



BETIC - Early Translation Accelerator (BETIC-ETA) Guidelines

INTRODUCTION

BETIC, IIT Bombay established **Early Translation Accelerator (ETA)** in March 2020, supported by Biotechnology Industry Research Assistance Council (BIRAC), the not-for-profit public sector enterprise set up by Department of Biotechnology (DBT), New Delhi.

The BETIC-ETA will enable **rapid translation of research prototypes (TRL 3) into marketable products (TRL 7) in association with industry partners**. It will operate as a centre out of BETIC Lab, and gradually augment existing facilities.

Activities and services of the BETIC-ETA will include clinical need validation, product design, rapid prototyping, pilot production, pre-clinical testing, clinical validation, intellectual property rights, regulatory compliances, business planning and funding avenues. BETIC team will leverage their facilities, processes, experience and network for this purpose.

Researchers and innovators utilizing the above services will be able to save considerable time, effort, funds and other resources that are wasted in identifying and coordinating with different vendors or consultants to develop, test and commercialize medical products.

PROJECT SELECTION

The overarching goal is to create **indigenous success stories** of novel medical devices. The overall selection is governed by considering *significance of the topic, state of technology, translational research required & expertise needed and risk attached* (as per agreement). The BETIC-ETA projects to be taken up have to fulfil corresponding **four criteria** as follows:

1. Unmet clinical need established,
2. Core research work, functional prototyping and preliminary testing complete (TRL 3-4),
3. IP potential: patent filed and/or documented know-how available to commercialize, and
4. Industry partner identified to license the technology.

Selection Process: The BETIC ETA project selection will be a **three-step process** as follows (based on BIRAC ETA guidelines – Annexure I):

1. BETIC ETA shall scout the potential technology in the medical device domain and consult the inventor (or) the academia from its partner network to discuss the translational projects. Proposals will be invited by the ETA to be considered further.
2. ETA Expert Committee will short-list the proposals, rank and select projects based on feasibility of implementation and potential of commercialization within one year.
3. ETA along with academia / inventors shall also scout for potential Industrial partner and conceptualize the translational project based on inputs from Industry. The collaborators (ETA,

academia/inventors and Industry partner) will sign an project development collaboration agreement outlining the scope, roles and responsibilities under the project.

The Indian industry partner will be **selected based on 3 criteria**: (a) *submission of a letter of interest*, (b) *commitment for financial support (up to 10% of the project cost) for funding the development and* (c) *intent to commercialise the technology*.

COLLABORATORS & ROLES

Each device project involves four main collaborators, who will contribute as follows:

1. Academia/ Inventor: Proof-of-concept or prototype along with documented research work
2. ETA: BETIC, IITB: Facilities, team and partners to translate POC into marketable product
3. Industry partner – Minority funding support and technology licensing
4. BIRAC – Majority funding support for the project (manpower, consumables, travel)

PROPOSAL SUBMISSION

The proposal document must contain the following details.

Project title, Researcher, Unmet clinical need, Novel solution, Proof-of-concept and Proposed commercialization pathway. Main proposal limited to 2 pages, with appendixes (market research, research summary, initial design, comparable products, relevant patents, publications), each in one page. Proposals will be periodically accepted and evaluated.

IMPLEMENTATION

Each selected project will be implemented by a dedicated team based on device type and activities required until commercialization. The following activities are envisaged:

1. Validate the unmet clinical need and evolve detailed specification of the product
2. Set up the milestones, activities, project team, timeline and budget of project
3. Design the product - mechanical, electronics, software, user interface (as applicable)
4. Verify and improve the product by simulation and rapid/functional prototyping
5. Carry out mechanical and electrical testing, and generate lab test reports
6. Plan and facilitate clinical validation after obtaining necessary ethical clearances
7. Draft and file provisional patent / design registration of the product
8. Prepare bill of materials, manufacturing and testing plans, and product costing
9. Create product dossier for submission to regulatory agencies for certification
10. Evolve the business plan and possible funding avenues.

