Implemented By:

Biotechnology Industry Research Assistance Council
Govt of India Enterprise

Department of Biotechnology,
Ministry of Science & Technology,
Government of India

Co - funded By
THE WORLD BANK

National Biopharma Mission for Accelerating Discovery Research to Early Development of Biopharmaceuticals
Innovate in India (i3)

Frequently Asked Questions

1. Eligibility Criteria

1.1 What is eligibility for company/academia/LLP/ NGO?

For Company - 51% shareholding resident Indian Citizen

a) Incorporation/Registration certificate.
b) 51% shareholding resident Indian Citizen and copy of passports in support
c) Details regarding in-house R&D facility, if any/ Incubation agreement
d) Audited financial details of last three financial years, if applicable

For LLP- 51% of partners should be resident Indian Citizen

a) Incorporation/Registration certificate.
b) Partnership deed or 51% shareholding resident Indian Citizen and copy of passports in support
c) Details regarding in-house R&D facility, if any/ Incubation agreement
d) Audited financial details of last three financial years, if applicable

Academia Can be Public, Private, Not for profit Research foundations.

a) Affiliation/Registration certificate.
b) Details regarding in-house R&D facility, if any/ Incubation agreement. Eligibility should be established by submission of documents
c) If the institution/public research organization is registered under/as Society or Trust, then criteria for Trust/Society must be fulfilled

Society/ Trust/ NGO/ Foundation/ Association

a) For Society - Registration certificate, for Trust - 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)

1.2 Whether partnership firm can submit a proposal considering the `legal eligible proponents' aspects?

No they are not eligible - A legal entity is required.

1.3 Who can be principle investigator of the project? How many investigators can be involved in each proposal?

Full time employee/faculty/scientist of the applicant entity. Proposal will have only one Principal Investigator (PI), others can be Co-PIs.

1.4 Whether any start-up can submit the proposal?

Yes, start-ups can apply, provided they fulfil the eligibility criteria mentioned in 1.1.

1.5 Can a Society be eligible to apply?

An Academic society which has research as mandate may be eligible.

1.6 Does the proposal have to have one agency as the primary applicant or is it permissible that two or more e.g. two start-ups or one start up and one company collaboratively applying for the grant?

Yes, one has to be Primary Applicant – others can be collaborators.

1.7 Can a funded (from other Govt of India agencies or venture capitalists) program seek funding through this program for specific milestones over the next 5 years that may not be covered in other grants?

Yes, if there is no overlap

2. Proposal Submission Criteria

2.1 Is there a word limit to the application?

Each section has a word limit. Other details can be uploaded.

2.2 What is the specific site for project submission and registration?

It is through BIRAC website **(http://www.birac.nic.in/nationalbiopharmamission.php**

2.3 Is there a format of the application?
Yes, the application format can be found at
http://www.birac.nic.in/nbm_proposal_submission.php

2.4 Is the applicant also required to give monitory contribution in the proposal?
No, monetary inputs from the applicant are not mandatory. However, any such financial commitment indicates the commitment of the applicant in the proposal.

2.5 What should preliminary data consist of? Is it literature based or generated by applicant?
The data which has been generated by applicant in the lab with respect to the proposal to support the proposed studies.

2.6 Is it possible to apply for multiple RFPs through a single project or a different project?

Yes, Separate application should be uploaded for different RFPs.

2.7 Are proposals on botanicals or New Chemical Entities eligible?

No

2.8 Is it possible to extend the timelines for submission of proposals?

No, the site will not accept proposals after the call closing time mentioned on the site as well as in the RFP document.

2.9 Can one apply simultaneously for bio therapeutics and facilities?

Yes, but through different applications

2.10 Is DSIR certification mandatory to apply?

No

2.11 Is there any particular stage at which product should reach at 4 years?

We are aiming to reach closer to market at the end of 5 years. You can also define in terms of TRLs mentioned on BIRAC website.

2.12 How many grants are you making and how are you thinking about the size and the numbers relative to the total fund?

This will be decided only after close of the call and proposal evaluation.

3. Documents submission

3.1 What are the necessary documents required by company/academia/LLP/NGO?

The details are mentioned in 1.1. Please refer to the RFP document page 3-5 also.

3.2 What are the documents required for academicians who have starter a company?

Establishment documents/any regulatory documents/recognition documents. The IP/ Technology should be in the name of the Company.

3.3 How do we provide evidence of scientific achievement to satisfy the "experience" evaluation criterion? Does this information have to be included in the Project?

