



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

Announce

COVID-19 Research Consortium Follow-Up Call

And seek Letter of Intent (LoI)

with a focus on

**Diagnostics, Vaccines, Novel Therapeutics, Repurposing
of Drugs or any other intervention
for control of COVID-19**



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) DISEASE (COVID-19)

The current outbreak of coronavirus disease (COVID-19) got reported first from Wuhan, China, on 31 December 2019. Coronavirus disease (COVID-19) is an infectious disease caused by a new virus that had not been previously identified in humans. COVID-19 has been declared as a pandemic by WHO due to the alarming levels of spread and severity. *Till date, there is no specific medicine to treat or prevent COVID-19.*

In response to the outbreak, there is an urgent need to accelerate development of diagnostics, vaccines, novel therapeutics and re-purposing of drugs for this novel coronavirus. In view of the limited current level of knowledge about the new virus, critical research questions need to be answered urgently, and ways have to be found to fund priority research that can contribute to curtail this outbreak and prepare for future outbreaks. Urgent need to develop safe and effective countermeasures that can be available, accessible and suitable for use in populations most in need. Research is an important integral component of the response to be able to identify key knowledge gaps and research priorities, and thereby accelerate the generation of critical scientific information and the most needed medical products to contribute to the control of 2019-nCoV emergency.

To support the preparedness, readiness and response for COVID-19, project proposals are being solicited for developing *Diagnosics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for control of COVID-19* by Industry/Academia/ Industry-Academia participation.



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

A. PROGRAM GOAL

The theme of the current RFP is:

Developing Diagnostics, Vaccines, novel Therapeutics, repurposing of drugs and any other intervention for control of COVID-19 outbreak". Projects submitted must take into account the criteria for affordability, wide-spread adoption and have a realistic possibility for scale-up. The scope of the RFP is inclusive of and not exhaustive of the following areas:

Diagnostics:

- To develop technologies/Assays/components for diagnosis of coronavirus and SARS-CoV-2 including diagnostic methods such as ELISA, Lateral Flow assay, Molecular diagnostics (PCR, Real Time PCR), Colorimetric tests, Chemiluminescence, Immunoassays, cell culture

Vaccines:

- Vaccine technology platforms, novel vaccine manufacturing technologies, vaccine candidates and enabling disciplines for corona virus vaccine development
- Type of candidate vaccine can be DNA, RNA, Live Attenuated Virus, Non-Replicating Viral Vector, Protein Subunit, Replicating Viral Vector at any stage of development
- In-licensing technology for optimization, scale-up and manufacturing

Novel Therapeutics:

- To develop in-vitro assay/animal models and standardize challenge studies
- Screen existing libraries (Biologicals and Chemicals) and identify potential hits for development
- Novel methods of B-cell isolation/ monoclonal antibody development



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

Repurposing of Drugs:

- Develop prophylaxis clinical studies and prioritize in healthcare workers
- Evaluate existing marketed drugs under a standard protocol in patients of COVID-19

Any other:

- Development of any other intervention/technology related to SARS-CoV-2 outbreak prevention and control

B. Key requirements for the proposed technologies/ products that will be considered:

- a. Developed process should be sustainable from an economic and environmental point of view
- b. The technology should be scalable

C. EXCLUSIONS- Examples of areas that will not be considered:

- a. Proposals not related to SARS-CoV-2
- b. Projects not having product development component
- c. The proposed concept not having commercialization potential
- d. The grant is not a research fellowship.

D. APPLICATION OPENING

Important dates for RFP:

Publication on – 5th April 2020

End date on- 15th May 2020 at 2.00 pm



सत्यमेव जयते



Department of Biotechnology (DBT)

and

Biotechnology Industry Research Assistance Council (BIRAC)

E. ELIGIBILITY: The proposals can be submitted by:

- a. Company (Start-up, Small, Medium or Large) incorporated under the Companies Act, 2013 having a minimum of 51% of the shares of the Company to be held by Indian Citizens (Indian passport holders).
- b. Limited liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum half of the persons who have subscribed their names to the LLP document as its Partners should be Indian citizens

(NOTE: The applicant Company/LLP should have adequate in-house facility to address the project implementation (which shall be evaluated during the proposal evaluation) or incubated with any of the recognized incubation facility. DSIR certificate is not mandatory).

- c. Academia (Public or Private Research Institute, University) having a well-established support system for research. The institute should have been established in India and have NAAC/ UGC/ AICTE or any equivalent recognition certificate or any other Public/Government supported organization
- d. Non-academic Individuals (NAI)

Application can be submitted by any of the above entities (a - d) jointly or severally

F. FUNDING MODALITIES

Funding Support: Grant-in-aid assistance will depend on the proposed activities.

