Proposal Submission under ATGC Grant Call

Part I Basic Information

- Name of the Institution submitting the Proposal:
- Address:

  Street
  City
  State: Pin Code
  Phone (Landline) Fax:
  Website
- Status of the Institution: Govt./Semi-govt./Private/NGO/Trust/Society
- Title of the Proposal:
- Relevant Area:
  - ❖ Drugs and Drug Discovery
  - ❖ Biotherapeutics and Regenerative Medicine
  - ❖ Vaccines
  - ❖ Clinical Trials
  - ❖ Devices & Diagnostics
  - ❖ Agriculture/Plant Sciences & Animal Biotechnology (including Aqua and Veterinary Sciences)
  - ❖ Industrial Biotechnology/Secondary Agriculture
  - ❖ Bioinformatics & Computational Biology
  - ❖ Clean Energy & Environmental Solutions
- Name of the Project Coordinator:
- Proposal Duration : Month(s) Max. of 24 months only
- Total Cost:
- Single/Multi-institutional:
- Scheme Component:
  (1) Academic Lead Translation (ALT)
  (2) Academic Industry Translational Research (AITR)
- Collaboration: Collaborator Details

Sl. No.	**Collaborator Name**	**Collaborator Type Academia/Industry**
1		
2		

Particulars of the Applicant

Project Coordinator Details

First Name
Last Name
Gender (Male/ Female)
Designation
Landline
Mobile
Email

Team Members

(i)
First Name
Last Name
Gender (Male/ Female)
Designation
Affiliation
Landline
Mobile
Email

(ii)
First Name
Last Name
Gender (Male/ Female)
Designation
Affiliation
Landline
Mobile
Email

Scientific Advisors or Mentors (If Any)

First Name
Last Name
Gender (Male/ Female)
Designation
Affiliation
Landline
Mobile
Email

Part II: Proposal Details

1. **TRL Status Current TRL** [ ] **Expected TRL** [ ]

2. **Proposal Summary**
   Provide a brief one paragraph overview of the proposal, i.e., the idea and the problem to be solved, rationale and brief project plan.

   [ ]

   Please upload a concept note explaining the technology with necessary figures and diagrams.

3. **Opportunity**
   What is the Potential societal and market impact? Provide details of the problem proposed to be solved.

   [ ]

4. **Briefly state the objectives and the proposed approach**
   Describe how the proposed project addresses the problem. Clarify the current status of the innovation, nationally and internationally.

   [ ]

5. **Novelty**
   Explain how the idea is innovative and how it is different from the existing products in the market or current state-of-the-art. Tabular representation of the difference between the idea and the other products in the market or competitive product which are under development will be appreciated. Concrete market data is encouraged.

   [ ]

6. **Challenges or risks factors associated with the project**
   What are the challenges and risk factors envisaged that may affect this project?

7. **Status of the Work Accomplished**

8. **Intellectual property**

i. Does the applicant or the applicant company own any IP related to this project. If yes, give details. Please mention the patent number, patent title and patent assignee.

ii. List of patents that appear to cover any part of the Technology of Interest or similar (and possibly overlapping) Technologies and thereby restrict the freedom to-operate in the Envisaged area.
(Please mention the patent number, patent title and patent assignee)

iii. If there are patents that are overlapping and may restrict FTO, does the applicant have the required license/s to practice these inventions for the purposes of the proposed project? Please provide license agreement details if any or provide information of the proposed next steps to obtain said license/s.

9. **Relevant references**

10. MoU between Academia & the Company

Who will own the IP rights for Commercialization on completion of Study (Transfer of rights from Academia to Industry)

11. Anticipated Outcomes & Deliverables

12. Business Strategy/Future plan of Commercialization

What do you envision to be the key next step to making impact with this innovation (e.g., sponsored research support, licensing, venture financing? What is the time frame?

