

# Guidelines for BIRAC - Early Translation Accelerator (ETA)

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## **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](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.