6th INDIA-SPAIN JOINT CALL FOR TECHNOLOGICAL CO-OPERATION IN BIOTECHNOLOGY 2019

DBT-CDTI CALL FOR PROPOSALS UNDER THE INDO-SPANISH PROGRAMME FOR TECHNOLOGICAL CO-OPERATION IN THE FIELD OF BIOTECHNOLOGY

On November 22nd 2011, a Joint Programme for Co-operation was established by the Department of Biotechnology of India (DBT) and the Centre for the Development of Industrial Technology, E.P.E. (CDTI), to promote and fund market-driven research and technology development as well as to encourage partnerships and business-led R&D&I collaborative projects between entities from both countries. Within this Programme, CDTI and DBT agreed to launch joint calls for proposals.

This call for proposals aims to launch ambitious joint R&D projects of a high international standard between Indian and Spanish organizations. Potential projects will be funded by DBT in India and CDTI in Spain.

CALL GUIDELINES:

1) NODAL IMPLEMENTING AGENCIES

The Department of Biotechnology, Ministry of Science and Technology, Government of India and the Centre for the Development of Industrial Technology (CDTI), Ministry of Science, Innovation and Universities, Government of Spain, are the nodal implementing agencies from the Indian and Spanish side, respectively.

The Department of Biotechnology (DBT) entrusted upon promotion of research, development and innovation in the field of biotechnology. DBT funds and supports all Indian universities, research organisations, non-governmental organisations and industry working in the area of biotechnology.

The CDTI is a Public Entity under the Ministry of Science, Innovation and Universities, Government of Spain, which fosters the technological development and innovation of Spanish Companies.

2) THEMATIC AREAS

This Call for proposals is a generic call open to collaborative R&D projects in all areas of biotechnology e.g. health biotechnology, industrial biotechnology, nano-biotechnology, agro-biotechnology, including biofuels and bioenergy, bioinformatics and biomedical engineering.

3) TYPE OF PROPOSALS

Industry-driven and market-oriented R&D projects, joint technological co-operation projects between investigators from academic/research organizations and/or industries in India and industrial partners (start-ups, SMEs and large companies), in Spain consisting in the development of new or substantial improvement of new products, processes or services will be considered.

The product, process or service must be innovative and there must be a technological risk involved.

The project should have an obvious advantage and added value resulting from the technological cooperation between the participants from the different countries (e.g. increased knowledge base, commercial leads, access to R&D infrastructure etc.).

The project must have a civilian purpose.

The project must be significant for all project partners in a well-balanced consortium.

Duration of projects: from 1 year up to 3 years.

The proposals have to cover the thematic areas mentioned in point 2 to enhance bi-regional co-operation and develop new partnerships as well as strengthen existing ones.

4) TIMETABLE

- Launch of Call for Proposals: 12th December 2019
- Deadline for Submission of completed applications: 27th March 2020
- Eligibility feedback to applicants: 3rdApril 2020
- Label concession (estimated): End September 2020

5) WHO CAN APPLY?

Eligible Spanish Applicants

Spanish consortia should include at least one company. Participation of research institutes/universities and other organizations is welcome as self-funded participants or subcontractors.

Eligible Indian Applicants

The Indian side of the consortium can either be led by a company or a research institution.

a) Industry (including SME/LLP/Startup) partners (documents mentioned below to be submitted along with application form):

- Indian Industry can be a partner in the consortium and are eligible for funding subject to fulfilment of DBT's administrative and financial norms.

- Should be an Indian Company registered under the Companies Act, wherein 51% (or more) of the ownership/shareholding/partnerships shall be held by resident Indian citizen(s); should be complying with General Financial Rules (GFR), 2017; and

- Submission of certificate of incorporation issued under Companies Act, Valid SIRO certificate for firm's in-house R&D recognition, Exemption Certificate (as applicable), Firm's Memorandum of Association, registration at Government of India's Public Finance Management System (PFMS) (https://pfms.nic.in) and Audited Account Statements for the past three years shall be obligatory.

b) Academic/Research Partners:

- Government of India supported or recognised (Public or Private) academia; research organisations and urban or other local bodies.

- Public and/or private universities and research organisations must have a well-established research support system, for basic or applied research.

