



Industry Innovation Programme on Medical Electronics

Concept Note

Call Open Date: 31 May 2015

Call Closing on midnight of 30 June 2015

**A BIRAC Initiative in partnership with
Department of Electronics and Information Technology,
Ministry of communications and Information Technology,
Government of India**

Prologue

BIRAC through its various flagship schemes is making significant investments in the medical devices sector and promoting the R&D of medical devices. BIRAC has supported more than 100 industries of Medical Fraternity and is supporting many ideas of young individual researchers, SME and large companies. Department of Electronics and Information Technology (DeitY) is already supporting the entire value chain of Electronics R&D activities in the country ranging from the basic components to sophisticated product development. These include development and deployment of indigenously developed medical electronic devices in healthcare centres across country.

Industry Innovation Programme on Medical Electronics (IIPME) is launched with an aim to promote and foster cutting edge technologies in the field of Medical Electronics. The project IIPME is a partnership project between the “Department of Electronics and Information Technology”, Ministry of Communications and Information Technology, Government of India and “Biotechnology Industry Research Assistance council”, a public sector undertaking of Department of Biotechnology, Ministry of Science and Technology, Government of India.

Introduction

Medical electronics is a branch of electronics that deals with design, implementation and use of electrical devices and equipment for medical purposes such as research, examination, diagnosis, treatment, assistance and care. Medical electronics utilizes field disciplines of both electronics and biomedical. Portable biomedical electronic devices are essential to move medical products from the hospital atmosphere to home, and to move medical examination from the laboratory and offer one-touch access to users. These devices offer secure access and enable both patients and doctors to stay in touch with each other remotely.

The IIPME will be one of its kinds, which will directly target the innovations in the medical electronics start-ups, SMEs and large enterprises and will also help in generating the ideas to keep ready the pipeline of new unmet medical Innovations.

To achieve the desired impact the IIPME will fund the innovations in three categories

- a. **Seed Grants (Idea to PoC):** This phase is for funding the projects, which are at initial stages of product development cycle. These awards are meant to provide an opportunity to test particularly bold ideas.
- b. **Early Transition:** The category is for the projects which have established the Proof of Concept and require incremental prototype innovations and validation; these awards are for projects which are at the early stages of translational research.
- c. **Transition to Scale:** The stage is for the projects which have already shown promising data on establishing the Proof of Concept and has generated enough validation data, these awards require demonstration of detailed preliminary data and are meant to provide an

opportunity to develop, refine, and rigorously test approaches that have previously shown promise in controlled or limited settings.

The Expression of Interest (EoI) and further the proposals received under the three phases will undergo a rigorous screening process which will shortlist and evaluate the proposed innovation. The proposals will be evaluated online by the **area review panel** comprising of experts from various academic institutes. The shortlisted proposals will be called for the presentation to the Technical Screening Committee at BIRAC and will be further screened. The shortlisted projects will be evaluated in detail by the technical and financial due diligence team at the company site and the projects which will clear all these phases will be finally approved for funding by the Apex approval board.

The Mandate

The scheme is launched with an objective of promoting and fostering the R&D in medical electronics arena in India. The programme aims to encourage development of innovative solutions that can make the technology available and bring significant changes in the medical electronics ecosystem.

The three main pillars of the programme includes:

- 1. To support cutting edge technologies in multi-disciplinary areas of Medical Electronics**

The project goal is **to fund** a portfolio of Indian Led pilot Projects that target innovations in the **multi-disciplinary areas** comprising of electronics, engineering, software, algorithms and information technology.

- 2. To foster and promote the research in Medical Electronics to make it available, accessible and affordable**

The program will **promote the scientific and technological research** in Medical Electronics sector so as to make innovative medical electronics **available, accessible and affordable** to the people at the bottom of the pyramid.

- 3. To address the challenges of R&D in Medical Electronics and develop the conducive ecosystem**

The project will help **to address the challenges of Medical electronics** fraternity and will bring in fast pace research and development in the untouched arena. The intention is to make the ecosystem conducive for development of medical electronics in India through supporting high risk innovations and making the funds available for the high value research.

The Context

Conventional medical electronics have evolved over time, which is obvious with the advent of handheld smart phone-sized ultrasound systems, digital stethoscopes and digital X-ray systems. Small-sized medical devices are available for monitoring blood sugar levels, insulin, blood pressure and blood coagulation levels at home, and can send periodical reports to a doctor in a connected environment. The potential benefits associated with this technology includes improved quality of healthcare, increased output accuracy, remote health data availability, precise billing mechanism, easy to update patient electronic records and increase in level of patient experience. On other hand, there are some negative aspects such as decrease in productivity of medical professionals, lack of standard terminologies, significant learning difficulties and issues related to violation of patient data security.

Medical electronics engineering ranges from model-driven embedded software design to PCB design and manufacture, and a large number of inter-related sub-sectors too. It covers a very wide range of technologies including radio frequency, analogue semiconductors, digital and microprocessor chips, digital signal processors, sensors, actuators, electromagnetics, optoelectronics and photonics, displays, embedded software, power supplies and antennae.

