Guidelines for Projects Supported under DBT-BIRAC Accelerated Translational Grant for Commercialization (ATGC) Scheme

---

Process Flow and Terms

DBT-BIRAC Joint Call

1. Background

Fundamental Science frequently yields discoveries that promise societal benefits in areas such as health care, sustainable energy, animal and marine biotechnology, agriculture etc. To encourage technological innovation, DBT envisages providing funding opportunities for fundamental research that is explicitly aimed towards application development. To take advantage of research results with potential for commercialization, DBT would enable academic researchers to take their fundamental research to next phase via translational research opportunities that launch their idea towards an end-use under Accelerated Translational Grant for Commercialization (ATGC).

In a process to fulfil the ambition of this program, **Department of Biotechnology (DBT)** in collaboration with **Biotechnology Industry Research Assistance Council (BIRAC)** will invite proposals in Accelerated Translational Grant for Commercialization (ATGC) scheme.

2. Program Guidelines

ATGC: To accelerate translational research leads beyond early stage validation and encourage academia to develop technology/product & processes.

Vision: To support translational research in Indian academic institutions in the cutting-edge areas of Biotechnology for application development.

Mission: To enable academic researchers to take their laboratory research leads with established proof-of-concept and early stage validation to the next phase via translational research opportunities.

Purpose:

1. To support proposals aiming for late stage validation

2. To accelerate translation of laboratory research beyond early stage validation through stage gate mechanism

3. Bridge the innovation gap through partnerships and to provide support system in terms of SoPs, GLPs, Regulatory Compliance Protocols, IP Support System, Market Intelligence and Patent Informatics.

2.1 The scheme has two categories

a) Academic Lead Translation (ALT)

b) Academic Industry Translational Research (AITR)

2.1 (a) Academic Lead Translation (ALT)

The objective of Academic Lead Translation (ALT) scheme is to promote validation of demonstrated Proof-of-concept (PoC) for a process/product. The academic institutions could do it independently or collaborate with other academic partners with complimentary expertise to translate the leads or in a contract research mode to develop the leads.

2.1 (b). Academic Industry Translational Research (AITR)

The objective of Academic Industry Translational Research (AITR) scheme is to promote validation of Proof-of-concept (PoC) for a process/product by academia with the involvement of industry or for validation by the industry in contract research mode.

2.2 DBT will fund the academic partner and industry will be funded by BIRAC.

2.3 Types of Proposals Supported:

1. Proposals with well-established proof-of-principle leading to development of prototype of a product /technology processes of national relevance or commercial potential.

2. Projects involving clinical trials (with necessary DCGI approvals), late stage validation of the technology, containment and field trials.

3. Proposals with TRLs as given below: (Mandatory). TRLs description is at www.birac.nic.in (BIRAC-TRLs).

Sl. No	Thematic Area	Stage	Required TRL	Definition
1	Drugs (including Drug Delivery)	Proof of Concept Established	TRL-4	Efficacy,& safety of candidate drug formulation is demonstrated in a defined animal model (Results of formulation studies, pharmacokinetic studies & ADME , PD , safety of candidate formulations at preliminary level and efficacy in *in-vivo* disease model)

2	Regenerative Medicine	Proof of Concept Established	TRL-4	Candidate Optimization and Non-GLP *in vivo* Demonstration of Activity and Efficacy **Animal Models:** Initiate development of appropriate and relevant animal models(s) for the desired indications and perform non-GLP *in vivo* toxicity and efficacy. **Assays:** Initiate development of appropriate and relevant assays and associated reagents for the desired indications. **Manufacturing:** Manufacture laboratory scale (non-GMP) quantities of bulk product and proposed formulated product. Demonstrate non-GLP in vivo activity and potential for efficacy consistent with the product's intended use (i.e., dose, schedule, duration, route of administration and route). Conduct initial non-GLP toxicity studies and determine pharmacodynamics and pharmacokinetics and/or immune response in appropriate animal models (as applicable). Initiate experiments to determine assays, parameters,

				surrogate markers, correlates of protection and endpoints to be used during non-clinical and clinical studies to further evaluate and characterize candidate(s).
3	Vaccines	Proof of Concept Established	TRL-4	Efficacy & safety of vaccine candidate is demonstrated in a defined animal model (Results of serological studies in different animals at preliminary level and efficacy in defined *in vivo* model, Manufacturing and QC release of vaccine for Studies, Scale up Development).
4	Clinical Trials	Early Stage Validation	TRL-5	Pre-clinical studies including GLP efficacy, acute and chronic toxicity, all the studies mandatory for safe exposure to humans such as repeat dose toxicity (RDT) and safety in animal model producing sufficient data for DCGI application for clinical trials.
5	Devices & Diagnostics	Proof of Concept Established	TRL-4	Medical Devices/Diagnostic Devices: Functional Prototype developed by integration of different modules and safety, efficacy and performance of candidate device or system demonstrated in a defined laboratory, Simulated Environment or animal model (with Institutional Animal Ethics Committee approvals). Diagnostic Kits: Optimized core components integrated into the kit or platform (Microfluidics/ filter paper/ LFA etc) along with the reagents to come up with a functional prototype of the kit. Integrated system tested