Duration: Project duration can be up to 24 months (*encouraged to develop the solution in 6-12 months wherever possible*)

Depending on the scope of activities and the applicant, the funding will be made available under DBT/different schemes of BIRAC/Ind-CEPI/National biopharma Mission



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

G. APPLICATION PROCESS

a. Process of application submission

- i. Proposals in the form of Letter of Intent are required to be submitted online only. Online proposal submission can be done by registered users. The RFP will be open for a period of 41 days. Process for submitting the proposals online is detailed below:
- ii. Log on the BIRAC website (www.birac.nic.in)
- iii. Registered users may log-in using the credentials and new users need to register the institution with by clicking on New User Registration.
- iv. In case of new user registration, a computer generated password is sent to the email-id provided at the time of registration.
- v. Upon login, the user is navigated to the page displaying the specific scheme link.
- vi. Click on the link under Programmes and the active call would be highlighted.
- vii. Click on the active call against which the proposal needs to be submitted.

b. Process for selection of the proposals

- i. The process of evaluation broadly comprises the following steps:
- ii. Eligibility check of mandatory legal parameters
- iii. Review of LOI by Scientific Advisory Group (SAG)
- iv. Presentation of applicant of selected proposals to SAG
- v. Final recommendations and execution of funding agreement
- vi. The proposals will be evaluated based on following criteria:
 1. Scientific Merit
 2. Technical strength of proposal
 3. Clarity of technical strategy
 4. Innovation level
 5. Level of Risk
 6. Investigator's Credentials and/or collaborative team's expertise.



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

H. SCOPE OF INTELLECTUAL PROPERTY GENERATED DURING THE DURATION OF THE PROJECT

- a. The New Intellectual Property (IP) rights will be as per the policy of the grant scheme,
- b. It is the responsibility of the Fund Recipients to protect the New Intellectual Property (New IP).

NOTE: For the purpose of this GLA, New IP means intellectual property generated during the conduct of the Project by the Fund Recipient(s), but excluding the intellectual property generated by the Fund Recipient(s) before execution of this GLA and any IP generated outside the scope of this GLA even during the term of this GLA.

I. PROJECT MONITORING & MENTORING

a. Project Monitoring Committee (PMC)

The projects shall be monitored/and mentored regularly by an Expert Committee constituted by BIRAC for each project. Site visits shall be conducted by specially constituted Expert Committees comprising two to three Technical experts and one financial expert. The Project Monitoring Committee (PMC) is responsible to;

- i. Monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives is contained in the Agreement.
- ii. Based on the foregoing, to assess and recommend:
 1. The release of next instalment or part release thereof by the BIRAC.
 2. revision of project duration
 3. closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
 4. inclusion of additional industrial/institutional partner(s), if the applicant requests involvement of such partner(s), in the overall interest of the Project,



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

5. mentor(s) to overcome any technological problem faced in the Project implementation; and
 6. Revision of the financial assistance.
- iii. To advise on issues related to securing of IPR and
 - iv. To advise on any other matter as referred to it by BIRAC and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of proposed Scheme.

b. Reporting of Progress

- i. On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.
- ii. The MCR will be assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget is released.
- iii. The Applicant will have to submit a duly certified Statement of Expenditure for the every 30th September and 31st March.
- iv. Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure will be made available as per requirement.

J. TERMS & CONDITIONS AND REQUISITES FOR FUND DISBURSEMENT

a. Agreement of funding

On announcement of Award, all concerned applicants need to sign the Grant-in-aid Letter Agreement (GLA) with BIRAC.

K. OTHER REQUISITES FOR FUNDS DISBURSEMENTS

- a. In addition to signing of agreement between all the concerned parties, following requirement needs to be completed before the first instalment can be released:



Department of Biotechnology (DBT)



and

Biotechnology Industry Research Assistance Council (BIRAC)

- i. A Board Resolution needs to be passed for acceptance of the Grant-in-aid offer by the BIRAC
- ii. Opening up a No-Lien Account with a scheduled/nationalized Bank in case of a Company
- iii. Letter of Authorization in case of Institute in the prescribed format of BIRAC
- iv. MoUs related to IP arrangements/collaborations/outourcing, etc needs to be in place.

L. ACKNOWLEDGEMENT OF BIRAC SUPPORT

Acknowledge the assistance of BIRAC while publishing, marketing the resultant Product or presenting in any manner the details of the Project, its progress or its success along with the “Disclaimer” that reference therein to any specific commercial product, process, views or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or assuming liability of any sort by the BIRAC. Use of BIRAC logo is not permitted without written approval.

M. CONTACT INFORMATION

Further information can be obtained at

BIRAC Website: www.birac.nic.in

Contact Person

Dr Artee, Manager-Investment: inv03@birac.nic.in