Request for Proposals (RFP) for
Development of Medical Devices and Diagnostics

under

Industry- Academia Collaborative Mission For Accelerating

Discovery Research to Early Development of Bio-pharmaceuticals

Innovate in India (i3) Empowering Biotech Entrepreneurs & Accelerating Inclusive Innovation.

Funded by

Department of Biotechnology, Ministry of Science & Technology,

Government of India

Co-funded through World Bank Loan Assistance

(Innovate in India for Inclusiveness Project)

through

Implementing Agency

Biotechnology Industry Research Assistance Council (BIRAC)

(A Government of India Enterprises)

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Section I - Program Overview - NBM

Industry-Academia Collaborative Mission For Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation", also referred to as National Biopharma Mission (NBM).

Funding agency

Department of Biotechnology (DBT) (Program co-funded by World Bank loan).

Implementing agency

Biotechnology Industry Research Assistance Council (BIRAC).

Background [1]

Towards strengthening the emerging biotechnology enterprise in India, Department of Biotechnology (DBT) Ministry of Science & Technology has initiated the Mission Program entitled "*Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation" ("Program").* Biotechnology Industry Research Assistance Council (BIRAC) setup by DBT is the Implementing Agency of *i3* Program (Program co-funded by World Bank loan).

The vision of the Program is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals including vaccines, biologics, medical devices and diagnostics to a level that will be globally competitive over the next decade.

This Request for Proposal (RFP) is to seek applications for the following:

1. **Medical Devices and Diagnostics**
   Applications are invited for development of therapeutic and diagnostic equipment in the areas of wound management, trauma & emergency medicine, surgical tools and implants.

[1] *For further details of the Program, see the National Biopharma Mission Document*

Section II – Application process, Instructions, Applicant eligibility criteria and other processes for the RFP at Section III

1. Application Timelines

Key Dates

RFP Publication	**31st October, 2019**
Application Due Date	**12th December, 2019 (5:00 PM)**

2. Application Guidelines and Process

The Proposal can be submitted online as per the required format. The call for the Proposal will be open for 06 weeks. The website will provide detailed user guide to facilitate the online proposal submission.

Process for submitting the proposals online is detailed below:

- Go to BIRAC's website or Go the URL: http://birac.nic.in/nbm
- Click on the RFP on NBM link under Programs and the active call would be highlighted.
- Click on the active call against which you wish to submit the proposal.
- Further details on 'How to Submit a Proposal' would be available in the User Guide available on the website.
- Log on to BIRAC website (http://www.birac.nic.in).
- If you are a registered user, log-in using the credentials, else you need to register your company/organization by clicking on New User Registration.
- In case of new user registration, a computer generated link will be sent to the email-id provided at the time of registration to generate a password.
- Once you login, you will be navigated to the proposal submission page under NBM link.

Instructions:

a) Applicants are advised to fill-up and submit their applications early without waiting for the last date in order to avoid any last minute contingencies. The system stops accepting applications automatically at midnight of the last date of receipt of application.
b) Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review. Applicants are advised to provide self-contained proposals with essential supporting materials provided as uploads.
c) Requests for changes in the proposal once submitted will not be encouraged.
d) Providing incorrect information intentionally is viewed adversely.
e) Please read through this RFP in its entirety and ensure that your application, budget and organization are in compliance with the eligibility criteria provided. Proposals for projects that do not meet the eligibility criteria and/or do not directly respond to the call area will not be reviewed, regardless of their quality. You are strongly encouraged to contact BIRAC if you are unsure about the eligibility or responsiveness of your project.
f) Proposed budget shall be made inclusive of all applicable taxes and shall be considered accordingly.
g) Information on all relevant pre-existing agreements/ MoUs in connection to the proposed technology, background IP, collaborations, outsourcing, consultancy, joint

ventures, consortium partnerships, IP licensing, technology transfer, material transfer etc. should be provided at the time of proposal submission.

h) Risk management proposal for the project should be submitted after scrutiny of the execution aspects of the project.