				in house with metabolite, serial dilution or ELISA or spiked biological samples. Biomedical Implants: Material safety and or imaging compatibility proven in *in vivo* small animal model study (with Institutional Animal Ethics Committee approvals). Functional Prototype implant device developed as per the design in a near GMP condition. Sterilization and packaging established.
6	Bioinformatics	Early Stage Validation	TRL-5	Developed software technologies to integrate with different aspects of existing system; Developed software technologies implementations conform to target environment interfaces; experiments with realistic problems; rigorous alpha testing.
7	Industrial Biotechnology/Secondary Agriculture	Proof of Concept Established	TRL-4	Concept proven from lab scale to Bioreactor level experiments under optimized conditions at less than 100L. Necessary approvals to be obtained for using GMOs (RCGM/GEAC).
8	Agriculture	Late Stage Research	TRL 5	Marker Assisted Selection**:** Development of homozygous lines for gene of interest through marker assisted foreground and background selection. Transgenics/ Gene Edits: Integration and the expression analysis of the trans/cis- gene in the T1 generation. Bio control: *In vitro* evaluation and screening of local strains against target pathogens or insects. Tissue Culture**:** Optimization of conditions for hardening

				and establishment of plants inside greenhouse/ net house.
9	Aqua Culture and Fisheries	Early Stage Validation	TRL 5	Component and or basic subsystem technology tested /validated in controlled conditions in smaller tanks in laboratory/hatchery with proper control following statistically designed protocols.
10	Veterinary	Early Stage Validation	TRL 5	Drugs/vaccines: Demonstration of proof of concept (PoC) in limited number of animals (by serological studies). Working on feasible formulation development and conducting safety and efficacy studies). Devices "High-fidelity" laboratory integration of components. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Diagnostics Establish all the diagnostic kits to have desired specificity & sensitivity based on the data generated.
11	Clean Energy & Environmental Solutions	Proof of Concept Established	TRL-4	Demonstrated technology at pilot stage.

2.4 What is not Supported?

1. Basic exploratory research proposals that aim to demonstrate scientific principles/techniques without technology commercialization objectives.
2. Proposals with no element of novelty and no plan to convert ideas into technology/product/services.

2.5 Thematic Areas:

- Drugs and Drug Discovery
- Biotherapeutics and Regenerative Medicine

- Vaccines
- Clinical Trials
- Devices & Diagnostics
- Agriculture & Animal Biotechnology (including Aqua and Veterinary Sciences)
- Industrial Biotechnology/Secondary Agriculture
- Bioinformatics & Computational Biology
- Clean Energy & Environmental Solutions

3.0 Operational Guidelines

3.1 Project Duration:

The funding is provided over a maximum period of 24 months in installments against agreed milestones. Proposed project duration can vary from 18 – 24 months. These projects will be aimed for Go or No Go decision points at the end of 24 months. The case for considering project extensions (only for promising projects) will be at the discretion of the Apex Committee of DBT based on the discernible outcome(s) at the end of 24 months or the projects can be accessed for the next funding cycle/follow-on grant of ATGC.

3.2 Intellectual Property (IP):

Background IP rights and the new IP both generated during the project will rest with academia only. However, the industry partner will have the first right of refusal for commercial exploitation of the project development. Project development, shall mean the technology/know how, background IP, New IP, .. and anything that is capable of commercial exploitations that generated from the project.

3.3 Target Groups:

1. DBT supported programs that have completed/ are about to complete with established proof-of-concept ready to go to the next phase for technology development, validation and commercialization; promising late translational leads ready for technology enhancement and commercialization; validation with clinical trials and field trials.
2. Projects submitted under grant call of DBT for ATGC
3. Potential proponents from BIRAC operated Programs

3.4 Eligibility Criteria:

1. The primary applicant should be an Academia and the Project Coordinator should apply with established proof-of-concept ready for validation with proven expertise in the proposed area of research; who will take responsibility for technical and managerial aspects of project execution.

2. The Project Coordinator will identify other academic Institute (s) and/ or a company/industry partner (if it is jointly with company which is registered under the Indian Companies Act, 2013). The company should have its own in- house R & D facility that are functional and adequate to execute the proposed project components.