- Submission of proof of establishment under Indian statue; recognition documents and registration at Government of India's Public Finance Management System (PFMS) - https://pfms.nic.in shall be obligatory.

c) Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research Foundations (documents mentioned below to be submitted along with application form):

- Government of India recognised not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations, having research as one of the imperative mandates.

- The Indian private R&D performing institutions and Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations should have experience of at least 3 years in scientific research, teaching, training and extension activities.

- Proof of registration at 'NGO DARPAN' of NITI Aayog (http://ngodarpan.gov.in/), Certificate of registration under Society Registration Act, Firm's Memorandum of Association, Registration at Government of India's Public Finance Management System (PFMS) (https://pfms.nic.in), Valid SIRO certificate for firm's in-house R&D recognition and audited account statements for the past three years shall be obligatory.

REGULATORY AND ETHICAL CONSIDERATIONS (IF APPLICABLE)

i). Research using hazardous microorganisms, genetically engineered (GE) organisms & products thereof for R&D purpose

In India, research using hazardous microorganisms, genetically engineered (GE) organisms & products thereof are governed under Rules, 1989 (Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells) of Environment (Protection) Act, 1986, according to which, necessary intimation/ recommendation/ authorization from concerned Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) & Genetic Engineering Appraisal Committee (GEAC) is obligatory based on type & scale of research operations.

Further guidance on regulatory considerations can be obtained from:

- Guidelines and Handbook for IBSCs, 2011
  http://www.dbtindia.nic.in/wp-content/uploads/9.-Guidelines-_Handbook_2011.pdf
- Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017
  http://www.dbtindia.nic.in/wp-content/uploads/Draft-Biosafety-Regulations-andBiocontainment-Guidelines-2017-FF.pdf
- Recommendations for Streamlining the Current Regulatory Framework, 2005
  http://www.moef.nic.in/divisions/csurv/geac/draftreport_rpharma.pdf

ii). Human and Animal Subjects Research

DBT and Spain are committed to ensure that projects involving human or animal subjects are protected from research risks in compliance with the rules and policies in respectively countries (ICMR/DBT policies).

All projects recommended for award that involve human or animal subjects will undergo ethics review as well as a review by the Indian Bioethics Committees prior to award request.

For information on ICMR policies, please consult:

- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017
  http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

India PIs of the consortium should apply to their institutional review boards (IRBs)/ institutional ethics committees (IECs) at the time of submission of proposal to obtain necessary bioethics approvals from all involved institutions. If selected, Indian PIs are required to submit proof of their institution's IRB/IECs approval to DBT.

iii). Authorizations for pre-clinical and/or human clinical trials

While exploring vaccine developmental studies in India, Investigators must satisfy regulatory and ethical provisions adopted under:

- Drugs and Cosmetics Rules, 1945 (as amended from time to time) of Drugs and Cosmetics Act, 1940
- Committee for the purpose of Control and Supervision of Experiments on Animals. http://cpcsea.nic.in/Auth/index.aspx
- Schedule 'Y' of Drugs and Cosmetics Rules, 1945 || Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to undertake Clinical Trials: http://cdsco.nic.in/html/D&C_Rules_Schedule_Y.pdf
- Guidance for Industry on Preparation of Common Technical Document for Import/Manufacture and Marketing Approval of New Drugs for Human Use (New Drug Application-NDA): http://www.cdsco.nic.in/writereaddata/CDSCO-GuidanceForIndustry.pdf
- Handbook: Good Laboratory Practice (GLP). Quality practices for regulated non-clinical research and development, 2nd ed. Geneva, World Health Organization, 2009 || http://www.who.int/tdr/publications/documents/glp-handbook.pdf
- Clinical Trials Registry of India (CTRI) – India http://ctri.nic.in/Clinicaltrials/login.php

Kindly Note: *The number of project partners should be optimum and correspond to the objectives of the project. Each project should clearly demonstrate the partner's essentiality, complementarities, and added value in jointly addressing the topic.*

6) HOW TO APPLY?

First stage - Common International phase:

- Joint R&D&I proposals must be submitted to CDTI and DBT, by the 27th March 2020 in order to consider the eligibility. Unilaterally submitted proposals shall not be considered.