The rapid advancement in information technology and healthcare consciousness has accelerated the scope for medical electronics. Fast growth in medical electronics is further influencing various demographic trends like consumers' expectations of more household medical electronic equipment, enhanced portability of complex imaging and monitoring systems, further miniaturisation of implantable equipment with lower energy consumption, and functional integration of equipment and applications in wireless and network technology.

The Indian Medical Electronics industry is currently valued at around USD 1 billion and has been growing at an average rate of 17% for past couple of years. It is strongly believed that growth will outperform the pace, resulting in the Indian Medical Electronics market reaching close to USD ~6.5 billion by the year 2020. There are many market factors which are influencing the growth of this industry such as Growing population, ageing, income base and associated disposable income, increasing socio-economic inclusion of rural and deprived in mainstream economy, heightened manufacturing innovation to create customized products to meet the needs of all income segments, changing disease prevalence pattern (e.g. early onset of diabetes and heart diseases) and growing awareness among the middle class to focus on early detection and disease prevention. (Source: Indian Medical Electronics Outlook 2020)

The current product affordability of medical technology is a major barrier for the market to be able to achieve its anticipated potential growth. However, prudent innovation methods can reduce manufacturing costs and eventually lower market prices. Additionally, an increased focus and reliance on domestic manufacturing of medical electronics, as opposed to the current dependence on the import market, will also help to improve this overall condition. Products customized and designed to match Indian patient requirement, have the potential to increase market penetration rate in Tier II/III cities. Enablers such as strong management information systems and innovations in telemedicine can allow for medical technology to be scaled to the masses in a cost effective manner.

To reach the target of USD ~6.5 billion by the year 2020, the medical industry has to break all the constraints and has to bring Innovations in medical electronics to design more cost effective products and reduce out of pocket expenses for patients fuelling demand for healthcare services. The Medical Electronics industry is also eyeing towards the government initiatives for consolidating the market.

Some reports and links which can be referred for Medical Electronics related information are:

Indian Medical Electronics Outlook 2020: The report gives an overview of market size, segmentation and challenges of Electronics sector in India.

Global Database: Medical etrack

Medical Electronics Market - Global Industry Analysis, Size, Share and Forecast, 2014 - 2020

<http://www.futuremarketinsights.com/reports/details/global-medical-electronics-market>

<http://deity.gov.in/content/rd-medical-electronics-health-informatics-division>

<http://deity.gov.in/content/research-development-electronics>

The Challenge

The first call of IIPME is open for addressing challenges in the Medical Electronics arena where health informatics and electronics can be integrated with medical requirements. The call will remain open till **30th June 2015** and proposals are invited online through the website www.birac.nic.in

The Medical Electronics is a subset of Medical Devices sector and the below mentioned figure clearly demarcates the devices sector from Medical Electronics. **The proposals are invited only in the electronics segment. Any proposal not in the scope of the call will be deterred.**

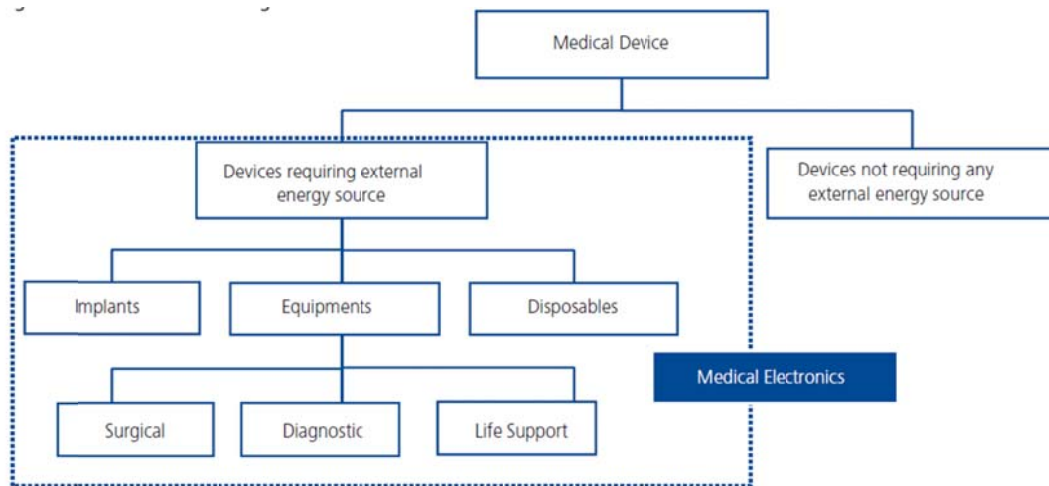


Figure: Segmentation of Medical Devices (Source: Indian Medical Electronics Outlook 2020)

The proposals are invited for medical technologies ranging from handheld devices to heavy base devices, wearable gadgets to wireless connected devices, and from RFID-based health tracking device to RADAR technology-based ultrasound machines.