   For company it is mandatory that minimum 51% of the shareholders must be Indian citizens having Indian Nationality. (Indian citizens does not include PIO & CPIO).
3. The Project Coordinator must be technically qualified with sufficient experience to execute the project. This should be demonstrated through publications/patents and earlier executed research projects.

3.5 ATGC Cycle: 4 months from application stage to funding

3.6 Support Documents for ATGC Application:

1. Letter of Agreement from key members of the technical team/engagement
2. Formal Agreement/MoU/Letter of support from academic partners
3. Formal Agreement or MoU between Academia and company
4. Letter indicating the TRL of the proposed study
5. Requisite regulatory approval for the study
6. Any other due diligence certificate requested by BIRAC/DBT

4.0 Call/Advertisement

1. A national call for proposal under the ATGC Program is to be launched on DBT website and in various leading Newspapers, & Scientific Journals.
2. The Call window inviting proposals typically will be for a period of six weeks to two months.
3. The applicant will submit an online application for funding by registering and logging- on the DBT website www.dbtindia.nic.in. Please note that applications are accepted online only.
4. Applicants should fill-up and submit their applications early honoring the established deadline, without waiting for the last date in order to avoid any last minute contingencies/clogging of website. The system stops accepting applications automatically at midnight of the last date of receipt of application.
5. Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review process. Applicants are advised to provide self-contained proposals with essential supporting materials

6. Requests for changes in the proposal once submitted will not be entertained.
7. Providing incorrect information or employing corrupt or fraudulent practices shall be viewed adversely.

5.0 Illustrative Activities:

5.1 ARP shortlisting

The Area Review Panel (ARP) will consist of eminent domain experts which is constituted with the requisite approval. The experts have to sign a no-conflict-of interest and confidentiality agreement after the proposals are assigned to them. The full proposals will be evaluated by ATGC Screening Committee and shortlisted for further screening.

5.2 The evaluation process by ATGC Screening Committee will be based on the below factors:

Evaluation criteria:

1. Scientific merit
2. Clarity of hypothesis
3. Relevance and ability to implement approaches
4. Background of the investigator
5. Feasibility of conducting the research in the present settings

The ATGC expert committee panel consisting of eminent domain experts may call for proponent's presentation or may recommend site visit of shortlisted proposals.

After Site visit the final recommendations will be processed for approval of the competent authority.

6.0 Financial concurrence and release of Governing Agreement by DBT/BIRAC

Subsequent to DBT APEX recommendation (if the total cost of the proposal is more than Rs. 5.0 crores), financial concurrence will be taken for company component by BIRAC followed by approval of MD- BIRAC and Chairperson BIRAC.

Subsequent to Expert Selection Committee of ATGC scheme recommendation (if the total cost of the proposal is less than Rs. 5.0 crores), financial concurrence will be taken for company component by BIRAC followed by approval of MD- BIRAC and Chairperson BIRAC.

Detailed financial due diligence for the company will be done by BIRAC as per existing guidelines.

The amount concurred for the company will be communicated to DBT.

Sanction Order will be issued by DBT to all parties with final milestones and budget. Further DBT will process MOU to Academia. BIRAC will process a separate GLA with company. MOU between funds recipient will be furnished before sanction order is issued by DBT which will be independent of any of the funders to reflect the mutual agreement aspects of the fund recipients, specifically roles and responsibilities, IP ownership for academia, first right of refusal to company, dispute resolution etc.

7.0 Funding

The funding support offered will be in the form of grant-in-aid. There is no cap on funding but budget proposed should be commensurate with activities.

No funds will be allocated under Nonrecurring head for the company. The fund disbursement will be milestone based i.e. 4 installments for 12 months project and 5 installments for ≥18 months project. The fund disbursement by BIRAC to industry will be milestone based and will be released in 4 installments in case of 12 months project and 5 installments in case of ≥18 months project. First installment (30%) on sanction of the project & last installment on completion of the project and submission of the project report (~ 10%). The remaining installment with 20%+ 20%+20% or 30%+30% release depending on the duration of project. PI will define the budget heads with due diligence and justification. The releases will be done based on recommendation of project monitoring committee from DBT and UC- SOE submitted by Industry. No extension of project duration will be considered, and will be closed on "as is" basis when the duration is completed.

8.0 Post Funding

The releases will be based on milestone based achievement which will be monitored by project monitoring committee duly constituted for the project. The fund recipient shall submit technical milestone attainment report periodically.

9.0 Acknowledgement

The funding support by DBT/BIRAC shall be duly acknowledge when publishing/showcasing/or presenting project particulars or outcomes, in the manner as prescribed by DBT/BIRAC.

Other Formalities

Fund releases for the project will be subject to fulfilment of certain formalities such as opening of no lien account by the company, submission of Board resolution by the company, submission of letter of authorisation by the academia etc.

For Further details/queries

Contact:

DBT:

BIRAC: