Frequently Asked Question

RFP :

- Medical Devices and Diagnostics

RFP:

- Enabling Indigenous Development of Technologies for Affordable biomanufacturing
- Biotherapeutics and Therapies

1. Eligibility Criteria

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

For Company *– 51% shareholding resident Indian Citizen.*

For LLP *– Minimum half the people who subscribe their name to the LLP document as its partners should be 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 and described in the RFP.*

Who can be Principal 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 – Others can be Co-PI's/ Collaborators.

Can a funded program (from other Govt. of India agencies or venture capitalists) seek funding through this program for specific milestones over the next 30 months that may not be covered in other grants?

Yes, one applicant can apply for the National Biopharma Mission grant if he/ she is a current recipient of another grant from the Government of India. However, the objectives and activities of the two grants should be different and there should be no overlap.

Whether a start-up can submit the proposal? Can aspiring entrepreneurs apply under the National Biopharma Mission?

Yes, start-ups can apply. Every applicant needs to fulfil the legal eligibility criteria and product categories as mentioned in the RFP.

Are companies eligible to apply on their own or do they require any collaboration with academic institutions?

Companies can apply solely or in collaboration with other companies or other academic institutions. Kindly refer the legal eligibility criteria mentioned in the published RFPs for further details.

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 in collaboration.

Can someone as an individual apply for the funding along with clinical collaborators?
No, individuals cannot apply. Kindly check legal eligibility criteria of proponents.

Can you give an example of a promising proposal?
A proposal would be favored if it fulfils the eligibility criteria and aligns with the requirements as detailed in individual RFP. There are no published examples.

Is there a word limit to the application?
Each section has a word limit. Other details can be uploaded as attachments.

What is the specific site for project submission and registration?
It is through BIRAC website (https://birac.nic.in/desc_new.php?id=599).

Is there a format of the application?
Yes, application format can be found at https://birac.nic.in/desc_new.php?id=599

Can a Society be eligible to apply?
An Academic society which has research as mandate may be eligible.

Is it possible to apply for multiple products through a single project or a different project?
Separate application should be uploaded for different products.

Is it possible to extend the timelines for submission of proposals?
No.

What is the procedure to be followed post approval?
The timeline for selection of proposals is around 24-28 weeks after closure of applications. 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 end of funding period?
The product should reach close to market entry level.

Is DSIR mandatory to apply?
No, depending on the legal status of the applicant entity.

2. Documents submission

What are the necessary documents required by company/ academia/ LLP/ NGO?
For Company & LLP- *Shareholding/ subscriber Particulars (most recent/ less than 3 months old), Other documents of registration.*
For Academia – *Establishment by Indian statue, recognition documents, affiliation certificates.*
For NGO *– Society Registration, member list.*
For further details, kindly refer to the RFP.

How do we provide evidence of scientific achievement to satisfy the 'expertise' evaluation criterion? Does this information have to be included in the Project?
Evidence for scientific / expertise achievements would be through providing information on publications, details of successfully funded projects, patents filed 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.

What is required for clinical investigation data? Whether regulatory approvals have to be mentioned in the application?
If one is applying for pilot/ phase I study, then he/she should submit the preclinical data; if applying for pivotal/ phase II/III study, then data of pilot/ phase I study and protocol of the mentioned trial should be provided.
Regulatory approvals should be mentioned whether you have them or you have applied for.

3. Submission

What will be the time and last date of submission?
Medical Device and diagnostics: Closing time will be exactly 17:00 hours (5:00 p.m.) IST of 12th December, 2019.

Enabling Indigenous Development of Technologies for Affordable biomanufacturing and Biotherapeutics and Therapies: Closing time will be exactly 17:00 hours (5:00 p.m.) IST of 26th December, 2019.

Can one submit multiple proposals?
Yes, an applicant can apply for different products in separate applications.

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

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 there is an important reason due to which 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 communicate the decision at every stage of evaluation. The decision making will be done within 24-28 weeks after closing of application.

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.

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?
There is no minimum or maximum limit, Applicant can propose a budget which is commensurate with the activities with justification and quotations.

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.

Is the applicant required to provide any monetary inputs in the proposal?
No monetary inputs from the applicant are essential. However, any such financial commitment indicates the commitment of the applicant in the proposal.

What cannot be funded? Where can I find additional guidance on allowable vs. not allowable costs?
Non-allowable cost includes:

- *Purchase or construction of a building/ space/ land.*
- *Rental costs for space.*
- *Recruitment costs for staff.*
- *Attendance at conferences.*
- *Legal fees.*
- *No funds directly to be funded through BIRAC for international studies. The international funding if needed for tests which are not available in India will be first verified by BIRAC and accordingly considered.*

For further details, kindly refer to the RFP.

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.

How specific should we be in the budget?
Please fill the details as per the format to the extent possible.

