation systems), while maintaining a focus on gaining new understanding of the actionable consequences of AMR gene flow.
- Includes data sources that could reflect AMR transmission dynamics between communities (e.g., modes of transportation and migration routes) or within communities over time (e.g., seasonal-related behaviors)

- Includes data sources that could indirectly reflect AMR burden (e.g., antimicrobial usage patterns or specifically how vaccination against respiratory or diarrheal diseases impacts antimicrobial use)
- Leverages opportunities to build in new ways on existing public health interventions or environmental monitoring platforms - and to bring together different research communities
- Characterizes type examples of the burden of AMR (e.g., exploring the role of AMR in community or hospital sepsis-related mortality, focusing on children)
- Contribute to control of infections in health care settings: Novel techniques, products to control hospital infection rates and break the chain of transmission of microbes in clinical settings. These would be ideally targeted for high-infection and low- resource settings, and therefore the product/technology needs to be developed with the final affordability and efficiency as priorities.
Exploratory work into developing low cost technologies to remove antibiotics and associated chemicals from effluents.

We will NOT consider funding for

- Proposals that do not address any of the above mandates.
- Proposals to develop diagnostic devices and technologies or for drug discovery. Although diagnostic devices and new drugs are potentially critical to AMR solutions, these areas are not unique to AMR challenges and should therefore be advanced more comprehensively against a broader landscape of possible needs and solutions. Thus, while excluded here, they may be part of a future request for proposals.
- Proposals without a clear application to surveillance or facilitating the development of new evidence describing the global burden of AMR
- Proposals seeking to apply existing tools in ways that do not transform our understanding of the global emergence or spread of AMR
- Incremental improvements to conventional solutions or typical disease surveillance. We will not consider local surveillance programs or projects or small improvements in surveillance, e.g., use of mobile data collection, automation of traditional processes, or improving access to existing tools or technologies.
- Proposals that simply expand the availability of primary data without a clear link to informing our understanding of global AMR epidemiology
- Ideas not directly relevant to low- and middle-income contexts
- Genomic and other laboratory-based approaches that lack a clear application to AMR surveillance or epidemiology

- Ideas focused on quantifying resistance in animal or livestock populations or in environmental samples without a direct linkage to how data would impact public health practice
- Proposals involving clinical trials in human volunteers or patients (note: use of existing datasets or other outputs from clinical trials may be considered, as long as the proposed approach is feasible within the time and financial envelopes provided).
- Proposals that do not fulfill the mandatory eligibility condition under point 3 (c)

c. Program Structure

i. Funding pattern

Proposal for developing proof of concept (12-18 months): Funded at up to \$100,000 USD each project, do not require extensive preliminary data and are meant to provide an opportunity to test particularly bold ideas, including applying approaches from outside the field or that bridge fields. New approaches could be piloted as additions to ongoing funded projects.

Collaboration

GCI encourages collaborations based on the belief that synergies between experts across diverse disciplines are important for the challenges that we seek to address.

Should you want to apply as a collaboration, please ensure the following questions are sufficiently answered in your proposal.

Are the applicants, including all sub-contractors, willing to collaborate and share experimental methods, data, and resources among the other independently funded members of the program consortium?

3. Rules and Guidelines

a. Application Process

Please be advised that the entire application process is online through the BIRAC portal.

- i. Proposals in the correct format will be submitted on the online portal by interested applicants
- ii. After an initial triage, review panels established under the Grand Challenges India partnership will evaluate the proposals submitted.
- iii. Post proposal review and legal eligibility check, the applicants will be invited to present their proposals in detail to TAG.
- iv. Pending financial and technical due diligence, the final awardees will be selected by the TAG.

- v. Once Due Diligence is successfully completed, award certificates will be awarded to the selected GCI applicants.
- vi. PMU- BIRAC will then enter into separate funding agreements with successful GCI cost recipient(s) to govern the project terms and conditions and fund disbursement modalities.

b. Application instructions*

1. Please visit the BIRAC website at www.birac.nic.in and follow the link to the registration and submission portal.
2. If you are applying to a BIRAC/GCI scheme for the first time, please note that you will have to register on the portal. The verification and activation of your new account may take upto 24 hours before you can apply for the scheme. Please take this into account while applying.
3. The online form needs to be filled completely with all appropriate documents uploaded.
4. Please also ensure that the Proposal Summary document is uploaded based on the format provided. Incomplete proposals will be rejected in the triage round.

* We will not be able to provide individual feedback to applicants those who are not selected for further rounds.

b. Schedule

11th April 2018- Call opens

25th May 2018- Call closes. Online portal will close at 11:59:59 pm on 25th May 2018.

October 2018- Awards announced

c. Eligibility criteria

This RFP is India-led; the programme is open to Indian academics, research institutions, companies, society, trusts and foundations.

Project cost will be sanctioned to researchers and innovators who are Indian individuals or Indian entities*, we also encourage partnerships with researchers of national/international expertise, subject to the call guidelines.

Note: Please read the following carefully to understand the category you will be applying under and the documentation that may be requested should your proposal be selected for further financial due diligence. This call is open to:

- i) In case of the applicant being an Indian academic scientist, researchers and Ph.D students (citizen of India) who must be willing to incubate at a recognized incubator submit a letter of intent for same.
- ii) **Companies**
 - Companies incorporated under the Indian Companies Act, 2013 having a minimum of 51% Indian ownership.
- iii) **Limited Liability Partnership**
 - Limited Liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens.
- iv) **Indian institution/ universities/ public research organization**
 - Academic institutions established in India and having NAAC/ UGC/ AICTE or any equivalent recognition certificate or any other Public/Government supported organization
- v) **Society/ Trust/ NGO/ Foundation/ Association**
 - Society/ Trust/ NGO/ Foundation/ Association established in India under the relevant Indian Law having at least half of the stakeholders (partners/ trustees/ members/ associates etc.) as Indians.

Experts of the relevant discipline as mentors should be a part of the proposal such as healthcare professionals, data analytics experts, m-health specialists, management experts, logistics experts, M&E experts among others.

* **Note:** *The evaluation of eligibility shall be based on the status of documents as on the closing date of the call.*

Through national and international collaboration, we expect that sharing experimental methods, data, and resources will ultimately improve the ability to compare and validate local research findings and to develop interventions and products that can have impact at a greater scale.

d. Evaluation Criteria

1. **Novelty and Innovation:** Does the proposal capture enough novelty to address the discussed challenges.
2. **Approach and methodology:** Is the research plan, objective and proposed schedule clearly presented and realistic. Is there clarity in the objectives and work plan? Are the proposed timelines and milestones appropriate, feasible, and technically sound? Is there a high likelihood of the objectives being completed in the given timeframe? Will the demonstration take place in difficult/ challenging India-centric setting?

3. **Future Deliverable/Translational Feasibility:** Relevance and clarity of anticipated outcomes & deliverables to future implementation of the projects and commercialization.
4. **Sustainability and adaptability of System:** Does the proposed solution take into account the complexity of the proposed geographical setting and context.
5. **Organizational and investigator capability:** Is the team composition covering key scientific and engineering challenges that this challenge is seeking to address? Is the research and development team appropriately trained, experienced, and positioned to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other proposed members? Is there strong evidence of substantive organizational capability and commitment? Is there experience in development of partnerships, and in multi-investigator projects? Are collaborative arrangements in place? Is there evidence of an infrastructure for data collection, transfer, and sharing?
6. **Best value:** Is the cost of the proposed effort reasonable relative to the complexity of the proposed work and the degree of risk and advancement proposed?

e. Allowable Costs

Usually the allowable cost will include:

- Indirect Cost/Non-Recurring Budget: **Equipment and Accessories** (Upto 20% of proposed cost) list of equipment's, if required and justification in relevance to the project activities (Quotations supporting proposed equipment and accessories)
- Direct Costs/Recurring Budget (Realistic figures): **Manpower** (Up to 30% of proposed cost), **Consumables** (Up to 20% of proposed cost), **Travel** (Inclusive of International travel, in case of International Collaborations) and **Outsourcing** (In case any activity to be outsourced)
- **Research Contingency and Overhead** of each Primary & Collaborating Partners (not exceeding 10% of the total Recurring Cost)
- **International collaborator(s) if any will be supported by BMGF directly, except travel expenses on actuals.**

***Note:** Justifications to be provided for roles of each aspect of manpower involved, consumables proposed, travel (Local and International in case if any), research contingency and trainings.

