

Accelerated Translational Grant for Commercialization (ATGC)

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 order to implement ATGC, the program *per se* is outlined below:

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.

The scheme has two components

- a) Academic Lead Translation (ALT)
- b) Academic Industry Translational Research (AITR)

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.

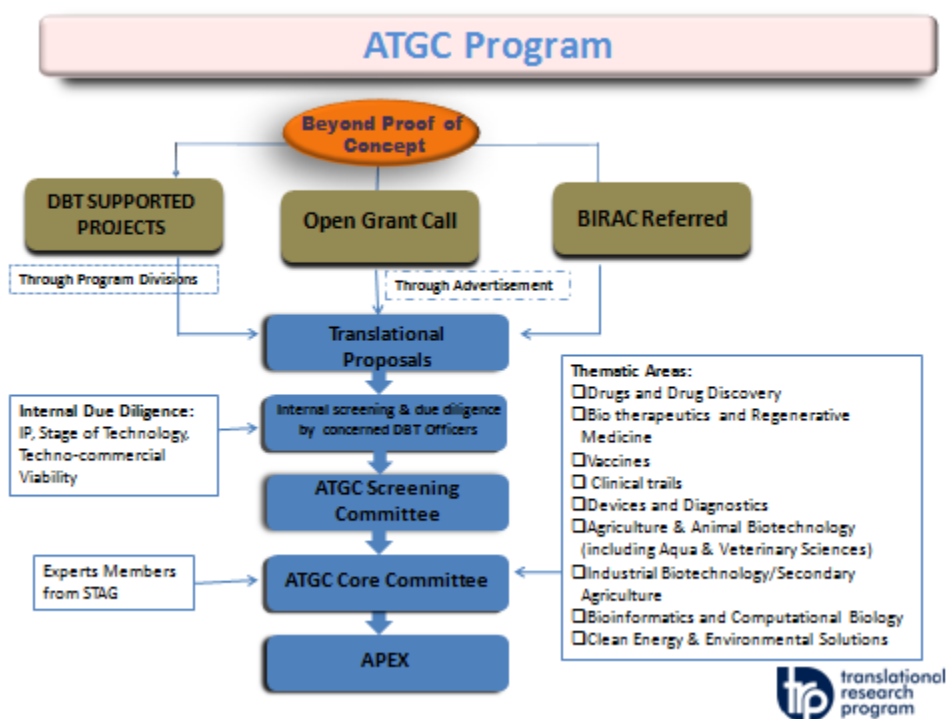
Academic Industry Translational Research (AITR)

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.

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

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 <i>in-vivo</i> disease model)
2	Regenerative Medicine	Proof of Concept Established	TRL-4	<p>Candidate Optimization and Non-GLP <i>in vivo</i> Demonstration of Activity and Efficacy</p> <p>Animal Models: Initiate development of appropriate and relevant animal models(s) for the desired indications and perform non-GLP <i>in vivo</i> toxicity and efficacy.</p> <p>Assays: Initiate development of appropriate and relevant assays and associated reagents for the desired indications.</p> <p>Manufacturing: Manufacture laboratory scale (non-GMP) quantities of bulk product and proposed formulated product. Demonstrate non-GLP <i>in vivo</i> 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,</p>

				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 <i>in vivo</i> 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	<u>Medical Devices/Diagnostic Devices:</u> 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). <u>Diagnostic Kits:</u> 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

				<p>in house with metabolite, serial dilution or ELISA or spiked biological samples.</p> <p><u>Biomedical Implants:</u> Material safety and or imaging compatibility proven in <i>in vivo</i> 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.</p>
6	Bioinformatics	Early Stage Validation	TRL-5	<p>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.</p>
7	Industrial Biotechnology/Secondary Agriculture	Proof of Concept Established	TRL-4	<p>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).</p>
8	Agriculture	Late Stage Research	TRL 5	<p><u>Marker Assisted Selection:</u> Development of homozygous lines for gene of interest through marker assisted foreground and background selection.</p> <p><u>Transgenics/ Gene Edits:</u> Integration and the expression analysis of the trans/cis- gene in the T1 generation.</p> <p>Bio control: <i>In vitro</i> evaluation and screening of local strains against target pathogens or insects.</p> <p><u>Tissue Culture:</u> Optimization of conditions for hardening</p>

				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	<u>Drugs/vaccines:</u> 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). <u>Devices</u> “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. <u>Diagnostics</u> 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.

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.

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

Operational Guidelines

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.

Funding Support:

The funding support offered will be in the form of grant-in-aid. There is no ceiling on funding level (quantum of budget is not capped) but will commensurate with activity. The fund disbursement is milestone based and is released in 3 installments.

First installment on sanction of the project (Equipment (minimal) + ~ 30% of the Recurring); second and third installments on completion of defined milestones (~ 30% of the Recurring each time); and last installment on completion of the project and submission of the project report (~ 10%). The release affected in installments may be utilized by the PI under permissible NR and R heads. PI will define the budget heads with due diligence and justification.

Intellectual Property (IP):

Background IP rights will rest with academia only. However, the industry partner will have the first right of refusal for commercial exploitation of the New IP.

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. BIRAC Referred Programs

Eligibility Criteria:

1. The primary applicant should be the Project Coordinator 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 (if multi-institutional) and/ or a company/industry partner (if it is jointly with industry; industry/company registered under the Indian Companies Act of 156, 2013). The industry/company should have its own in-house R & D facilities that are functional and adequate to execute the proposed project.
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.

ATGC Cycle:

4 months from application stage to funding

Support Documents for ATGC Application:

1. Letter of Agreement from key members of the technical team
2. Formal Agreement/MoU/Letter of Agreement from academic partners
3. Formal Agreement or MoU with industry partner
4. Letter indicating the TRL of the proposed study
5. Requisite DCGI approval for clinical trial study
6. Any other due diligence certificate requested by DBT

Application Process:

1. DBT will launch a national call for ATGC Program. The Call for Proposals will be advertised on DBT website and in various leading Newspapers, & Scientific Journals.
2. The Call window inviting proposals is typically open for a period of six weeks to two months.
3. The applicant needs to 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 are advised to 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 will be viewed adversely.