Evidence for scientific achievements would be through providing information on publications, details of successfully funded projects, patents filled etc. These can be provided as additional uploads

4. Other Queries related to Submission and Evaluation

4.1 What will be the time and last date of submission?

Closing time will be exact 5:00 PM of 15th February, 2019. Any requests for extension of timelines will not be entertained.

4.2 What will be Start date of the project/Funding?

From the day of execution of funding agreement (GLA), expenses will be considered for reimbursement/ disbursement.

4.3 Can you critique a draft of my application?

You may write to BIRAC for specific clarifications on proposal submission.

4.4 What if there is an important reason we might miss the application deadline?

The proposal will not be considered after close of call.

4.5 How soon will I learn if my proposal will not be competitive?

There will be minimum four stages of proposal evaluation. PMU-BIRAC will communicate with the applicate at every stage of evaluation. Final decision will be within 24 weeks of submission.

4.6 Will you provide feedback from the review to applicants?

Yes, we will be sharing comments from evaluation committee.

5. Funding Nature

5.1 What would be the Minimum/Maximum amount provided under the scheme Against the different RFPs?

There is no minimum or maximum limit, Applicant can propose a budget commensurate with the activities along with justification. But this will be operated through a single dedicated No-lien account.

5.2 What would be the nature of funding association? Equity/Soft Loan/Grant? Is there a soft loan or a grant model for the private company?

This is totally a grant based program.

5.3 What cannot be funded? Where can I find additional guidance on allowable vs. not allowable costs?

- Regulatory approval fee.
- Civil Construction fee.
- No funds to be funded through BIRAC directly for international studies. The international funding if needed for analytical testing, facility or models which are not available in India will have to be supported with justification, which will be verified by BIRAC and then considered for funding.
- Prosecution/litigation fee is not allowed.

Additional guidance on "Allowable and Not Allowable" costs can be found in the RFP document.

5.4 What will be the bindings for the applicants through this grant?

Agreement with the Grantees would be undertaken to ensure alignment with the end goals of the Program. These binding requirements would be variable based on the type and nature of the RFA. For example:

- For Biosimilars, the grantee will need to provide the product at competitive market prices to ensure adequate access that is affordable to large section of the population

- For facilities, the grantee will need establish a governance system and an Agreement where (i) There should be a fee for service model and the services would be available to BIRAC and other Government grantees, start-ups, academia and SMEs at subsidized rates, as compared in industry standards. (ii) Prioritization of projects being supported through the Program (based on capacity and capability) iii) Services rendered by the facility will be periodically monitored by monitoring committee consisting of BIRAC representative and experts from industry or academia.

5.5 How shall BIRAC be facilitative in ensuring alignment of binding expectations between multiple donors for the program?

BIRAC Legal Cell will work on mutually acceptable agreements.

5.6 How specific should we be in the budget?

Please fill the details as per the online format to the extent possible. In case of any issues in doing so you may contact PMU.

5.7 Will this grant opportunity be offered again in the future?

The grant opportunity maybe announced again only if the committee feels that the appropriate proposals have not been received through this RFP.

6. IP

6.1 To whom will new IP belong to applicant or collaborator?

IP will belong to the Applicant/fund recipient. Whether it belongs to the collaborator will depend on their mutual agreements. Background IP will belong to the relevant party.

6.2 What will be the royalty clause?

Royalty is applicable in the event of commercialisation of product, and only for those products which do not come under National Pricing Control.

6.3 Are there expectations on IP and revenue sharing with BIRAC, after funding?

BIRAC will have non-exclusive licence to the project IP (IP generated during implementation of the project only for research of national priority). Background IP will belong to relevant party.

There is no revenue sharing clause with BIRAC. Royalty shall become applicable in the event of commercialisation of product only for these which do not come under National Pricing Control. Global Access principles should be complied by the grantee in order to bring the results into public domain without undue delay.

Affordability has to be built into the pricing on account of the government support under this mission to develop the product.

6.4 Whether the product sales will be through government channels or through market directly?

Product sales will be through market for all bio therapeutic products.

7. Agreement

7.1 What is the Grant agreement to be signed?

Grant-In-Aid-Letter agreement will signed between the BIRAC and applicant plus collaborator (If any) with specific terms and conditions.

7.2 What is the Funding Mechanism?

Disbursement will be based on Milestones. The grantees would work with the PMU-BIRAC and develop a comprehensive work plan with budgets against deliverables and R&D plan subsequent to which the first quantum of funding would be released. Further disbursements would be done on verification of milestones achievement. Periodical reporting against pre-defined activities shall be done by the grantees to the PMU.