3. Evaluation Methodology

a) PMU-NBM, BIRAC will screen the proposals for responsiveness to all the specified administrative and procedural provisions required in the RFP. If the application is found to be incomplete or unresponsive to the provisions described in the RFP, the application will be considered ineligible.

b) Proposals that meet the eligibility criteria will be submitted for peer-review by national and international reviewers to assess the proposal merit (and other review criteria as specified above). Reviewers will be checked for conflicts of interest and will sign confidentiality agreements. Information may also be shared with selected third parties for the purposes of independent audit, evaluation and assessment of activities.

c) The Scientific Advisory Group will collate the results of the reviews, make their own assessments and recommend shortlisted applications for further screening to the Technical Advisory Group.

d) Grantees may also be invited for interviews or sought written clarifications when it is felt beneficial to ensure that any outstanding questions are resolved prior to concluding the full review.

e) Technical and financial due diligence process would be carried out by PMU-NBM, BIRAC.

f) Final decision on applications to be funded will be made by Technical Advisory Group.

All personal data will be stored and used by or on behalf of DBT/BIRAC in accordance with the Acts and confidentiality norms.

DBT/BIRAC reserves the right not to process your proposal if you are ineligible to be a proponent or the subject of your proposal not fall within the RFPs' remit. Mere consideration of the Proposal in no way implies that section of Grant-in Aid will be forthcoming.

4. Legal Eligibility Criteria

Who can apply?

The proposals can be submitted:

i. Solely or by consortium of Indian Companies **OR**

ii. Solely or by consortium of LLP **OR**

iii. Solely or jointly by Non-profit organizations/ Government entities/ Institutes/ R&D Organizations **OR**

iv. Jointly by an Indian Company and Non-profit organizations/ Government entities/ Institutes/ R&D Organizations/ LLP **OR**

v. By a Consortium of Indian Companies along with Non-profit organizations/ Government entities/ Institutes/ R&D Organizations

Criteria Particulars for the Proponent entities

- **Indian companies**
  An Indian Company is defined as one which is registered under the Indian Companies Act, 2013 and minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport [Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders].

- **Non-profit organizations/ Government entities/ Institutes/ R&D Organizations**
  This will include Academic Research Institutes, Universities, Research Foundation, Medical Colleges and Institutes – both public and private who are valid legal entities such as Trust, Society or established under central or state statute.

- **Limited Liability Partnership**: A limited liability partnership is defined as one which is incorporated under the Limited Liability Partnership Act 2008. Minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens. [Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders].

Relevant documents for submission in the application:

1. Applicant being an Indian academic scientist and researchers: -

a) Copy of passport (from academic scientists & researchers) or self-declaration of citizenship attested by a gazetted officer.
b) Either incubation agreement; or letter of intent in favour of applicant, issued by Incubation centre (which states that the incubation centre is willing to give facilities to applicant for the project applied for).

2. Companies: -

a) Incorporation certificate.
b) Share holding pattern as per BIRAC format in support of 51% eligibility criteria.
c) Details regarding in-house R&D facility, if any; or Incubation agreement.
d) Audited financial details of last three financial years (i.e. 2014-15, 2015-16, 2016-17), if applicable.
e) Copy of passports of the shareholders (in support of 51% eligibility criteria) or self-declaration of citizenship attested by a gazetted officer.

3. **Limited Liability Partnership: -**

a) Incorporation/Registration certificate.
b) Partnership deed; or list of subscribers which states that minimum half of the partners are Indian citizens.
c) Copy of passports of Indian partners/subscribers or self-declaration of citizenship attested by a gazetted officer.
d) Research mandate/ details regarding in-house R&D facility, if any/ Incubation agreement.
e) Audited financial details of last three financial years (i.e. 2014-15, 2015-16, 2016-17), if applicable.

4. Indian institution/ universities/ public research organization: -

a) Affiliation/registration certificate or statute reference for establishment.
b) Details regarding in-house R&D facility, if any/ Incubation agreement.
c) If the institution/public research organization are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust.

5. Society/ Trust/ NGO/ Foundation/ Association: -

a) Society:

i. Society registration certificate.
ii. Details regarding in-house R&D facility, if any / Incubation agreement.
iii. CA certificate (supporting the fact that half of the members of the society are Indian citizens)

b) Trust:

i. Trust deed.
ii. Details regarding in-house R&D facility, if any / Incubation agreement.
iii. CA certificate (supporting the fact that half of the members of the trustees are Indian citizens)

c) NGO/ Foundation/ Association:

i. registration details/certificate.
ii. Details regarding in-house R&D facility, if any / Incubation agreement.
iii. if the NGO/Foundation/Association are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust

For Technical eligibility refer to Section III

5. 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.