BETIC team will maintain detailed records in line with **ISO 13485** quality management system. Depending on the product complexity, the total lead time will be 6-12 months.

COMMERCIALIZATION

Intellectual Property Rights will be managed as per prevailing rules approved by IIT Bombay. Provisional patents and design registrations will be filed by the Institute, with researchers and other contributors named as inventors. The background IP or interests in the background technology shall remain with the academia, or the originator/inventor entity. The project IP that will be generated while it is being implemented by ETA shall be jointly owned by ETA (IITB) and the academia, or the originator/inventor entity unless agreed otherwise.

As per project development and collaboration agreement the IP will be **licensed to industry partner** supporting the project based. The licensing will be covered by a separate licensing agreement with mutually agreed terms and conditions (license fee, royalty, duration). Alternately, the collaborators may further decide to license the technology to interested **Industry partners/ start-up company** incubated by the researcher with support from other partners and funding agencies. The licensing revenue will be distributed among collaborators as per mutually agreed revenue sharing agreement.

EXPERT COMMITTEE COMPOSITION (Approved by BIRAC)

The Expert Committee for project selection and review comprises the following members.

1. Prof. S. Kanagaraj, Mechanical Engineering, IIT Guwahati (Chairman)
2. Dr. Manish Agarwal, P.D. Hinduja National Hospital & Medical Research Centre, Mumbai
3. Dr. Dasmit Singh, B.J. Medical College & Sassoon General Hospital, Pune
4. Dr. P.R.H. Varma, Head, Bio Medical Technology Wing, SCTIMST, Thiruvananthapuram
5. Prof. Renu John, Head, Centre for Healthcare Entrepreneurship, IIT Hyderabad
6. Prof. Sai Siva Gorthi, Instrumentation & Applied Physics, IISc Bangalore
7. Dr. U. Chandrasekhar, Program Director (AddWize), Wipro 3D, Bengaluru
8. Ms. Suhani Mohan, Founder & CEO, Saral Designs Pvt Ltd, Mumbai
9. Mr. Nitin Deshmukh, Founding Partner, Kotak Investment, Mumbai
10. Mr. Mayur Sirdesai, Private Equity Professional, Somerset Healthcare
11. Dr. P.K.S. Sarma, GM & Head-Technical, BIRAC
12. Dr. Dhiraj Kumar, Sr. Manager-Technical, BIRAC

Guidelines Potential Conflict of Interest (Annexure II)

The translation of research into commercially viable devices involves multiple stakeholders: academia, industry, inventors, ETA members, etc. An independent EXPERT committee has been formulated to select, guide and recommend the projects to be taken under the ETA. Although the process and criteria for implementation are delineated actual and potential conflict of interest may arise. The Annexure II describes the guidelines on conflict of interest while handling the BETIC-ETA projects.

CONTACT (BETIC Team)

BETIC, IIT Bombay, Powai, Mumbai-400076; eta@betic.org | +91 22 2576 4399 | www.betic.org

Guidelines for BIRAC - Early Translation Accelerator (ETA)

Introduction:

The development of an idea into a product is a multi-step process which includes discovery (laboratory activity), early translation (validation to make the discovery industry ready) and product development (industrial activity). Of these, the important link i.e. early translation is often missing and eventually prevents scientific research from turning into a useful commodity for the society and therefore into an economic activity. The gap between basic research and product needs initiatives that help translate early discoveries made in a basic research setting into potentially valuable validated technologies. In the Indian setting, this sort of translational model does not currently exist and hence even though many exciting discoveries are made in the lab, very few see the light of day in terms of being commercialized.

Early Translation Accelerator (ETA), focusses on catalyzing transformation of young academic discoveries (publications/patents) with possible commercial and societal impact into economically viable ventures and technologies. The proposed set up is expected to collaborate with academic investigators, engage industry and to leverage international translation ecosystems. Supporting early translation accelerator for establishing validation/proof-of-concept is in line with the BIRAC's mission of facilitating translation of innovative ideas into biotech products and attracts industry to take validated technologies (originated from academic labs) forward in terms of development.