The area of Focus includes but not limited to;

1. **Imaging and navigation** – Requirement of improvements in minimally invasive techniques and therapy delivery technologies that result in advances in imaging and navigation technologies which will continue to improve diagnostic accuracy and enhance surgical capabilities.
2. **Technologies for chronic diseases** – Need for cost effective and accurate chronic disease management with focus on disease states, such as obesity and diabetes.
3. **Convergence of medical device and bioinformatics** – This convergence will result in early and faster diagnosis, better prognosis, and tailored therapy.
4. **Increasing the Outreach through Medical electronics** –
 - a. Innovative service models involving “Big data” and “Social Media” enabled devices for improving health delivery model
 - b. Portable home based packaged medical electronics based on system integration
 - c. Medical Electronics for Community Health Programs

Inclusion and Exclusion criteria

Example of few technologies which can be supported in the call are as mentioned below but not limited to;

- Advanced robotics based technologies
- Minimally invasive surgical techniques
- A microchip retina implant
- Electronic devices to manage diabetes and other lifestyle based diseases
- Disposable medical and electronic probe assemblies for minimally invasive applications
- Disposable catheter cables, disposable EEG sensors/ lead wires, disposable
- Advances in diagnostic like Cardiac imaging, CT scans, X-ray, Molecular Imaging, MRI, and Ultrasound-imaging including hand held devices
- Ventilator support system
- Human Body powered Batteries
- Integration of informatics with Health Delivery system

Example of few technologies which does not fall under the purview of the call are as mentioned below but not limited to;

- Antibody based diagnostics kits without any electronic component
- Innovative hospital consumables like surgical gloves, thermometers
- Drug eluting Stents
- Biomaterials or tissue engineering based technologies
- Lab development or Infrastructure based projects
- Software Applications for creating awareness
- Semiconductors, sensors without any medical benefit

Funding Support Available

The budget allocated for the Medical Electronics call is INR 10 Crores. We consider funding 6-9 innovative technologies in Category A and 2-3 innovative technologies in category B and C each.

Funding available per project in each category is as mentioned below:

Seed Grants: A grant-in-aid up to Rs. 50 lakhs for a period of 18 months.

Early Transition: Amount not exceeding INR 100 lakhs is available over the period of 24 months as Grant in aid. The project cost would be matched equally by BIRAC and the industry.

Transition to Scale: A mix of grant & loan for a period of 24 months is available. The project cost would be matched equally by BIRAC and the industry.

Expression of Interest (less than 5 pages)

The applicants are invited to submit online Expression of Interest (EoI) on BIRAC website which includes the parameters like;

1. Executive summary (~1 page)

At the beginning of this section, include one or two sentences in bold that capture the essence of your idea. The summary should indicate what is the specific problem that the project seeks to address, what is the approach proposed to solve this problem and why the project is innovative, and what is the expected impact of the project – if successful – at the end of the grant period.

2. Goals (~1 page)

Describe the specific goals of the project and how they are responsive to the program scope and goals noted in the Request for Proposals. Indicate the specific problem that the project seeks to address and explain why the proposed solution is unconventional or creative and why it improves upon the best existing alternatives. Specify any hypotheses that will be tested. If applicable, briefly present any relevant preliminary data. Indicate what are the expected results of the project – if it is successful – at the end of the grant period. Briefly indicate what are the next steps might be and how the project's results could lead to further progress and innovation.

3. Approach (~1.5 page)

Identify the major objectives of the project that will be pursued to reach the project's goals. Summarize the research activities for each objective. Indicate how the research activities for individual objectives will be judged successful and highlight important research milestones that will be used to track progress. Define the critical experiments that will prove or disprove the relevant hypotheses.

4. Capabilities (~1/2 page)

Summarize how the expertise and experience of the investigators and their organizations will help in achieving the goals of the project. Describe the resources and facilities available for conducting the proposed research.

5. Collaboration (~1/2 page)

If relevant, indicate the role in the project of collaboration with other individuals and organizations, including experience, resources, and facilities these collaborations would bring to the proposed research.

6. Budget (~1/2 page)

Describe how the proposed work will be performed within the budget allocated for the relevant grant type, including a summary of the budget that will be allotted to each research objective for each year of the project.

The applicant can also upload a concept paper of the technology proposed with required figures and graphs.

Timelines

Activity	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Call for LoI												
Road shows to increase outreach												
Eligibility Checks and ARP												
MeAG Meeting												
Full Proposal Submission												
SV and MEIP with MeAG												
Apex Board Meeting												
Financial and Legal Concurrence and Agreement Signing												

What's in for Applicants?

1. Mentorship from various subject matter experts and KOLs
2. Funding support for testing the bold ideas
3. Networking Platform
4. Opportunity to scale up the validated technology/product

The scheme document with details on the implementation of the program including below mentioned is available as Annexure to the document.

1. Details of the Categories
2. Eligibility Structure
3. Operational Mechanism – Application Process
4. Evaluation Indicators
5. Funding Mechanism
6. Project Monitoring & Mentoring
7. Intellectual Property Management

We seek only online 'Expression of Interest' from Innovators, Start-ups, SMEs and large Indian companies individually or in partnership / consortia mode on or before

30th June 2015

Contact Person:



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DEITY -
BIRAC

INDUSTRY INNOVATION PROGRAM ON
MEDICAL ELECTRONICS

PROJECT IMPLEMENTATION DOCUMENT

Introduction

The project “Industry Innovation Programme on Medical Electronics” is a collaborative project between the “Department of Electronics and Information Technology”, Ministry of Communications and Information Technology, Government of India and “Biotechnology Industry Research Assistance council”, Department of Biotechnology, Ministry of Science and Technology, Government of India.