Other Requisites for Funds Disbursements to Company

In addition to signing of agreement between all the concerned parties, following requirements need to be completed before the first instalment can be released:

- A letter of authorization by the Head of the Academia and/or A Board Resolution from the Company Partner for acceptance of the Grant-in-Aid under NBM.
- Opening up a No-Lien Account with a scheduled/ nationalized Bank.
- MoU with collaborator(s) (if applicable).
- Commitment to comply with Clinical Research Validation and Management Framework (CRVMF) http://birac.nic.in/nbm/uploads/2019/08/crvmf.pdf
- Commit to obtain all applicable environmental authorizations, prior to the commencement of product development activities.
- Include qualified environmental / EHS engineer in the team for implementation of Environment and Health Risk Management Plan (EHRMP). Requirements on Environmental aspects may be found at – http://birac.nic.in/nbm/uploads/2019/08/emf.pdf
- Comply with EMF requirements during all stages.

- Submit and comply with the Project Risk Management Plan during all stages. (http://www.birac.nic.in/nbm/cms/page/resources)

6. Program Monitoring Mechanism

Project Monitoring Committee (PMC)

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.

7. Reporting of Progress

i. On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format.
ii. The MCR will be assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget will be released.
iii. The Applicant will have to submit a duly certified Statement of Expenditure for every 30th September and 31st March.
iv. Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure will be made available as per requirement.

8. Contact Information

Further information can be obtained at BIRAC website (www.birac.nic.in) or National Biopharma Mission website (http://birac.nic.in/nbm/) or at 011-24362107.

Contact Person:

Dr. Kavita Singh, Mission Director, PMU- National Biopharma Mission

Email: technical.birac@gov.in

Dr. Hardeep Vora, Programme Manager, PMU- National Biopharma Mission

Email: nbm3.birac@nic.in

Section III – Details of the RFP for Medical Devices and Diagnostics.

The National Biopharma Mission announces a Request for Proposals to support product development of medical devices and diagnostics that address the Indian healthcare needs.

A. Objective:

The objective of the Mission is to support:

- Development of medical devices and diagnostic products so as to advance their development and bring them closer to the market.
- Development of an ecosystem that would spur indigenous manufacturing in the medical devices and diagnostics sector.

B. Technical Scope:

This call seeks proposals to accelerate indigenous development of medical devices and diagnostic products. The primary focus of this call is towards therapeutic and diagnostic equipment in the following areas:

1. Wound Management – Different types of wound management medical devices (with or without antimicrobial activity).
2. Trauma and Emergency medicine.
3. Surgical Tools – High end medical devices and robotic devices used for surgeries.
4. Implants – Different types of medical devices of implantable nature for human use.
    - Prosthetic devices (such as limbs or whole body prosthesis) or cosmetic devices (such as breast implants) will not be considered.

C. Product Development Stage:

This call will support the following stages of product manufacturing and testing which can be completed in 30 months duration:

1. Pilot batch manufacturing – Manufacturing of limited number of prototypes for further compliance and regulatory testing only. The number of prototypes should be based on the testing requirements.
2. Compliance testing – Testing of equipment/ device/ material for biocompatibility (*in-vitro* only), physico-chemical testing, EMI-EMC testing etc. for certification.
3. Preclinical testing – Preclinical testing in large animals only (including dogs, sheep, goat, pig and non-human primates) for medical devices. Proposals for testing in other animals such as mouse, rat, rabbit, hamster, guinea pig etc. will not be considered.
4. Human clinical testing – Clinical investigation/ clinical performance evaluation of medical devices in humans. These studies need to be undertaken through a CRO.

D. Pre-requisites For Application

1. Early stage research and development, including prototype development is **NOT** under the scope of this call.
2. *In-vitro* diagnostics (IVDs), rehabilitation devices, IT-based medical devices (such as hospital management systems, AI-enabled medical devices etc.) are also outside the scope of this call.
3. The stage of product development at the time of application should be above TRL-4 (Technology Readiness Level-4) as described in the table below.
4. Ethical and regulatory approvals for the product development/ testing need to be taken by the proponent as part of the studies. All compliance studies (*in-vitro* and/or *in-vivo*) need to be conducted at accredited laboratories as per the respective applicable standards and/or Medical Device Rules 2017. The organization that would conduct the above tests should provide performance certificates acceptable to the regulatory agencies in India. A clinical partner may be included wherever necessary.

Definition of Technology Readiness Level-4	
TRL-4	**Proof of concept established**
Definition (Medical Devices including diagnostic devices)	Functional Prototype developed by integration of different modules and safety, efficacy and performance of candidate device or system demonstrated in a defined laboratory, Simulated Environment or animal model (with Institutional Animal Ethics Committee approvals)
Definition (Biomedical implants)	Material safety and or imaging compatibility proven in *in-vivo* small animal model study (with Institutional Animal Ethics Committee approvals). Functional Prototype implant device developed as per the design in a near GMP condition. Sterilization and packaging established.

Note: The scientific and technical committee of National Biopharma Mission reserve the right to reject a proposal without review, based only on content of the application, even if the product belongs to one of the above categories and conforms with the pre-requisites.

E. Duration of Proposals Under the Call:

The proposals can be up to **30 months duration** only.

F. Technical Eligibility Criteria:

- Collaboration with a clinician will be preferred, and is essential for human studies. The members of the collaboration should demonstrate prior experience in product development.

- Applicants from academic institute should have relevant expertise in the product segment as demonstrated through publication/ patent/ technology transferred/ product under development.
- Proposal by company should demonstrate experience in product development and a competent team.
- The applicant should have adequate in-house facility to address the project implementation (which shall be evaluated during the site visit).
- A clinical investigation plan should be presented for human studies that address study protocol, risk analysis of medical device, expected AE/SAE, cohort size, expected duration of follow-up etc. However, approvals from regulatory agencies may be submitted before the study initiation.

G. Funding Mechanism

Allowable costs include

- *Personnel*: All personnel recruited for the development of the product *only* are allowed to claim costs. Researchers and PIs who receive a salary from the host institution as permanent or fixed term staff members may NOT claim salary reimbursement from BIRAC grants.
- *Technology Consultants*: These may include both national and/or foreign consultants who provide a service and capability that is not available among the project partners. Preference should be given to national service providers.
- Equipment cost may be considered depending on the rationale.
- Supplies and consumables for the equipment.
- Travel & accommodation: Must be directly related to the execution of the project or travel related to seeking technology transfer.
- Institutional overhead (maximum 8% of recurring budget or Rs. 20.0 lakhs, whichever is lower) are allowed. Institutes receiving DBT support/ funds are not eligible for any overheads.
- Outsourcing: Funding for activities that cannot be completed on the premises of the applicant or collaborator(s). CROs hired for the proposal must be Indian organizations.

Non-allowable costs:

- Purchase or construction of a building/ space/ land.
- Rental costs for space.
- Recruitment costs for staff.
- Attendance at conferences.
- Legal fees.
- Any trials or tests conducted outside India, unless the service is not available in India.

H. Mechanism of Support

Support provided to candidates selected in this call will comprise of:

- Direct funding – Funding provided would be dependent on the current stage of development and the proposed activities to be conducted.

- Access to a group of experts from industry and academia with expertise in Medical Device discovery, development, clinical investigation, Indian health care delivery systems experts, regulatory experts, IPR and legal experts.

I. Evaluation and Decision Making Criteria

a) Proposal merit

- Is the proposal aligned with the objective of the RFP?
- Does the proposal demonstrate preliminary work of the identified product up to TRL-4 which will be useful for the proposed scope of work?
- Has the applicant provided adequate description of the existing manpower and infrastructure to understand the present capabilities?
- Does the proposal describe prior experience in product development?
- Are objectives and activities well defined?

b) Team/ Applicant:

- Is the applicant competent to ensure effective conduct of the proposed work? Does the team have relevant capabilities and appropriate experience for the same?
- Are the team roles and responsibilities clearly defined?
- Has the applicant collaborated/ consulted with a clinician in the respective field for the product development?
- Is need for consultants and/or technology transfer clearly identified?

c) Implementation and Infrastructure:

- Is the implementation methodology and work plan adequately detailed and realistic?
- Have the resources (technical and management people, equipment, collaboration, outsourcing needs etc.) required over the time frame been comprehensively mapped?
- Has the applicant anticipated difficulties/ challenges that may be encountered? Have alternative tactics and mitigation plans been considered in case of failure?

d) Business Strategy:

- Has the applicant provided any market surveillance details for the said product?
- Has the applicant provided any details on cost effectiveness of the product vis-à-vis existing products in the market?
- Has the applicant identified any specific clients or business opportunity for the product after development?

e) Budget Estimates:

- Is the proposed budget reasonable in light of the defined scope of work in terms of milestones and activities? Have reliable references been provided for justification?
- Is the resource allocation across various stages sufficient and appropriate?