Critical components of ETA:

1. Continuous flow of discoveries, with potential applications, from academic investigators.
2. A scientific component that evaluates, collaborates, and provides technology access to the discovery projects.
3. Early engagement with industry and investors to help drive the discoveries and validated technologies towards successful commercialization through mentoring, partnerships and Technology transfer.

Who Can Apply?

- Bio incubators
- National Research Laboratories
- Government funded Laboratories
- National Institutes with demonstrated experience in performing translational activities in the proposed area.

What can be considered under ETA?

Discoveries from Healthcare, agriculture, industrial biotechnology and other important areas of Biotechnology may be considered for validation under early translation accelerator. The criteria for selection, assessment of progress and graduation may be put in place by individual ETAs and the committees with experts from academia, industry, investors and IP/regulatory fields to ensure the discoveries are ready to be taken up by ETA and the discoveries considered under ETA are industry ready once developed and they are expected to be part of development cycle, along with the inventor or originator of such scouted technology.

What is expected from ETA?

1. To scout potential technologies
2. To showcase some unique expertise that is different from others and which will give better chances of success for such identified technology
3. To define focused areas and to collaborate with external organizations for specific expertise towards accelerating the Technology Readiness Level (TRL).
4. To identify an industry to invest part of the money (at least 10%) for incubation before taking up the technology
5. To consider multiple projects in parallel and to ensure their success
6. To complete the projects within the timelines of 12-18 months (If the committee recommends, Project duration can be maximum 24 months.)
7. To take up 3-5 projects within the first phase of ETA support that will be provided for 30 Months.

Budget:

To achieve sustainability towards the core functioning of the ETA module through technology transfer etc. ETA can propose budget for core module (not more than Rs. 1 crore, Funding may be provided for bench-top equipment and man power, travel and contingency.) along with project budget (depending on the number of projects to be taken up) during the submission of proposal for setting up of ETA. The actual project budget will be decided after due diligence. The projects should be identified within 3 months of establishment of an ETA. The budget (which will be not more than Rs.200 lakhs) for each ETA Project will be recommended by ETA expert committee as per the objectives/activities.

Planning grant amounting to Rs. 10 lakhs will be given to ETA once it is recommended by expert committee on 'Translational Activities'. Milestones and final budget (after deducting kick off budget) will be decided after identification of projects.

Governance Model:

The following governance model to be adopted for implementation of ETA:

1. The proposed accelerator should be anchored at Bio-incubator, University Innovation Cluster or Government Institutes/Universities and to work with academic and industrial partners.
2. The management of Bio-incubators or Cluster Innovation Centers for Biotechnology in the case of University Innovation Clusters to take the responsibility of programme and overall operations whereas the applicant from Government institutes/Universities is expected to take the responsibility. They need to form expert committees with academia-industry participation to help identify projects, project approvals, periodic assessments, exit strategy, collaborations etc. These committee to have BIRAC nominee/representative also. ETAs should manage comprehensive documentation on project selection, progress, monitoring & outcomes and to share them with BIRAC on regular intervals.
3. ETA shall form internal guidelines or implementation of ETA based on these BIRAC guidelines and execute the acceleration program
4. ETA shall scout the potential technology in the specific domain and consult the inventor (or) the academia to discuss the translational projects in such scouted technology. The background IP or interests in the background technology shall remain with the academia, or the originator/inventor entity. The project IP that will be generated while it is being implemented by ETA shall be jointly owned by ETA and the academia, or the originator/inventor entity unless agreed otherwise. ETA shall also scout for Industrial partner and conceptualize the translational project components specific to sustain the commercial interest of the identified industrial partner.
5. The translational project shall be implemented at the ETA except the outsourcing aspects as projected in Proposal. Any such specific aspect of the project that requires external enablement can be considered under outsourcing. The inventor entity or the Academia from whom the selected project's technology has been scouted can be considered under outsourcing if required.
6. The financial outgo towards outsourcing or specific expertise requirements and consumables shall be met under the individual project cost.
7. The minimum Industrial investment is expected at 10% of the total project cost and additional contribution to the project cost beyond 10% can be aimed at even upto 100%.