7.3 Will we be able to negotiate any of BIRAC's standard contract terms and conditions if selected?

No. These are non-negotiable

8. Selection Process

8.1 What is the procedure to be followed post approval?

The timeline for selection of proposals is around 20-24 weeks. The decision will be communicated to the selected applicants and GLA (Grant-In-Aid-Letter agreement) will be signed subject to fulfilment of financial and legal clearances.

8.2 What will be the process or criteria for evaluation?

The Committee's recommendations are based on the evaluation parameters like scientific merit, national relevance, competition, track record of the applicant and also on how the project has been presented in terms of milestones, timelines etc. Each component will have their own weightage.

Please refer to the National Biopharma Mission Document and RFP available on BIRAC website for more details.

8.3 If not selected can it be reconsidered?

No, reconsideration or representation is possible. The decision of the Advisory Groups is final.

8.4 Do you have certain types of evaluations, for example qualitative vs. quantitative, that you would support over others?

Both Qualitative and Quantitative parameters are important. While Qualitative parameters will assess technical strength and competence, the quantitative parameters are important for determining the end point of the project, timelines and milestones both these are important.
Please refer to the National Biopharma Mission Document and RFP available on BIRAC website for more details on evaluation criteria.

8.5 Who shall be responsible for evaluation/selection of the proposals?

The PMU will work within the established assessment framework.
The Scientific Advisory Group would assess the merit and quality of research proposals and recommend the most appropriate applicants for consideration by site visit committee and Technical Advisory Group.

Please refer to the National Biopharma Mission Document and RFP available on BIRAC website for more details

8.6 How many grants are you making and how are you thinking about the size and the numbers relative to the total fund?
This will be decided only after close of the call and proposal evaluation.

Specific Questions related to RFPs

9. Biosimilar Product Development

9.1 Are the development of polyclonal antibodies against the desired disease are eligible?
No

9.2 Would biosimilars for products other than the listed ones in RFP be also eligible?

PMU NBM has identified these products on the basis of patent expiry of original Biologic between 2015-2020, for RFP on Biosimilar Product Development. Other products may also be considered if the market demand in the country can be justified.

9.3 Is it necessary to have an IP / patent for the proposed technology before proposal submission?

Not mandatory. However all Background IP should be in the name of the Applicant and it is the responsibility of the applicant to protect the new IP generated through the funded work. A limited support of 2 Lakhs (project related) may be sought for protection of IP.

9.4 What are data required for Biosimilar Product Development? Whether regulatory approvals have to be mentioned in the application?

Preclinical data should consist of upstream and downstream processes, product characterization, and stability of drug substance/drug product. Regulatory approvals applied for and received should be mentioned at each stage with timelines. If application for clinical development, the clinical study plan should be submitted.

9.5 What kind of studies are considered under POC for Biosimilar Product Development?

Characterization of the product and establishment of biosimilarity with innovator molecule.

9.6 What are required for proposals for clinical trials? Whether regulatory approvals have to be mentioned in the application?

If one is applying for Phase 1 Clinical trial, then he/she should submit the preclinical data and Clinical Trial Protocol and Investigator's Brochure. If applying for Phase 2 or 3 then data of previous clinical trials and protocols of the proposed trial. Regulatory approvals should be mentioned as applicable or if applied for.

9.7 If POC has been established by collaborator outside India than is an Indian Applicant eligible?

Yes, However Indian Applicant should have complete legal; access to technology / IP right. Indian applicant should submit the necessary documents showing the technology transfer from foreign party.

9.8 If clinical trials are funded by any other funding source, can NBM provide the remaining supporting budget?

Yes, we can do co-funding.

9.9 Whether cellular immunotherapies fit under this call for Biosimilar Product Development?

No

9.10 What will be the nature of guidance and support during different phases of the specific product development?

<u>Methodology of Support for specific product development would be through:</u>

- Direct Funding of product development activities through various stages including, preclinical development, and production of clinical grade material and early phase human clinical trials.
- Projects will be monitored and mentored through a Project Monitoring Committee (PMC) that would bring together a group of Global and National experts from industry and academia for
    - Development of Product Development Plan
    - Guidance and support during different phases of product development
    - Creation of strategies and plans for clinical trial plans/designs and engagement of an enriched study population
    - Development of a regulatory strategy
- Access to the following affordable services and solutions supported developed through other calls of the Program:
    - GLP compliant analytical facility for characterization of the Biosimilar Products
    - GMP manufacturing CMC facility for manufacturing Preclinical and Clinical Trial material

  Please see the RFA for more details**.**

9.11 What are the timelines from being able to seek support from the shared facilities being set up under the program, if I wish to use it for my product? For similar support if needed in the interim what shall be the process of seeking it from BIRAC.