Whether project administrative overhead support is available?
Kindly refer the allowable cost section of the RFPs.

5. IP

Will IP belong to applicant or collaborator?
IP will belong to the Applicant. BIRAC will have non-exclusive license 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 clause.

Are there expectations on IP and revenue sharing with BIRAC, after funding?
BIRAC will have non-exclusive license to the project IP (IP generated during implementation of the project only for research of national priority). Background IP will belong to relevant party. 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 products.

6. Agreement

What is the Grant agreement to be signed?
Grant-In-Aid-Letter agreement will be signed between the BIRAC and applicant(s) with specific terms and conditions.

What is the Funding Mechanism?
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 approval of BIRAC.

Projects must be budgeted on a milestone basis. Funding will be awarded for 30 months, subject to the applicant complying with agreed milestones. The grantees would work with the PMU at BIRAC to develop a comprehensive work plan with budgets against deliverables, 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 submitted application for the proposed product should be within the areas as mentioned in the RFPs.

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 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 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 (SAG) would assess the merit and quality of proposals and recommend the most appropriate applicants. Further, based on site visit report and recommendations of the SAG, the Technical Advisory Group will make the final recommendations.

Please refer to the National Biopharma Mission Document available on 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

A. Medical Devices and Diagnostics

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

The projects shall be monitored and mentored regularly by a Project Monitoring Committee (PMC) constituted by PMU-NBM, BIRAC for each project. The PMC is responsible for the following:

- *Monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives contained in the Agreement.*

Based on the foregoing, to assess and recommend:

i. *Release of next instalment or part release thereof by the BIRAC.*
ii. *Revision of project duration.*
iii. *Closing or dropping or modifying any of the components of the Project within the overall approved objectives, budget and time-frame.*
iv. *Mentor(s) to overcome any technological problem faced in the Project implementation.*
v. *To advise on issues related to securing of IPR.*
vi. *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.*

Application towards which areas will be considered for the medical devices under this RFP?
The medical devices product development applications will be considered for the areas of Wound management, Trauma and Emergency Medicine, Surgical Tools and Implants.
The definition of a medical device and an implantable medical device as per the Medical Devices Rules 2017 shall be applicable at the time of evaluation of proposals for eligibility check (the definition of a medical device will be as per Chapter I and definition of an implantable medical device will be as per the Fifth Schedule of the Medical Devices Rules 2017)

Whether the funding support is available only for the product segment identified in the RFP? Is the scope of application limited to the list of products mentioned for the medical devices? Will other related technology and product concepts be entertained too?
The scope of application is limited to the product segments mentioned.

Can we apply for development proof of concept?
The call will support product development only above Technology Readiness Level – 4 (TRL-4) as described in the RFP. This would include pilot batch manufacturing, compliance testing, preclinical testing and clinical investigation.

Will this call support establishment of facility for product manufacturing?
No. The call will not support establishment of a facility or infrastructure for pilot/ commercial manufacturing activities.

Is it necessary to have an IP / patent for the proposed technology before proposal submission?
Not mandatory.

What is the end point/ deliverable of the Medical Device product development?
We are aiming to reach close to market entry level.

Whether the clinical investigation comes under the scope of application?
Yes, pre-clinical testing & clinical investigation comes under the scope of the application but it should be as per the Medical Devices Rules 2017.

Can a proposal be submitted for manufacturing or commercialization aspects of any identified product segment?
No.

B. BIOTHERAPEUTICS

i. Enabling Indigenous Development of Technologies for Affordable Biomanufacturing.

ii. Biotherapeutics and Therapies.

What are the products supported under Indigenous development of technologies for affordable biomanufacturing and what are the stages of support?

Products identified under the indigenous development of technologies are media and supplements for mammalian cell culture, resins for protein purification, filtration system for bulk filtration, viral-clearance, buffer-exchange and concentration of drug substance and drug products along with disposable polymer based compatible storage bags for storage of biotherapeutics.
Development of these products will be supported for early phase development and validation up to validation of technology for commercial manufacturing.

What kind of financial support will be provided for Indigenous development of technologies for affordable biomanufacturing?

Proposals will be supported for purchase of equipment for product development, clean-room/sterilization facility, consumables for technology validation and quality control, outsourcing for technology development and travel.

What are the products supported under biotherapeutics? And what stages of product development will be supported?

The call will support next generation biotherapeutics like bio betters, monoclonal antibodies, antibody fragments and antibody drug conjugates. The call will support proposals from early phase study to pre-clinical/clinical development depending upon the product/technology readiness state.

What kind of support will be provided for the proposals under development of new therapies?

Under the call development of cleanroom/ cGMP facility for a CAR-T therapy proposal with an existing construct and completed early phase study will be supported for pre-clinical/ toxicology, clinical study. Establishment of cGMP facility for generation of viral particles for modifying the T-cells will also be supported.