8. First right of refusal to the project's results shall lie with the partnering Industry.
9. Once project funding is approved, ETA shall enter into a Technology accelerator agreement with the originator/inventor entity or the academia and the industrial partner contributing towards the project.
10. Technology transfer is the expected outcome under ETA and hence, in the event of such successful technology transfer with the industrial partner, transfer consideration/Tech Transfer proceeds (after tax deductions) can be shared among the ETA and the academia or the inventor entity on mutually accepted ratio.
11. If the industrial partner exercises the "First right of refusal" and opts out, then both ETA and the academia or the inventor entity shall have nonexclusive right to scout for other industrial partner.

Selection of Projects:

Selection of projects to be based on the demand, target groups and the source of technologies. The ETA expert committee is expected to evaluate the projects to be considered under ETA based on the following parameters:

- Available data to consider as ETA project
- Clarity on objectives to be achieved under ETA
- Strength to accomplish the objectives
- Commercial potential (The technology should have a sizeable market as well as Intellectual Property (IP) generation potential)
- National importance
- Mandate of ETA
- Technology readiness level {TRL 5 or above (Early Stage Validation) at the start of the project and TRL 7 or above (Late Stage validation or Pre commercialization) by the end of the project}. Project should move at least two TRL level above. (Please visit http://www.birac.nic.in/desc_new.php?id=443. For TRL definitions).

The ETA team should be very clear about the risks attached to a process/product (safety, technology limitations, or commercial potential) before taking it up for further development. The projects should have prior appropriate approvals, where necessary.

The ETA would also preferably take up projects which have a broader significance, in terms of technological impact or social relevance, beyond the immediate specific application

of the project. The ETA shall rule out conflict of interest and related party funding, while selecting the projects.

Sustainability model of the proposed ETA:

The ETA will initially be provided financial assistance from BIRAC for establishment of additional infrastructure and initial operational expenses including rental and utilities cost, consumable costs, man power etc. However, all projects would have financial contribution from industry, which will be from 10% initially to 100% after 30 Months.

Second Phase for ETA (in scheme document):

Second Phase for existing ETA may be considered if the expert committee on 'Translational Activities' recommends the same. However, ETA is expected to present, along with completion presentation for the first phase, justification for second phase, 3-5 projects that are ready for translation and recommended by ETA expert committee. The second phase proposal; shall clearly bring out the outcome status of first phase in terms of the following:

1. Entry level of the project TRL and the TRL acceleration achieved at ETA
2. Industrial uptake of the scouted technologies and the commercial exploitations status as applicable.
3. Extent of sustainability achieved through the technology transfer with the Industrial partners.
4. Prospective acceleration scope based on enhanced ETA capabilities that were acquired by way of Project equipments etc under Phase 1.

The second phase shall allow Rs.50 lakhs for Core ETA.



Annexure II

Guidelines on Potential Conflict of Interest for BETIC-ETA, IIT Bombay

The translation of research into commercial devices in this project involves multiple stakeholders: academia, industry, inventors, ETA members, etc. An independent EXPERT committee has been formulated to select, guide and recommend the projects to be supported under the ETA. Although the process and criteria for implementation are delineated, actual and potential conflict of interest may arise. This document describes the guidelines on conflict of interest while handling BETIC ETA projects. The avoidance of conflict is important to the integrity and philosophy of ETA. The intent of this section is not to eliminate all possible situations leading to conflict of interests, an obvious impossibility. Rather, it is to enable an interested person to recognise situations that may be subject to question, to take steps to minimise such conflicts and to ensure that such situations are properly reviewed and, if necessary, corrected. All potential conflict of interest situations should be handled and all relevant activities are conducted in a manner consistent with the values of ETA, IITB and public values and interests. This policy makes all stakeholders related to ETA aware that no one should use his/her position in one role for personal gains in the other role, and when necessary, explicit permission of relevant stakeholder may be obtained.