The project goal is to fund a portfolio of Indian Led pilot Projects that seems to target innovations in the multi-disciplinary areas comprising of electronics, engineering, medical devices, healthcare, software, algorithms and information technology. The project will help to address the challenges of Medical electronics fraternity and will bring in fast pace research and development in the untouched area.

To achieve the desired impact the IIPME will fund the innovations in three categories

- a. **Seed Grants (Idea to PoC):** This phase is for funding the projects, which are at initial stages of product development cycle. These awards do not require preliminary data and are meant to provide an opportunity to test particularly bold ideas.
- b. **Early Transition:** The category is for the projects which have established the Proof of Concept and require incremental prototype innovations and validation; these awards are for small risk projects which are at the early stages of translational research.
- c. **Transition to Scale:** The stage is for the projects which have already shown promising data on establishing the Proof of Concept and has generated enough validation data, these awards require demonstration of detailed preliminary data and are meant to provide an opportunity to develop, refine, and rigorously test approaches that have previously shown promise in controlled or limited settings.

First Call of IIPME

The first call of IIPME will focus on below mentioned areas of Medical Electronics:

1. **Imaging and navigation** – Requirement of improvements in minimally invasive techniques and therapy delivery technologies will result in advances in imaging and navigation technologies which will continue to improve diagnostic accuracy and enhance surgical capabilities.
2. **Technologies for chronic diseases** – Need for cost effective and accurate chronic disease management with focus on disease states, such as obesity and diabetes.
3. **Convergence of medical device and bioinformatics** – This convergence will result in early and faster diagnosis, better prognosis, and tailored therapy.
4. **Increasing the Outreach through Medical electronics** –
 - a. Innovative service models involving “Big data” and “Social Media” enabled devices for improving health delivery model
 - b. Portable home based packaged medical electronics based on system integration
 - c. Medical Electronics for Community Health Programs

Description of Categories

Category A

Seed Grants (Idea to PoC): This phase is for funding the projects, which are at initial stages of product development cycle. These awards do not require preliminary data and are meant to provide an opportunity to test particularly bold ideas.

Funding Support: A grant up to Rs. 50 lakhs is available for a period of 18 months.

Eligibility: This category is open to:

- Indian start-ups (Incorporated under the Indian Companies Act and having a minimum of 51% Indian Ownership) (Less than 3 years old as on the date of advertisement)/Indian entrepreneurs (Indian citizen willing to form a Company as per Indian Law).
- Indian Academic Scientists, Researchers, PhDs, Medical Degree Holders, Biomedical Engg Graduates (who must be willing to incubate in a business incubator)
- No DSIR certification is required

Category B

Early Transition: The category is for the projects which have established the Proof of Concept and require incremental prototype innovations and validation; these awards are for small risk projects which are at the early stages of translational research.

Funding Support: Amount not exceeding INR 100 lakhs is available over the period of 24 months as Grant in aid. The project cost would be matched equally by BIRAC and the industry.

Eligibility: This category is open to:

FOR COMPANIES (For profit/ nor for Profit)

- Incorporated under the Indian Companies Act having a minimum of 51% Indian ownership.
- DSIR recognition.

FOR INDIAN INSTITUTION/ UNIVERSITIES/ PUBLIC RESEARCH ORGANIZATION WHO CAN BECOME CO-APPLICANTS ALONG WITH THE COMPANY

Established in India and having NAAC/ UGC/ AICTE or any equivalent recognition certificate.

NOTE: Applicants and Co- applicants should not have any other legal disqualification that will prohibit them from participating in the scheme process and execution of necessary agreements thereafter.

Category C

Transition to Scale: The stage is for the projects which have already shown promising data on establishing the Proof of Concept and has generated enough validation data, these awards require demonstration of detailed preliminary data and are meant to provide an opportunity to develop, refine, and rigorously test approaches that have previously shown promise in controlled or limited settings.

Funding Support: A mix of grant & loan for a period of 24 months is available. The project cost would be matched equally by BIRAC and the industry

Eligibility: This category is open to:

FOR COMPANIES (For profit/ nor for Profit)