13 Regulatory/Ethical Clearances & Approvals

- **DCGI Approval** Yes ☐ No ☐ NA ☐
- **RCGM Approval** Yes ☐ No ☐ NA ☐
- **GEAC Approval** Yes ☐ No ☐ NA ☐
- **National Biodiversity Approval** Yes ☐ No ☐ NA ☐
- **Pollution Control Board Approval** Yes ☐ No ☐ NA ☐
- **Any Other Approval** Yes ☐ No ☐ NA ☐

Any other Information Relevant to the Proposal

Proposal Objectives and Work Plan

Methodology/ Experimental Design

Objective	Detailed Work plan	Alternate Strategies
Objective 1	Method 1	Alternate 1
Objective 2	Method 2	Alternate 2

Objective Wise Activities and Timelines

Objective 1:

Activities	Month of start of activities	Month of end of Activities	Indicators of Progress	Role of Main Applicant	Role of the Collaborator
ACT 1			IP 1		
ACT 2			IP 2		
ACT 3			IP 3		

Objective 2:

Activities	Month of start of activities	Month of end of Activities	Indicators of Progress	Role of Main Applicant	Role of the Collaborator
ACT 1			IP 1		
ACT 2			IP 2		
ACT 3			IP 3		

Proposal Milestones

Objectives	Activities	Month of End of activity (In months)	Indicators of Progress	Select Milestones	TRL
Objective 1	ACT 1		IP 1		
	ACT 2		IP 2		
	ACT 3		IP 3		
Objective 2					
	ACT 4		IP 4		
	ACT 5		IP 5		

Part III: Budgetary Details

Details of Equipment Proposed

Equipment/ Accessories	Capacity	Quantity	Specific Requirement in the Project with Justification	Total Estimated Value (Rs. in Lakhs)

Human Resource

Position	No. of Positions	Qualification	Experience (in years)	Duration for which to be hired (in months)	Role in the project	Proposed Monthly Salary (Rs. in Lakhs)	Total Cost

Consumables Details

Items	Quantity	Units (e.g., g/ ml etc.)	Approximate Cost (Rs. in Lakhs)	Justification for the Requirement
Total Amount Required for Consumables:				

Justification for Other Recurring Heads

Other Cost (Rs. in Lakhs)	Justification

Total Budget

Non Recurring Cost (Rs. in Lakhs)

Equipment/ Accessories	Total

Recurring Cost (Rs. in Lakhs)

Human Resource (A)	Consumable (B)	Other Heads (C)	Total (A+B+C)

Total Cost (Rs in Lakhs):

Account Holder Details

Account Holder Name	Postal Address	Phone No	Email Id
University/Institution			

Bank Details

Account No.	Type	Bank Name	Branch Name	IFC Code	MICR Code	Phone No.
University						

Part IV: EXISTING FACILITIES

1. Laboratory:

a. Human Resource:

b. Equipments:

c. Other resources such as clinical material, animal house facility, glass gourse, experimental:

Part V: Biodata of Investigators
Project Investigator Details:

I) Name:
Designation:
Department:
Institute:
Date Of Birth:
Sex:
SC/ST:

II) Education Details:

S. no.	Institution Place	Degree Awarded	Year	Field of Study
1				
2				
3				

III) Employment Details:

S. no.	Institution Place	Position	From (Date)	To (date)
1				
2				
3				

IV) Honors/Awards:

Sl. No.	Reader	No.	Description
1.			
2.			

V) Publications:

Sl. No.	Reader	No.
1.		
2.		

Uploaded additional information

Publication Details:

Uploaded list of Publication in the peer review Journal of impact factor 1 and above

S. no.	Title of Paper	Author	Reference of journal	Year

VI) Project(s) submitted/being pursued/carried out by Investigator:

(a) Ongoing
(b) Completed in last three years
(c) Submitted

S. no.	Title of Project	Funding Agency	From Date - To Date	Current Status of Project (Role)	No. of Scientists	Approved Cost

VII) Professional Experience and Training relevant to the Project:

DECLARATION

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.