Description:

1. **Conflict of Interest:** A conflict of interest usually involves a conflict between the public duty and the private interests of an Individual, in which the Individual has private interests which could improperly influence the performance of their official duties and responsibilities for the referred purpose. Some of the situations which may lead to potential conflict of interest are listed in following section “**Situations leading to Conflict of Interests**”
2. **A person from or associated with ETA/ BETIC/ IITB/ Academia/ Inventors/ Industry Partners/ Expert Committee/ BIRAC** may hold positions which are of trust and confidence owe fiduciary responsibilities to entities supported by the services of the ETA. Persons associated with ETA (investigators, members, employees, associates, advisors, expert, panel member, mentors, promoters, staff, students etc) directly employed or in various capacities other than for employment may also face situations leading to conflict of interests.
3. **Interested person:** These personnel may become ‘interested person’ if they have potential gain in terms of direct, indirect or finical interest from the activities supported by ETA. Any immediate family member of these personnel has potential gain in terms of direct, indirect or finical interest from the activities supported by ETA.
4. **Confidentiality:** Further during the development, certain proprietary information may also be exchanged between various parties which are of confidential or sensitive nature. The confidentiality of such information needs to be maintained.

Situations leading to Conflict of Interests: Certain situations leading to conflict of interests are explained herein below. However, the list is not exhaustive, and hence situations having actual or potentials for conflicts of interest though not covered in this document will nonetheless be subject to

these guidelines. Conflict of interest may arise in respect of a particular application in the following situations (this list is indicative and not exhaustive):

1. The involvement of a Panel member/ Expert/ individual in any current application– example. as an applicant for funding or as the supervisor of an applicant, etc.;
2. Membership/ Directorship of a Panel member in an organization involved in any current submitted application under the programme;
3. Ownership of shares by a Panel member in a company involved in any current, established or submitted application, or if the future of the company will be significantly affected by the success of the application.
4. Holding any technical/scientific positions in an organization involved in any current submitted application under the programme.
5. Any personnel, from or associated with ETA, is in a position to influence a decision for acquisition of laboratory and other equipment which could benefit an industry partner in which he/ she is an interested person.
6. Any personnel, from or associated with ETA, is in a position to circumvent prevailing policies for making use of IITB's various facilities for the benefit of an industry partner in which he/ she is an interested person.
7. Any personnel, from or associated with ETA, is in a position to make use of the suppliers and service providers of IITB for undue advantage of an industry partner in which he/ she is an interested person.
8. Any personnel, from or associated with ETA, procures consultancy assignments or other business in name of IITB and outsources them to the industry partner in which he/ she is an interested person.
9. Any personnel, from or associated with ETA, is in a position to influence policy decisions of ETA/IITB/Academia with an intention to benefit an industry partner in which he is an interested person.
10. Use of personnel from or associated with ETA (employees or students) to perform a work for an industry partner without any compensation when the work is not related in any way for their academic pursuits.
11. A person who is interested in one industry partner and also involved in a decision-making process affecting other industry partners leads to situation of conflict of interest.
12. When an industry partner, its promoters, employees and staff or any interested person acts in manner to benefit the industry partner at the disadvantage of ETA/IITB/Academia/Inventors/ BIRAC.
13. An industry partner, its employees and its staff having access to ETA resources are in position to exploit them by bypassing ETA/IITB's policies.
14. When any personnel, from or associated with ETA (investigators, members, employees and associates, promoters, employees and staff) are neglecting their respective commitments to ETA/IITB/ Academia for their association with industry partner.
15. Any personnel, from or associated with ETA (employees and associates) are in position to use sensitive information pertaining to industry partner for their personal advantage.

