Implemented By:
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THE WORLD BANK

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

Frequently Asked Questions

1. Eligibility Criteria

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

For Company- 51% shareholding resident Indian Citizen

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

Academia Can be Public, Private, Not for profit Research foundations. Eligibility should be established by submission of documents as required by relevant Indian statue /recognition.

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

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

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 Coordinator – Others can be PI /Co-PI's

Whether any start-up can submit the proposal?

Can apply

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 – other can be collaboration.

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

Can you give an example of a promising proposal?

A proposal would be favoured if it fulfils the eligibility criteria and aligns with the requirements as detailed in individual RFAs. There are no published examples.

Is there a word limit to the application?

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

What is the specific site for project submission and registration?

It is through BIRAC website **(http://www.birac.nic.in/desc_new.php?id=340).**

What is definition/dimension of consortia?

Consortia is just a term. It can be two, three or multi institutional.

Can a Society be eligible to apply?

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

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.

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

Separate application should be uploaded for different RFPs.

What are required for clinical trail data? Whether regulatory approvals have to be mentioned in the application?

If one is applying for clinical trial 1 then he/she should submit the preclinical data, if applying for phase 2 or 3 then data of previous trials and protocol of the mentioned trial. Regulatory approvals should be mentioned whether you have or you have applied for.

Are proposals on botanicals eligible?

No

Is it necessary to submit the work plans in the Pert format? Is there any specific format to submit pert chart?

Right now you can submit in Pert format. Any additional information can be uploaded.

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 mechanism.

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

No

Are new bio therapeutics for listed diseases in RFPs eligible or not?

No, only biosimilar are eligible.

Can one apply simultaneously for bio therapeutics and vaccines?

Yes, but through different applications

What is the procedure to be followed post approval?

The timeline for selection of proposals is around 12-16 weeks. After this decision will be communicated and also the reviewers comments to the proposal which will not be selected. All the proposals which will get selected will undergo financial due diligence and then GLA (Grant-In-Aid-Letter agreement) will be signed.

Is there any particular stage at which product should reach at 5 years?

We are aiming to reach close to market entry level.

Is DSIR mandatory to apply?

No

2. **<u>Documents submission</u>**

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

For Company & LLP*- Shareholding/ subscriber Particulars, Other documents of registration*

For Academia – *establishment by Indian statue and recognition documents*

For NGO – Society Registration

Who can be the PI /coordinator (full time or part time) for the company?

Full time employee/faculty/scientist of the applicant entity.

What are the documents required for academicians who have acquired the company?

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

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.

Description or can we submit a separate bio sketch? If a bio sketch is allowed, in what section of the proposal do we submit this information?

Institutional description and bio-sketch both are important requirements of the Proposal. Please see Proposal format, visible after registration on BIRAC website, for further clarity.

3. Submission

What will be the time and last date of submission?

Closing time will be exact 11:59 midnight of 15th December

Can one submit multiple proposals?

Yes

What will be Start date of the project/Funding?

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

Can you critique a draft of my application?

You may write to BIRAC for specific clarifications on proposal submission

What if I missed the RFP workshop?

You may write to BIRAC for specific clarifications on proposal submission. Alternatively the FAQs would also be published online on BIRAC website.

What if I missed the deadline for the letter of intent?

There is no requirement for Letter of Intent. Only full proposal is to be submitted.

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

The proposal will not be considered after close of call

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

BIRAC will to communicate the decision at every stage of evaluation. The decision making will be done with 12-16 months.

How will I be notified of any changes in the RFP, any new information uncovered, or the answers to questions that are asked by other grant seekers?

Please visit our website regularly. We will post all queries

Will you provide feedback from the review to applicants?

Yes, we will be sharing comments from evaluation committee.

4. Funding Nature

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 with justification

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.

What are the budget limits for each grant?

Applicant can propose the budget requirement commensurate with project activities with justification

What are the timeline for financial evaluation?