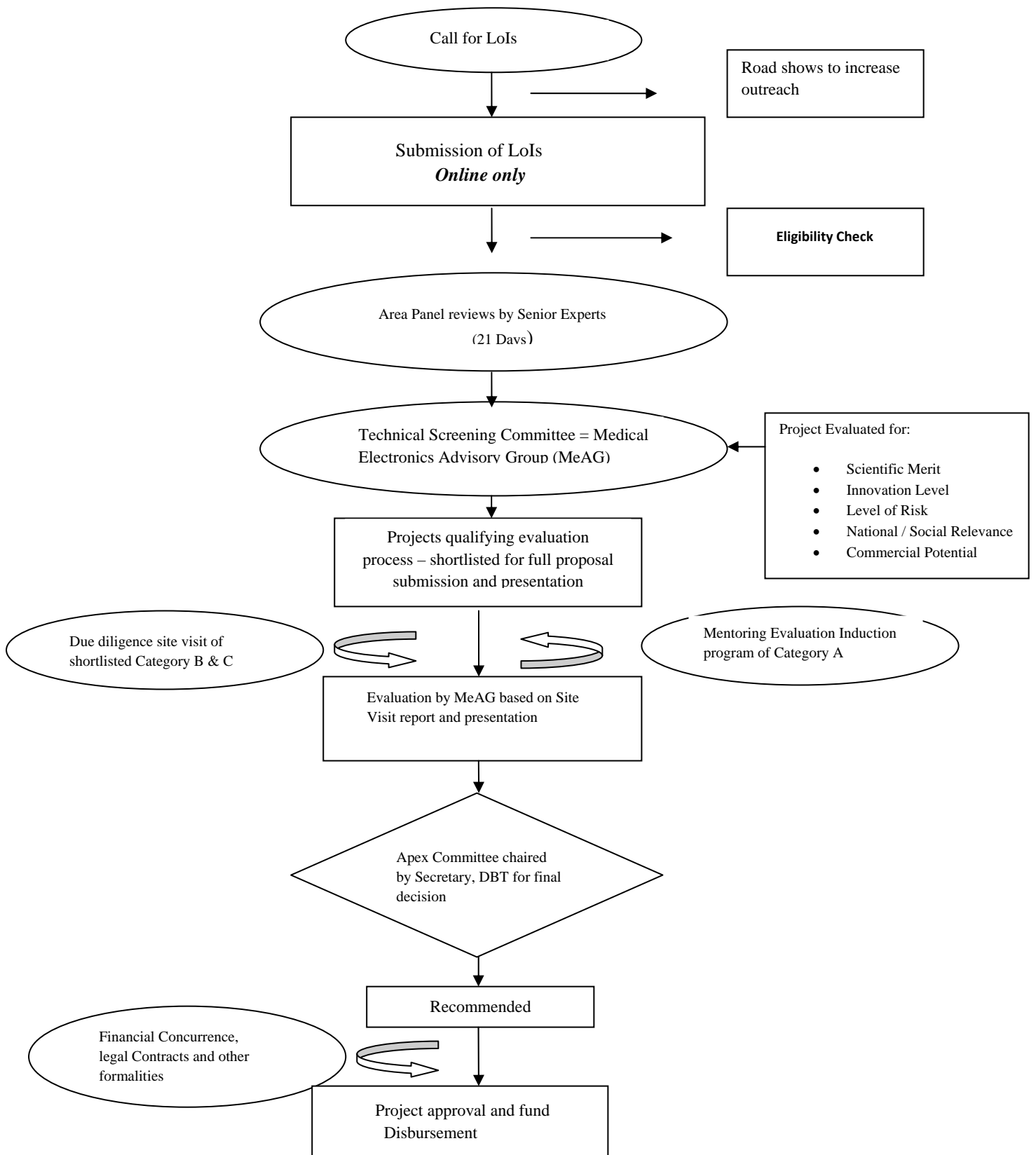
- Incorporated under the Indian Companies Act having a minimum of 51% Indian ownership.
- DSIR recognition
- The product should have gained necessary approvals from the concerned regulatory authority (-ies) for pilot studies.
- It is desirable that the projects show partnership or a consortium between product/service innovator Company, an implementer/deployer (Research Foundations, Section 25 companies etc) and clinical partner(s). Any such Partner for execution/implementation can become Co-Applicant in the proposal. Co-Applicant should have been established as a legal entity under the relevant Law of India having at least half of the stakeholders (owners/partners/ trustees/ members/ associates etc) as Indians. Local/state/ Central Departments can also become part of the execution/ implementation/ survey etc.

Operational Mechanism

Application Process

1. The call for interesting ideas (LoI) will be announced once a year on the thematic areas as mentioned above
2. Road shows will be organized for the outreach of the IIPME program at various national institutes relevant to Medical Devices R&D.
3. The LoI will be submitted online through registration at BIRAC website
4. The eligible LoIs will be displayed on the BIRAC and Deity website for external and internal evaluation by experts (Area Review Panels).
5. The LoIs will also be scrutinized by the Medical Electronics Advisory Group (MeAG) meeting at BIRAC.
6. The selected ideas will be called for submission of Full proposal through online portal.
7. Full proposal will be reviewed online by subject experts
8. Mentoring and Evaluation (M&E) Induction Program will be organized for Category “A” shortlisted applicants. The applicants will get mentorship on grant writing skills, proposal technicalities, Documentation skills, financial requirements and Technical aspects.
9. Site visits will be organized for Category “B” and “C” applicants.
10. Revised proposal submission by the applicants (If required based on the M&E Induction program or site visit recommendations.
11. Advanced Evaluation and Recommendation will be carried out by MeAG based on the revised proposal, the reports of the lead discussants and the BIRAC facilitators for shortlisted proposals.
12. Final Approval of the shortlisted projects will be by Apex Board
13. BIRAC shall process the sanction of fund after financial, legal concurrence, due approval etc

Process Flow Diagram



The verticals of Evaluation Process

A. Evaluation of eligibility of the applicants and the co-applicants

Document needed for evaluation of eligibility:

FOR COMPANIES (For profit/ not for Profit)

1. Legal status- Certificate of incorporation
2. DSIR certificate or application applied for DSIR
3. Custom duty/ Income tax exemption for DSIR units should not be uploaded for documenting eligibility
4. Shareholding pattern in required format
5. A pdf stating year of establishment, Manufacturing, Trading, Imports and Marketing as well as R&D activities.
6. True copy of the Section -25 License

FOR PARTNERSHIP firms/ Society/ Trust/ NGO/ foundation/ Association

1. Legal status-Registration Certificate under Society Act, if the firm is registered. State/Central Act or any relevant certificate of registration
2. Partnership Deed Or Trust Deed
3. DSIR/ SIRO recognition
4. Income tax exemption certificate such as 12AA
5. Document listing out the names, citizenship and addresses of the partners, trustees, members of the governing body, directors as applicable ,
6. Pan Card copy of the establishment as Proof of Legal identity
7. Bye-laws of the entity
8. A pdf stating organization involvement in social innovation or S&T activities must have active participation in India. They need to submit an illustration of their active programs in the country as well as their accomplishment when requested.

FOR SOLE PROPRIETORSHIP

1. Legal status- Registration Certificate (in case of registered unit)
2. Name, citizenship and addresses of the proprietor.
3. Certificate/registration document issued by the sales tax/professional tax authorities.
4. Certificate/license issued by the municipal authorities under Shop & Establishment Act or other relevant statute
5. Registration / licensing document issued by the Central Government or State Government Authority / Department.

6. Importer Exporter Code (IEC) issued by the Office of Directorate General of Foreign Trade (DGFT) etc., (Any two of the above documents would suffice. These documents should be in the name of the proprietary concern.)

FOR LIMITED LIABILITY PARTNERSHIP

1. LLP agreement.
2. The Incorporation document and DPIN of the designated partners.
3. Specific production, manufacturing, sale, distribution or business licenses issued by local authorities

For Institution/ Universities/ Public research organization

1. Establishment certificate or Founding document indicating year of establishment
2. NAAC/ UGC/ AICTE or any equivalent recognition certificate.

B. TECHNICAL EVALUATION

Area review Panels

The area review panel will comprise of various experts on the thematic areas on which the call will be announced. The ARP will be responsible for technically evaluate the project through BIRAC online portal.

Technical Screening Committee = Medical Electronics Advisory Group (MeAG)

For each call of the IIPME a MeAG will be formed. The MeAG will comprise of Key Opinion Leaders and Subject Matter Experts from the Medical Electronics, Biopharmaceutical and financial sector.

The responsibilities of MeAG

1. The MeAG will be responsible for reviewing and short-listing the LoIs submitted.
2. The MeAG will recommend the constitution of the Mentoring and Evaluation group
3. The MeAG members may participate as mentors and as site visit experts
4. The MeAG will undertake advanced review and recommendation for funding.

Project Monitoring Committee = Mentoring and Evaluation Group (M & E)

The Mentoring and Evaluation group will be formed for the shortlisted LoI and will comprise of 3-4 members.

The responsibilities of M & E

- i. The M&E will be responsible for mentoring the applicant and evaluating the proposals as per evaluation indicators
- ii. The mentoring will be in the form of
 - a. Grant writing skills
 - b. Proposal requirements
 - c. Technical aspects
 - d. Financial requirements
 - e. Documentation Practices
 - f. Regulatory Requirements
 - g. Business models
- iii. The Evaluation of the proposal will be done as per the **evaluation indicators**
 - a. National Importance / Unmet Need
 - b. Societal Impact
 - c. The Commercial Value
 - d. The affordability
 - e. Innovation
 - f. Objectives and Timelines
 - g. Infrastructure requirements
 - h. Competence & Expertise
 - i. Budget Requirements
 - j. Business model
- iv. The M&E member may become the lead discussant for the MeAG.

Funding Mechanism

Award Capitals

Awards in the IIPME will be in the form of Grant & Loan. The maximum cap for each category is pre-determined and is as mentioned below:

Affordable product Development

Category A: A grant up to Rs. 50 lakhs is available for a period of 18 months

Category B: Amount not exceeding INR 100 lakhs is available over the period of 24 months as Grant-in-aid. The project cost would be matched equally by BIRAC and the industry

Category C: A mix of grant & loan for a period of 24 months is available. The project cost would be matched equally by BIRAC and the industry

Funding, Cost Sharing and Disbursement Policy

More than one milestone can be clubbed for the projects which are less than 18 months duration.

This scheme provides for a BIRAC contribution as per the various categories of the scheme and as mentioned above.

The contribution of the Government is as per the Apex Committee recommendations based on the Technical Committee's Evaluation. This is assessed as per defined set of criteria as mentioned in the evaluation Vertical section

The fund disbursement is milestone based and will be released in 4 - 5 instalments as per the timeline of the project

1st Instalment on signing of Contract - 30%

2nd Instalment on completion of 1st Milestone (6 months) and submission of corresponding fund utilization particulars- 20%

3rd Instalment on completion of 2nd Milestone (12 months) and submission of corresponding fund utilization particulars - 20%

4th Instalment on completion of 3rd Milestone (18 months) and submission of corresponding fund utilization particulars - 20%

5th Instalment on Submission of Report and submission of corresponding fund utilization particulars - 10%

More than one milestone can be clubbed for the projects which are less than 18 months duration or amounts to less than Rs. 50 Lakhs. No single project will get more than 25% of the total corpus as support.