Budget heads without cap will be considered on case-to-case basis and based on call specifics by Technical Advisory Group (TAG).

f. Warranty

The GCI Applicants shall warranty that the statements and particulars contained in the full proposal and supporting documents are correct. They have to further warrant that they are under no contractual restrictions or legal disqualifications or any other obligations which would prohibit them from undertaking the present Project, entering into any Agreement in this regard etc.

g. Project Intellectual Property

The initiative is guided by the Memorandum of Understanding on the collaboration between the Department of Biotechnology, Govt. of India and the Bill & Melinda Gates Foundation signed on July 18, 2012 and as such must consistent with the commitment that projects and investigators funded under initiatives make global access commitments to ensure the fruits of their research are available to those most in need. This will include, but not limited to, the ability to license any technology developed under this agreement to manufacturers in India subject to these global access commitments and to the relevant provisions of the Indian laws including specific requirements on licensing under the Patents Act 1970.

To this end, project IP means intellectual property generated during the conduct of the Project by the GCI applicants, but excluding the intellectual property generated before initiation of this Project and any IP generated outside the scope of this Project even during the term of this Project. The ownership and control of the intellectual property shall remain with the GCI cost recipient(s), or other collaborating organizations or institutions as agreed with the cost recipient, subject to any applicable local policies and the collaborative process described above, including arrangements between the cost recipient and other individuals or institutions.

GCI cost recipient(s) agree to conduct and manage the Project and the resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, “Funded Developments”) and any IP that arises in the manner that ensures “Global Access.” Global Access requires that

- 1) The knowledge and information gained from the Project be promptly and broadly disseminated
- 2) The Funded Development is made available and accessible at an affordable price to people most in need within developing country.

Establishing suitable Global Access agreements among the GCI cost recipients will be a condition of receiving funding.

During the term of this Agreement and for 5 years after, you will submit upon request annual intellectual property reports related to the Funded Developments, Background Technology, and any related agreements using the PMU-BIRAC's templates or forms, which the we may modify from time to time.

h. Confidentiality

During the tenure of the Project, BIRAC will undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/generated from the Project for any purpose other than purposes in accordance this RFP. Please note that all proposals, documents, communications and associated materials submitted (collectively, "Submission Materials") will become the property of BIRAC and will be shared with other funding partners or potential funding partners.

Number of applications received and the countries from which they originated will be published. The proposals will be subject to confidential external review by independent subject matter experts and potential co-funders, in addition to in- house analysis.

4. Research Assurances

a. Data access principles

BIRAC has the right to the technical data generated during the project for all the GCI funded projects.

The fund recipient shall permit BIRAC through its authorized representative access to the premises, during regular business hours, where the Project is being/shall be carried out and provide all information and produce or make available the concerned records for inspection and monitoring of the Project activity, required by BIRAC or the concerned committee under the RFP. BIRAC will as needed share this data with a Technical Advisory Group or with the funding partners.

b. Indemnification

GCI applicants shall, at all times, indemnify and keep indemnified the Funding Agency/ BIRAC against any claims or suits in respect of any losses, damages or compensation payable in consequences of any accident, death or injury sustained by the employees of the Company or by any other third party resulting from or by any act, omission or operation conducted by or on its behalf. Further GCI applicants shall, at all times, indemnify and keep indemnified PMU or Funding Agency/ BIRAC against all claims/damages etc. by any infringement of any Intellectual Property Rights (IPR) while carrying out its responsibilities/work under the Project and this Agreement.

GCI applicants shall share the health information which develops through observational studies, surveys for the validation of the proposed solution into the programme setting and the like (the "Data") that would be beneficial to furthering the research goals with funders and global partners.

In the event of data sharing, there shall be separate governing terms.

c. Research Ethics and Regulatory Approvals

GCI Cost recipient(s) shall be responsible to obtain all the necessary requisite approvals, clearance certificates, permissions and licenses from the Government/local authorities for conducting its activities/ operations in connection with the Project.

5. The fund disbursement and project implementation shall be governed by the specific funding agreement that will be duly executed.

6. Dispute resolution and Arbitration:

In the event of any dispute or difference between the Parties hereto upon or in relation to or in connection with this RFP, such dispute or difference, shall be resolved amicably and in good faith by mutual consultation.

If such resolution is not possible, then the unresolved dispute or difference whatsoever arising between the Parties out of or relation to the construction, meaning, scope, operation or effect of this RFP or the validity the breach thereof or in respect of any defined legal relationship associated therewith or derived therefrom dispute shall be submitted for arbitration to International Center for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India. The Authority to appoint the arbitrator(s) shall be the ICADR. The Arbitration under this Clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996. The award made in pursuance thereof shall be binding on the Parties. The venue of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language. The provision of this Clause shall not become inoperative notwithstanding the Contract expiring or ceasing to exist or being terminated or foreclosed.

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