# Industry Innovation Programme on Medical Electronics

## Concept Note

**A BIRAC Initiative in partnership with**

**Department of Electronics and Information Technology**

**Ministry of communications and Information Technology**

**Government of India**

Department of Electronics and
Information Technology

Biotechnology Industry
Research Assistance council

## Prologue

BIRAC through its various flagship schemes is making significant investments in the medical devices sector and hence 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.

The project "**Industry Innovation Programme on Medical Electronics**" 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", 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 various 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 Grant (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.

## The Mandate

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 seems to target innovations in the **multi-disciplinary areas** comprising of electronics, engineering, medical devices, healthcare, software, algorithms and information technology.

2. **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 feasible for medical electronics R&D in India

3. **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 in India to address the pressing challenges associated with the development of innovative medical electronics and **making it available, accessible and affordable** to the people at the bottom of the pyramid.


## 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.

# The Challenge

**The area of Focus includes but not limited to;**

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

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 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.**
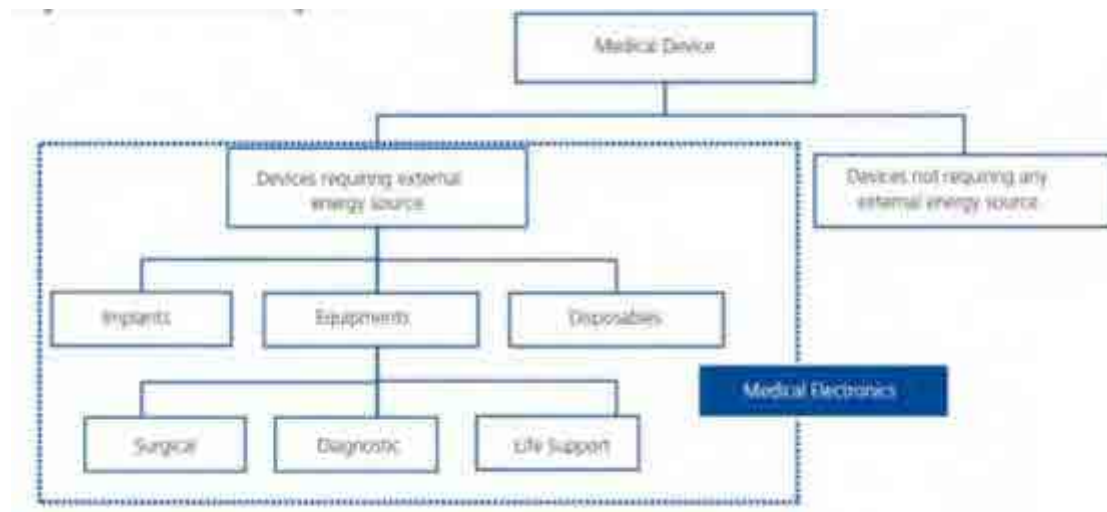


**Figure: Segmentation of Medical Devices (Source: Indian Medical Electronics Outlook 2020)**

**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

# 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-in-aid up to Rs. 50 lakhs 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 LIMITED LIABILITY PARTNERSHIP
- - 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 a period of 24 months as Grant in aid and Loan. The project cost would be matched equally by BIRAC and the industry.

If the Project proposal has Academic Collaborator (s) and the total Project Cost exceeds Rs. 100 Lakh, then the total contribution of BIRAC to a Company for the Project will not exceed Rs. 50 Lakhs. The contribution to the Academic Collaborator will be in addition to the amount approved for the Company applicant.

**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/ not 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 desirous 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.

**Letter of Intent** (less than 5 pages)

The applicants are invited to submit online letter of Intent (LoI) 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 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 the expected results of the project at the end of the grant period. Briefly indicate what 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.**

**Important Information**

1. The call for proposals will remain open till **10th March 2017** and applicants will be able to submit the LoI anytime during this period.
2. The submitted LoI will be evaluated three times during this period with evaluation cycle starting from **10th July 2016, 10th Nov 2016 & 10th March 2017**.
3. The LoIs received before the starting date of a particular evaluation cycle will be considered for that evaluation cycle. LoIs received after the starting date of evaluation cycle will be considered in the next round of evaluation.

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