Royalty clause - Payment of Royalty

The Company shall pay royalty to BIRAC at the rate of 5 (five) per cent on annual net sales of the product developed with BIRAC's assistance. Payment of Royalty shall be due beginning with the first sale of the product and the liability to pay royalty will terminate upon the first of any of the following three events to occur:- a) 5% Royalty had been paid to BIRAC for a period of five (5) years; (b) The Royalty amount paid to the BIRAC becomes equal to twice the amount of the grant-in-aid disbursed or (c) in case of foreclosure in accordance with Clause 9.

'Net Sales' for this purpose shall mean gross sales excluding excise duty and sales tax, as certified by the Chartered Accountant. Royalty for each financial year shall be payable to BIRAC within 60 (sixty) days of close of corresponding financial year. In case of delay in payment of royalty, the Company shall be liable to pay simple interest at the rate of 12 (twelve) per cent per annum on the amount of default in payment of royalty for the period of delay

Loan and Recovery Mechanism

The loan will carry a simple interest of 2-3 % per annum. Interest shall accrue from the date of release of loan instalment to industrial partners.

The repayment of the loan component as well as interest by the industry partner will be in ten equal half yearly instalments and repayment would commence one year after the completion of the project as per the defined objectives/time schedule as listed in the programmes. In the case of clinical /field trials, the phase - I , II and III could be treated as separate projects and completion of each of these would be considered as completion of project duration.

The project implementation period would be treated as the moratorium period and therefore the interest accrued during the implementation period would be amortized and will be payable by the industry partner in a maximum of 5 half - yearly instalments commencing one year from the completion of the project.

In case the industry partner transfers the know - how/patent/technology of the project financially assisted by BIRAC, the industry partner shall take prior written permission from BIRAC. Before giving the written permission, BIRAC shall be entitled to recover the grant amount disbursed along with simple interest @ 5% p.a. to be calculated from the date of release of the grant.

Project Monitoring & Mentoring

The projects are monitored/and mentored regularly by an M&E for each project. Site visits are conducted by specially constituted Expert Committees comprising two to three Technical experts and one financial expert. The Mentoring and Evaluation (M&E) is responsible for

- I. To monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives contained in the Agreement.
- II. To keep track of financial sustenance of the fund recipient. Based on the foregoing, to assess and suggest:
 - i. Recommend the release of next installment or part release thereof by the BIRAC.
 - ii. closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
 - iii. inclusion of additional industrial/institutional partner(s), in the overall interest of the Project,
 - iv. mentor(s) to assist in overcoming any technological problem faced in the Project implementation; and
 - v. Revision of the financial assistance.
- III. To advise on issues related to securing of IPR; and

- IV. 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 the Scheme.

Reporting of Progress

1. On Successful completion of each monitorable Milestone the Company and other Partners are required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.
2. The MCR is assessed by the M&E for its completion. On recommendation of the M&E, the next Milestone budget is released.
3. Each partner has to submit a statement of Expenditure for the Budget available for the specific milestone being reported upon. Both Company (if any) and BIRAC Contribution are to be accounted for.

Confidentiality

During the tenure of the Project, the 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 scheme document. The BIRAC shall not have any obligation of confidentiality with respect to any information that:

- a. is in the public domain by use and/or publication at the time of its disclosure by the disclosing party; or
- b. was already in possession of the recipient prior to receipt from the disclosing party; or
- c. is properly obtained by the recipient from a third party with a valid right to disclose such information and such third party is not under confidentiality obligation to the disclosing party; or
- d. was disclosed to any third party on a non-confidential basis prior to commencement of the Project; or
- e. was developed by the recipient, as established by acceptable written record, independently of the disclosure of information by the disclosing party; or
- f. is required by public authority, by law or decree.

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, in addition to in- house analysis.

Data Access Principles

BIRAC has the right to the technical data generated during the project for all the joint 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.

Indemnification

Applicants shall, at all times, indemnify and keep indemnified the 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 their employees or by any other third party resulting from or by any act, omission or operation conducted by or on its behalf. Further applicants shall, at all times, indemnify and keep indemnified 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.

Research Ethics and Regulatory Approvals

Applicant(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.

- a. Any project that involves the use of animals must be compliant with Institutional Animal Ethics Committee
- b. All projects having Clinical Trial Component shall comply with all applicable national and International regulatory frameworks.

Intellectual property Management and Translation

If there are any pre existing restrictions on IPR or publications arising from the research, a written statement that details them should be provided. Restrictions on intellectual property may affect the eligibility to apply to BIRAC.

Establishing suitable Intellectual Property Management Agreements among the Applicants and Co-Applicants will be a pre- condition for receiving funding. Provisions therein should govern the mechanisms and approaches to (a) identify Key Background Technologies and ensure freedom to achieve the goals of the Project (b) secure, if necessary, and manage and allocate IP rights (c) report inventions, (d) publish research results of the Project (including making available data and materials), (e) describe post - project development plans, and (f) develop strategies, to the extent possible, for the commercialization and sustainability of the Project's results.

Apart from the standard funding terms, project specific terms and conditions of funding will be negotiated on a case-by-case basis and a funding agreement will be put in place post the decision to fund the project.

Apart from SIIP, Intellectual property that arises under the award will be owned by the applicants' and co-applicant(s). Background intellectual property must be freely available to enable both the project to be performed and translation of the arising intellectual property to be realised. They will be responsible for the filing, prosecution and maintenance of IP arising out of the project and its own pre-existing (background) IP which is used in the project.

Patent Policy

- a. No cost shall be borne by BIRAC to protect or maintain any background IP.
 - b. Any patent applications and patents directed toward BIRAC supported inventions, if subsequently granted, for BIRAC supported inventions shall not be sold or assigned without prior written approval of BIRAC.
 - c. The cost towards the protection and /or maintenance of the Project IP can be built- in as one of the budget components.
 - d. Patents or patent applications directed toward BIRAC supported inventions shall not be abandoned without first notifying BIRAC and permitting BIRAC to elect to take title and pursue the application at its own expense. At the election of BIRAC, Applicant shall assign title of any BIRAC supported inventions to BIRAC at no additional charge.
 - e. The results of BIRAC supported research shall be submitted for publication within a reasonable time, consistent with the need to protect intellectual property when indicated.
 - f. Prosecution of patent applications directed toward BIRAC supported inventions and payment of all costs involved with seeking patent protection is the responsibility of the Applicant. Government filing and prosecution fees for BIRAC supported inventions may be charged to the grant.
 - g. Certain provisions for March-in-rights, price control and licensing are applicable for nationally important proposals if notified by specific "Order of BIRAC" as provided hereunder.
- I. With respect to the Project IP in which the Applicant has acquired title under this project, the BIRAC under whose funding Agreement the IP was made may exercise the right to receive a royalty-free license for the use of the intellectual property for the purposes of Government of India; the BIRAC reserves its right to require the fund recipient to license others and requires that any one exclusively licensed to market the innovation in India must manufacture the product in India, if the BIRAC determines that such -

- (i) Action is necessary because the Company or licensee/s has not taken, within a reasonable time, effective steps to commercialize the New IP in such field of use;
 - (ii) Action is necessary to meet requirements for public use or national interest and such requirements are not reasonably satisfied by the Company or licensee/s;
- II. Licensing/Sale of technology:
Subject to the determination of any of the two conditions under the preceding clause, the BIRAC, after taking into consideration the fund recipients' requirement for reasonable expansion and the demand supply gap at the appropriate time, shall have the right to require the fund recipient to provide the technical know-how of the product/process developed under the Project to other entrepreneur(s), on such terms and conditions as may be mutually agreed among the BIRAC, the fund recipient and such other entrepreneur(s).
- III. Price control:
If invoked, this aspect is based on case-to-case negotiation and based on other relevant demand and supply factors.

Licensing Policy

- a. Applicant must include provisions in all licenses and other revenue generating agreements for BIRAC supported inventions with third parties that bind the third parties to provisions of this agreement relating to the Global Access Strategy of BIRAC for the benefit of the developing world.
- b. Applicant may not enter into any license or other revenue generating agreement with a third party for the development and or exploitation, in any way, of a BIRAC supported invention without first providing written notice to BIRAC.
- c. BIRAC may opt for a transferable, irrevocable, perpetual, nonexclusive, royalty free license for BIRAC supported inventions with the right to sublicense, to use, manufacture, make, have made, produce, reproduce, copy, distribute, offer to sell, and sell the invention for the benefit of the developing world. Exercise of the license is at BIRAC' sole discretion, which it does not intend to undertake unless BIRAC determines that the Applicant or licensee(s) has taken inadequate steps toward making the invention available to the developing world within a reasonable time at a reasonable cost

Publication of Research Results

Applicant shall seek to publish the results of BIRAC supported research as expeditiously as is consistent with the need to seek patent protection. Data and materials produced with BIRAC funding shall be made available through peer reviewed Journals, trade

publications, public databases or repositories where suitable ones are available or, where these are not available, through other appropriate means of sharing.

Timelines

Activity	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Call for LoI												
Road shows to increase outreach												
Eligibility Checks and ARP												
MeAG Meeting												
Full Proposal Submission												
SV and MEIP with MeAG												
Apex Board Meeting												
Financial and Legal Concurrence and Agreement Signing												

Other Requisites for Funds Disbursements to Applicant

In addition to signing of agreement between all the concerned parties, certain requirements need to be completed before the first installment of the funds as will be specified in the corresponding Sanction Order.

Formats

- a. Milestone Completion Report (MCR)
- b. Utilization Certificate and Statement of Expenditure
- c. Agreement of funding
- d. Board Resolution template
- e. No-lien account certificate template

Contact Information

Further information can be obtained at BIRAC website www.birac.nic.in or

Sonia Gandhi

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