Few shared facilities are already being funded by National Biopharma Mission. These will be available from March 2019 onwards. Once these are functional, information will be available on BIRAC-NBM website. Interim, support can be sought from existing facilities within the country and funding for the same be considered through the Program.

9.12 Whether only biosimilars will be supported or novel molecules can be also submitted?

This particular call is for only biosimilar development and clone development for monoclonal antibodies and therapeutic recombinant proteins.

9.13 The support is only for R&D or it may also extend for the development of infrastructure?

The support will be for the products which have established Proof of Concept. The equipment cost required may be supported as per the project requirement and BIRAC norms. There will be a separate RFP for facilities. Please refer to the allowable and non-allowable costs in the RFP.

9.14 Can we do a clinical trials in India from overseas academia/CRO?

Yes, one can do that but cost of clinical trials will be borne by applicant.

10. Biosimilar Clone Development

10.1 What are data required to be submitted for Clone development for Biosimilar?

Applicant must submit the strategy and preliminary data of expression of clone in a cell line.

10.2 What is the expected endpoint for this RFP?

The clone developed as an outcome of the awarded grant should be evaluated based on relevant attributes and found to be suitable for further development for a commercial Biosimilar product.

11. Facilities

11.1 What existing strength and capabilities are required?

The applicant should have minimum infrastructure ready in terms of space, minimum manpower or instruments.

11.2 What kind of preliminary data is required for facility?

One has to show their existing strength in terms of space, minimum manpower & instruments, competence of the team, governance model and financial sustainability plan.

11.3 Will new facilities by applicants without prior experience be supported?

The applicant should demonstrate prior experience in running a service facility (industry) or have expertise in the area of testing requested (academia).

11.4 What will be the period of grant for a facility?

The grant will be for upto a maximum of 4 years. But majority of the grant for facility will be disbursed in the first two years, followed by release of the remaining grant based on the milestones mentioned in the GLA.

11.5 What will be the governance model?

Operational model and the accessibility of these facilities could be through multiple ways depending on the project stage and services required. For e.g. fee per service model (unbundling of services so that each service can accessed individually) or through collaborations (involve co-development of the product). Standard CRO/CMO modalities of function would be adapted to provide cost-affordable and efficient services.

The facility usage rates will be subsidized for BIRAC and other Government grantees, academia, public institutes, start-ups and small companies. A % of space would be also be available for use by these.
The facility should also devote a % of time for education and training of identified trainees for capacity building.

11.6 What will be the sustainability model?

The continuation of services of the facility beyond the 4- year grant period to be thought of. The model should demonstrate if and when the facility will be self-sustainable with a business model and financial plan, mentioning potential clients.

11.7 What is expected as the usage model?

These facilities would provide affordable and accessible services. Please refer to the RFP document for more details.

11.8 Whether construction cost can be funded for development of Facility?

No, civil construction fee will not be funded.

11.9 If someone going to build process development laboratory, can analytical lab facility can be also funded?

In process development lab, mainly upstream and downstream processes are developed but analytical lab needs more than the development of the process. Therefore it cannot be clubbed under process development lab. It is a separate RFP. However, we are inviting applications from those who have an existing process development lab and wish to establish a GMP manufacturing facility or vice versa.

11.10 If someone is having an existing process development lab performing non-GMP manufacturing can they apply for PDL-GMP combined facility?
Yes, they can apply.

11.11 If someone is having an existing process development lab only, can they apply for PDL-GMP combined facility?
Yes, they can apply. Please refer to "Expectations from the facility" section in the RFP for further details.

11.12 Facility projects will require large amount of fund in first go then how it will be milestone basis?

For facilities, we are generally giving 50 % of the fund at the time of signing of the agreement so this will solve the purpose.

11.13 Is the future vision required to be included at the time of submission of project for facility?

Yes, a vision in terms of sustainability and continuation of services of the facility need to be included.

12. Cell Line Repository

12.1 What existing strength and capabilities are required for a repository?

The ability to maintain, authenticate, characterize and store cell lines and expression systems.

12.2 What are the requirements in terms of infrastructure for a Cell Line repository?

Dedicated space and instruments required for storage. For details please refer to the RFP document.

13. Novel Cell Line Development

13.1 Is it necessary to submit the strategy?

Yes, a brief strategy is required, if you do not wish to disclose all details. The trait which is targeted and expected end point must be mentioned.

13.2 What is the final expectation from this RFP?

Please refer to the RFP document which clearly describes the benchmarks expected from the new cell lines developed through this call.

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