4 months from 15th December

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

- *Regulatory approval fee.*
- *Operational Overheads.*
- *Civil Construction fee.*
- *No funds directly to be funded through BIRAC for international studies. The international funding if needed for facility or models which are not available in India will be first verified by BIRAC and then looked into. This can be part of applicant cost.*
- *Prosecution/litigation fee not allowed.*

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 vaccines (The Agreement will have a specific Pricing Clause for Government / Public Health use

- 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) the services would be available to BIRAC and other Government funded research, start ups and other small companies. at subsidized rates, as compared in industry standards. (ii) prioritization of projects being supported through the Program (based on capacity and capability)

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.

How specific should we be in the budget?

Please fill the details as per the format to the extent possible.

Whether to apply for general operating support (GOS) and/or project administrative overhead support?

General operating support

Will this grant opportunity be offered again in the future?

As of now RFPs for Phase I have been announced. RFP's for Phase II will be announced subsequently for other activities. The activities of Phase I maybe announced again only if the committee feels that the appropriate proposals have cannot been selected through this RFP.

5. <u>IP</u>

Will IP belong to applicant or collaborator?

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

What will be the royalty clause?

There is no royalty if the product has a national pricing control. In other cases if there is a commercial market use royalty clause may be applicable, which will be discussed case to case.

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. Royalty shall become applicable in the event of commercialisation of product only for these which do not products come under National Primary 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 due to the government support under this mission to develop the product.

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

Product sales will be through market for all bio therapeutic products. For vaccines there will be an effort to try and introduce it into the Government system.

Will there be any scope for support to acquire any specific technology under the mission?

There is a provision for acquisition of technologies of national priority and if required by the components of the Mission program. This will be negotiate by BIRAC. However there will be no exclusive technology acquisition.

6. Agreement

What is the Grant agreement to be signed?

Grant-In-Aid-Letter agreement will signed between the BIRAC and applicant with specific terms and conditions.

What is the Funding Mechanism?

Disbursement will be based on Milestones. The grantees would work with the PMU at BIRAC 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.

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

No. These are non-negotiable

7. Selection Process

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. The applicant should have freedom to use the technology.etc.

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

If not selected can it be reconsidered?

No reconsideration or representation is possible. The decision of the committee is final.

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 available on BIRAC website for more details

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

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

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.

8. Specific Questions related to product development

Bio therapeutics/ vaccine

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

Would bio therapeutics for diseases other than asked in RFP be also eligible?

BIRAC has identified these diseases based on the occurrence mortality and morbidity and unmet need to have a treatment or cure. But if someone has done studies on any other diseases and thinks that of nationally important BIRAC these will be looked into it

What kind of studies are considered under POC?

For vaccines- *Identification of appropriate antigens, purification and immunogenicity determination in appropriate models.*

For Bio therapeutics- *Characterization of the product and preliminary establishment of similarity with innovator molecule*

For Devices and diagnostics- *Critical function established. Laboratory studies whether aim to validate analytical predictions of separate components of the technology.*

If POC has been established by collaborator outside India than can Indian Applicant eligible?

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

If completed the preclinical trails or phase 1 clinical trials and are in the process of getting regulatory approval, can they apply?

Yes, one can apply to us but in that case the funding will start subject to regulatory approvals.

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

Yes, we can do co-funding.

Whether a developed protocol tested in patients for treatment for Dengue Fever, Dengue Haemorrhagic Fever and Dengue Shock Syndrome with repurposed Antiviral and Anti-Cytokine agents for further trials can be submitted?
Treatment options will not be funded under this program.

Whether cellular immunotherapies fit under bio therapeutics?

*Yes, it fits under Bio therapeutics***.**

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, production of clinical grade material and early phase human clinical trials.*
- *Projects will be monitored and mentored through a Product Development Unit (PDU) that would bring together a group of Global and National experts from industry and academia for*

    - *Development of Product Development Plan and Target Product Profile*
    - *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:*
    - *GCLP compliant facility for vaccine characterization and validation in clinical stages of development*
    - *Translation Research Consortia for:*
        - *Access to novel assays*
        - *Conduct of Challenge/protection studies in Transgenic/Humanized Mice and Non-Human Primate Models*

Please see the RFA for more details.