  ✓ Indian applicants must submit proposal to DBT (see indicated e-mail) as single consolidated PDF file by Friday, 27th March 2020 (20:30 IST) to ic.dbt2019@gmail.com

  Additionally, a duly signed (by Lead Investigator) & forwarded (by Utmost Authority of the organization) short covering letter introducing the application shall be submitted along with full proposal (with good quality prints on both side of the page (1 original + 1 photocopy) at the latest by 27th March 2020 to the following DBT's contact point:
  • Dr Manish Rana, Scientist-'E', Division of International Cooperation, 6th Floor, Department of Biotechnology, Block-2, CGO Complex, Lodhi Road, New Delhi-110003.

- ✓ In Spain the participants will have to submit a formal R&D international project application through CDT's website (https://sede.cdti.gob.es/)

Documents:

- Indian and Spanish co-applicants must elaborate a single project proposal application (Annex 1 – **Application Form**). The Bilateral Co-operation Form must emphasize how the proposed collaboration adds value, main technology highlights and innovations, activities to be developed by the Parties involved underlining the collaborative work being carried out on each side, their expertise, etc.

  Please note that this Application Form must be sealed and signed by all co-applicants at the end of the document, expressly indicating name and designation of the authorized signatory in the organisation. Any other relevant information not expressly mentioned on the form and that the applicants consider relevant may be included as Annexes.

- In addition to the Application Form, co-applicants have to submit the following documents as relevant appendices:

  - **Consortium Agreement** in English whereby the co-applicants should agree upon the ownership, access rights and exploitation of intellectual property generated during the co-operation, to be submitted to CDTI and GITA. The Consortium Agreement needs to be sealed and signed by all co-applicants.

  - **Additional specific documents required by DBT**
  - **Additional specific documents required by CDTI**

Second Stage - National level

Only those proposals which have positive eligibility by CDTI and DBT will be able to submit the individual R&D&I proposal in its own language established by each agency.

- The funding Proposal is required to be submitted in English by DBT.
- The funding Proposal in Spanish required by CDTI:

Only industrial partners, individually, are able to summit the funding proposal and other required documents through the electronic services at https://sede.cdti.gob.es/. Application must be submitted within 20 working days after receiving the notification of eligibility.

The complete details of the Call are available on DBT's and CDTI's websites: http://http://dbtindia.gov.in/and http://www.cdti.es

Applicants are recommended to contact the nodal representatives at their national funding organizations whose contact details are given below:

SPAIN

Unit of Foreign Technological Action

CDTI-E.P.E. - Centro para el Desarrollo Tecnológico Industrial
C/ Cid 4, Madrid - 28001

http:www.cdti.es

Phone: +34 91 581 04 89 (Spain)
+91 11 4129 3000 (India)

Fax: + 34 91 581 55 94
E-mail: india@cdti.es

INDIA

DBT (India)

Dr. Manish Rana
Scientist E

Division of International Cooperation
Department of Biotechnology
Ministry of Science and Technology
Block-2, CGO Complex, Lodhi Road
New Delhi - 110 003, India
Phone: 2436 3012
E-mail: manish.rana@nic.in

7) ELIGIBLE COSTS AND FUNDING

The project must clearly specify the costs of each and all the activities pertaining to the project and specify the costs to be respectively borne by the Spanish and Indian partners. The cost of the Indian and Spanish partners must be eligible under the laws that may be applicable in each country and under internal regulations of CDTI, Government of Spain and DBT, Government of India, respectively.

The funding conditions from DBT are set in INR and the ones from CDTI in €. Budgets must be expressed in the local currency of each applicant. All figures and budgetary conditions in this Call refer to the value of both currencies on the date of the launch of the Call.

None of the countries budget (namely the budget of its entities participating in the proposal) can have more than 70% of the global budget.

The Spanish company will be funded according to the International Technological Cooperation Projects' conditions identified on CDTI's website. CDTI can only provide funding to Spanish companies subject to budget availability.