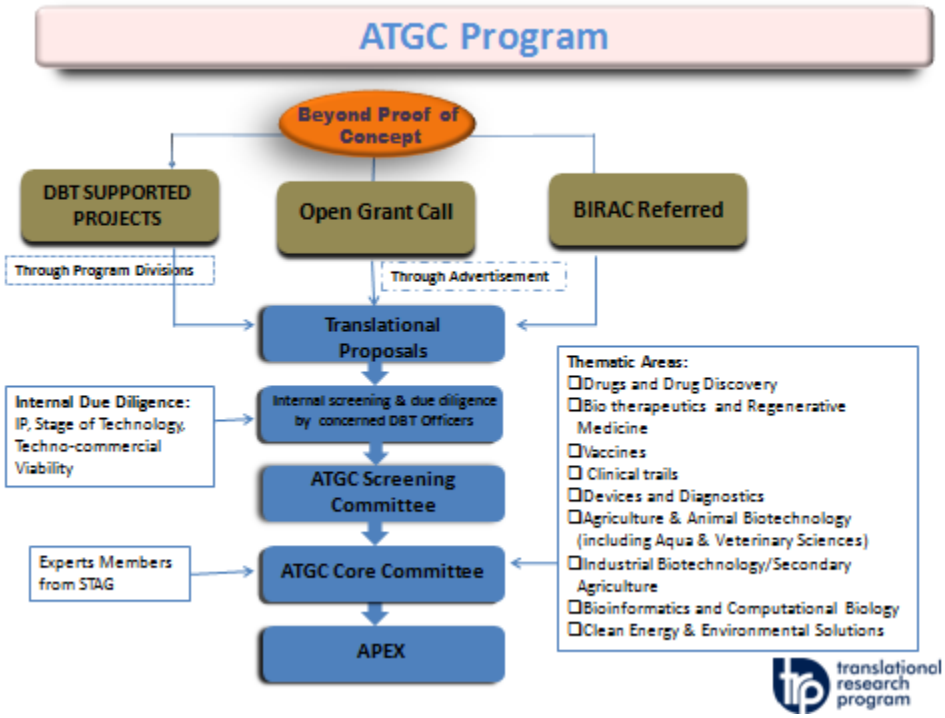
Academic Industry Translational Research (AITR)

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 *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	<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

				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.

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

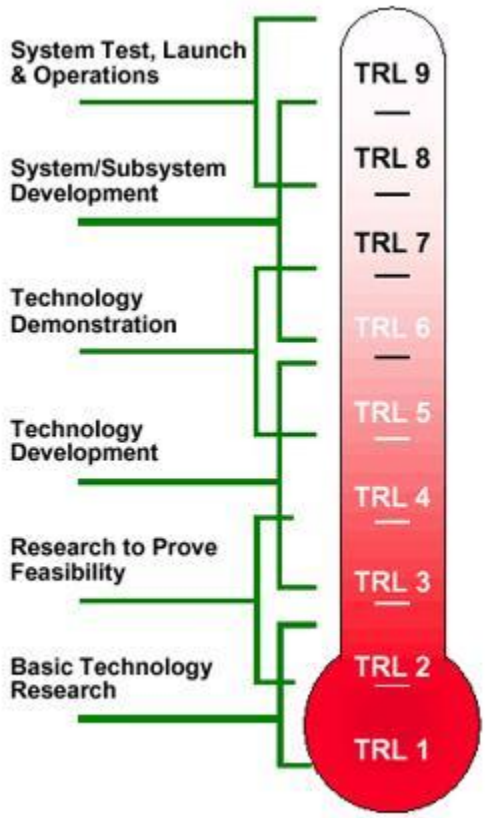
Application Process:

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.

TECHNOLOGY READINESS LEVELS (TRLs)

Technology readiness levels (TRLs) is a measure of estimating technology maturity of core technologies in a program during the selection process and in subsequent monitoring and evaluation phases until these technologies, or products utilizing them, attain market readiness. Originally introduced by NASA, the TRL scale is a metric with nine technology readiness levels for describing the maturity of a technology from ideation stage (TRL-1) to highest degree of application/commercial readiness (TRL-9). Levels in between covers establishment of proof of concepts, prototype developments, functional validations from models to real operational environments and clearances of mandatory regulatory barriers between levels towards market introduction of these technologies/products.



NASA Technology Readiness Levels

References:

a.) Gustav Notander, EIT Health, European Union (Technology Readiness Levels – TRL-NASA's contribution to Horizon 2020.

b.) Technology Readiness Assessment (TRA) Guidance. U.S. Department of Defense, (2011).

c.) Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India (2016), Department of Biotechnology, India.
d.) The TRL Scale as a Research & Innovation Policy Tool-EARTO Recommendations (2014).
e.) TRL-NASA ESTO (https://www.nasa.gov/pdf/458490main_TRL_Definitions.pdf).
f.) Banke, J., August 20, 2010, Technology Readiness Levels Demystified, NASA.
g.) Crop Research Technology Readiness Level (TRL)(2016)-United State Department of Agriculture National Institute of Food and Agriculture Institute of Food Production and Sustainability.

Technology Readiness Levels Required for Applications

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