In what way support will be provided to aid in the development of the Product Development Unit?

Please refer to the above.

What are the timelines from being able to seek support from the shared facilities being set up under the program? For similar support if needed in the interim what shall be the process of seeking it from BIRAC

It is anticipated that the shared facilities will be available within two years from Program initiation. Interim, support can be sought from existing facilities within the country and funding for the same be considered through the Program.

Whether similar or only generics will be supported or novel molecules can be also submitted?
This particular call is for only bio therapeutics which have been listed in the RFPs, development of monoclonal antibody for identified diseases in RFPs will be also supported.

How GLP laboratory can be time driven?
There are several GLP laboratory already available in Nation, we are going to strengthen them and within 12 months of the time period they should be available for use.

What do you mean by early phase clinical trials? Is it preclinical, Phase I, II?
Early phase clinical trials means they should have completed preclinical trails.

Can we do a clinical trails in India from overseas academia?

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

Novel vaccines means novel candidate or novel platform?

The first criteria should be on diseases of national importance. India centric diseases will be on top priority. Than should be novel candidates.

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

Yes

Facilities

What existing strength and capabilities are required?

The applicant should have minimum infrastructure ready in terms of space, minimum manpower or instruments. BIRAC will support upto an agreed % of cost.

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 funded researchers, 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.

What is expected as the usage model?

These facilities would provide affordable and accessible services. There are no conditions for access of these facilities, except for the fee for the services to be provided.

Whether construction cost can be funded for development of Facility?

No civil construction fee will be funded.

What is the type of funding available for facility?

Its grant based funding. BIRAC would consider a % of the cost based on Committee's decision.

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

In process development lab we are mainly developing upstream and downstream process but analytical lab needs more than the development of the process therefore it cannot be clubbed under process development lab.

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

We are generally giving 30 % of the fund at the time of signing of the agreement so this will solve the purpose. Recurring cost can be borne by applicant.

A Medical Devices & Diagnostics

Whether the funding support is available only for the product segment identified in the RFP?

Yes, the product segments listed under RFP are identified after detailed brainstorming meeting and hence are of high national importance. This RFP has only asked for platform technologies.

What is the business model to provide access to the common facilities mentioned in the RFP?

The business models will be decided as per the requirements and availability of the facility. The fees for using the facility will be at subsidised rates.

Is a technology acquisition project for any identified core technologies eligible for support?

Yes, should be supported with all legal documents of technology acquisition and commercialisation rights in India.

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

The support will be for the technologies which have established Proof of Concept. The equipment cost required may be supported as per BIRAC norms. There will be a separate RFP for facilities.

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.

The deliverable / end point of proposal is core technology development or Medical Device development?

The core technology needs to be developed and demonstrated through the development of medical devices in collaboration with other medical devices companies.

Whether funds can be provided to update the product technology - LCD touch screen interface, Li-Ion battery etc, develop 3-4 models to create an entire range and Testing / Approval by relevant certifying agencies?

No, only those core technologies identified under RFP will be supported.

Whether whole exome assays to analyse patients tumour's genetic make- up and match with relevant first line therapies can be supported under the "Medical Devices & Diagnostics category"?

No, only those core technologies identified under RFP will be supported.

Whether Regulatory Filing Fees is included in the project Cost?

No, the fees required for regulatory approvals (Indian or CE marking) is not included in project cost.

Whether the clinical investigation comes under the scope of application?

Yes, pre-clinical & Clinical comes under the scope of the application but it should be as per the new rules for Medical devices 2017.

Whether a project for developing shared facilities for the identified Core technologies be included?

A separate RFP for sharing facility will be released however if requirement is highly relevant appropriate access will be made available.

Can a proposal be submitted for manufacturing or commercialization aspects of any identified product segment?

No

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