Managing Conflict of Interest: Since situations leading to conflict of interests are inevitable, it is expected that the interested persons follow transparency in their actions based on full disclosure of relevant information by them. Following guidelines are suggested for management of actual or potential conflict of interests and to address disputes arising out of conflict of interests and maintenance of confidentiality:

- Appropriate disclosure of the conflicting situations involved in a decision or transaction
- Abstaining from participating in decision making process or transactions involving such situations,
- Obtaining appropriate approvals to avoid conflicts,
- Reporting of the breach of the policy without deliberate intention or knowledge.

Corresponding declaration forms are available in Annexure III.

If any conflict of interest arises or dispute arises in terms of these guidelines, the same should be reported to:

- If it pertains to BETIC-ETA, it should be reported to the Principal Investigator (BETIC, IITB),
- If it pertains to IITB, it should be reported to the Dean R&D, IIT Bombay.

If required, the above authorities will refer the matter to the BETIC-ETA EXPERT committee for approvals/ feedback or Director IITB as the case may be, whose decision in the matter shall be final.



Annexure III

Declaration by Principal Investigators (PI) /Co-PI/Expert/Staff of BETIC-ETA

I, _____ the Principal Investigator/Co-PI/Expert/Staff associated with the project “Biomedical Engineering and Technology Innovation Centre - Early Translation Accelerator (BETIC-ETA)” currently working as (Designation) at (Organisation) hereby declare that:

I am aware that the BETIC-ETA may be associated with the following organisations (Academia/ Inventors) and Industry Partners for development and commercialisation of medical devices.

Organisation (projects applied)	Potential Industry Partners
COE Pune (1)	Orthoheel Pvt Ltd.
IIT Bombay (3)	OM Surgicals Pvt. Ltd
MIT ADT, Pune (1)	Ayu Devices Pvt Ltd
VNIT, Nagpur (1)	Dynasense Technologies Pvt. Ltd
MGM, Sanpada (1)	Eclipse Prism Medical Devices Pvt. Ltd.
Swarup Hospital, Kolhapur (1)	Shradha Industries Ltd
KJSCE, Mumbai (3)	
GHRCE, Nagpur (1)	

I have read the guidelines on potential conflict of interest for BETIC-ETA, IIT Bombay.

- I have no potential conflict of interest to declare with the organisation/ industry partners associated with BETIC-ETA project.
- I have following potential conflict of interest to declare with the organisation/industry partner _____.
 1. _____
 2. _____
 3. _____
- Since I have a potential conflict of interest, I hereby declare that I will abstain from participating in decision making process or transactions involving this industry partner in the project.

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

Signature: _____

Date: _____

Declaration by IP Owners

We, _____ and _____ the owners of the IP _____ hereby declare that:

We are aware that the BETIC-ETA will be associated with the following Industry Partners for development and commercialisation of medical devices.

1. _____ Pvt. Ltd

We have read the guidelines on potential conflict of interest for BETIC-ETA, IIT Bombay.

- Our board members or employees have no potential conflict of interest to declare with the industry partner _____ Pvt. Ltd.
- Our board members or employees namely _____ have following potential conflict of interest to declare with industry partner _____ Pvt. Ltd.
 1. _____
 2. _____
 3. _____
- 4. Since our employees have a potential conflict of interest, we hereby declare that these employees will abstain from participating in decision making process or transactions involving this industry partner in the project.

We hereby certify that the information set forth above is true and complete to the best of my knowledge.

Signature: _____

(Authorised signatory on behalf of the Owner of IP)

Date: _____

Declaration by Inventors

I, _____ one of the inventors of the IP _____
_____ hereby declare that:

I am aware that the BETIC-ETA will be involved with the Industry Partner _____ for development and commercialisation of medical devices using above IP.

I have read the guidelines on potential conflict of interest for BETIC-ETA, IIT Bombay.

I have no potential conflict of interest to declare with the industry partner _____.

I have following potential conflict of interest to declare with the industry partner _____.

1. _____
2. _____
3. _____

5. Since I have a potential conflict of interest, I hereby declare that I will abstain from participating in decision making process or transactions involving this industry partner in the project.

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

Signature: _____

Date: _____