DBT will support of the approved budget costs in the following two categories (as per DBT norms):

a) Grant-in-aid 100% to research institutions:

- Government of India supported or recognised public or private academic institutions or research organisation, and urban or other local bodies;
- Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/Research foundations, having research as one of the imperative mandates

Eligible costs for funding are: Capital expenditure (equipment's) || Manpower || Consumables || Travel (local and international travel) || Contingency || Overheads || Outsourcing || others. (Academia can factor in additional sub heads (in other category) such as training & awareness; workshops; publications; review meetings, etc. under expenditure based on the requirement of the project).

b) Grant-in-aid 50% to Industry:

DBT's support to Industry shall not exceed 50% (up to maximum of Rs. 1.5 Crore) of the total project cost and the remaining 50% contribution shall mandatorily come from the Industry;

The cost breakup for the DBT component of the proposal shall be: Capital and Manpower costs (emoluments will be as per prevailing Govt. of India norms) each not exceeding 30% of the DBT supported project cost; and balance will

cover consumables and travel costs. Contingency & overhead costs will not be permissible;

SMEs or Startups can be funded up to INR 25.0 Lakhs for proof of concept, in which 80% can be Grant-in-aid with the balance to come from SME/ Startup.

c) Non-Admissible Cost from DBT

i. Regulatory approval fees;
ii. Prosecution/litigation costs;
iii. Insurance coverage;
iv. Salary of investigators;
v. Capital expenditure for the purchase of assets such as office furniture, motor vehicles, Office equipment viz. desktops, laptops, tablets, cell phones, scanners, printers, photocopy machines, and renovation or extension of facilities such as buildings and laboratories;
vi. Capital expenditure toward technology(ies), demonstration plants and associated field equipment(s), hardware, software etc. for test and analysis from consortium partner(s) from abroad;
vii. Expenditure toward rental and utilities;
viii. International travel to countries other than the one participating within the consortia;
ix. Mere attendance at conferences/ symposiums/ congresses

Kindly Note: Mobility: exchange research visits between Europe and India. Travel costs, living expenses and visa costs are eligible for funding. Eligibility is subject to national regulations.

8) REVIEW PROCESS AND EVALUATION

Projects first will be evaluated at the national level according to the following criteria:

1. Technology maturity stage / proof of concept
2. Technical Capability (team, infrastructure etc.)
3. Ability to deliver/complete the project
4. Financial Capability/Health of the project
5. Project Balance in terms of costs and efforts between the IPL & ITPL
6. Commercialisation Capability.
7. Novelty of Product / Technology
8. Novelty of process / functionality /integration/service
9. Potential of Business and Commercialization success with reference to Target Market
10. Expected economic results from the accomplishment of the project.

All received proposals are peer reviewed and processed independently by both sides. After having received the recommendations of the respective evaluation panels, DBTand CDTI will jointly arrive at a mutual understanding on the projects to be funded.

9) EVALUATION CRITERIA

The evaluation criteria are the following:

- Crucial Criteria
  - Financial capacity of Partner
  - Formal Agreement between Partners

- Basic Assessment Criteria
  - Partnership and Partners
    - Well balanced partnership
    - Added Value through co-operation
    - Technology Capacity of all Partners
    - Managerial Capacity of all Partners
  - Project Structure
    - Methodology and Planning Approach
    - Milestones and deliverables
    - Cost and financing structure
    - Financing commitment of each Partner

- Technology and Innovation
  - Technological Advance
    - Degree of technological maturity and risk
    - Technological Achievements
  - Innovation
    - Degree of innovation
    - Geographical / sector impact

- Market and Competitiveness
  - Market and profitability
    - Market size
    - Market access and risk
    - Return on investment
  - Competitive advantages
    - Strategic importance of the project
    - Enhanced capabilities and visibility

10) FUNDING DECISIONS

DBT and CDTI will, after having formed their mutual understanding on the projects to be funded, make their funding decisions according to their normal procedures and rules and on a non-exchange of funds basis. CDTI and DBT will inform the beneficiaries about the funding decisions according to their normal practice.

11) REPORTING AND PROJECT OUTPUT

Funding granted by DBT and CDTI will be governed by the general terms and conditions of each funding organization, respectively. Both parties will carry out an international follow-up until the completion of the projects and inform the counterpart about the success or failure of the international cooperation at the end of the project.

If required, each participant should submit financial and technical reports to their national funding organisations, according to national regulations. The progress and final results of each individual contract/letter of grant will be monitored by the respective national funding organisations.