



Department of Biotechnology (DBT)
&
Biotechnology Industry Research Assistance Council
(BIRAC)

announce

CALL FOR PROPOSALS

on

COVID 19-Therapeutics

Background:

The occurrence of COVID-19 elevated intense attention not only within India but internationally however still we do not have fully approved (by US-FDA or CDSCO) medication for treating people infected with the novel coronavirus SARS-CoV-2. People infected with this new coronavirus have reported a wide range of symptoms – ranging from mild to severe illness - often appearing 2-14 days after exposure to the SARS-CoV-2 virus. As the disease counts rise in India, it is of utmost importance to develop therapeutics that could be helpful in treating the patients infected with Corona virus. Effective strategies for prophylaxis and holistic management are of paramount importance in curtailing the progress of the disease and reducing burden on hospitals.

DBT/BIRAC have already announced two calls, under COVID 19 consortium, inviting proposals in the areas of Vaccines, Therapeutics, Diagnostics and Any other intervention. In continuation, the present call is being announced in the area of Therapeutics.

Objectives

The scope of this call is to address at least one of the following objectives:

- Development of therapeutics to address a rapid response towards the current COVID-19 outbreak: relevant “clinical ready”-assets including approved therapies or compounds in development, which could be repurposed for use in treating patients with the coronavirus.

- Development of therapeutics to address the current and/or future coronavirus outbreaks: identification of new potential assets and approaches that could be utilised including preventive strategies and combination approaches and could also address potential resistance. This may also include optimisation of promising treatments used in rapid response.

Proposals:

Research proposals **with established, robust Proof of Concept i.e. TRL 4 and above** (BIRAC website may be visited for TRL definitions) are invited in the following areas

- Novel molecules
 - Drug repurposing (e.g. **but not limited to-** antivirals, anthelmintic, antimalaria, anti-Inflammatory, immunomodulatory, anti-RA, anti-hypertensive, anti-coagulants, H2-blockers, protease inhibitors, etc.)
- Combination therapy for synergistic effects
- Biologics –
 - ✓ Neutralizing Antibody therapy
 - ✓ Hyperimmune Globulin
 - ✓ Immunomodulators
 - ✓ Recombinant proteins
 - ✓ Novel mAbs
 - ✓ Repurposed mAbs – (example Tocilizumab)
- Cell-based products and Gene Therapy products
- Stem cells such as UCMSC, WJMSC, BMSC
- Exosomes and other novel Drug Delivery Systems

In addition to the above, development of in-vitro assays and in-vivo models (irrespective of TRL) for evaluating therapeutics will also be considered.

- All proposals must clearly define how samples are to be obtained, safety and documentation of sample collection process, transport and usage in the lab must be defined as per current COVID-19 sample handling guidelines issued by RCGM/DBT.
- Proposals requiring isolation of live virus and or testing of live virus mediated viral functions against a therapeutic agent must demonstrate access to verified BSL-3 facilities. They must also include the detailed SOPs for the same and obtain local IBSC and EC approvals prior to fund release.
- If pre-clinical animal models were not used prior to the trial, the same must be clearly justified in the proposal.
- Proposals must address both efficacy and toxicity aspects of the therapeutic approach.

- Proposals involving human clinical trials must describe cGMP production, toxicity testing and scalability of the therapeutic product as per drug manufacturing regulations and will require approval from CDSCO.
- Additionally, immunologic readouts should be part of the study design to evaluate the therapeutic approach.
- **Study duration: All studies should be for a period of not more than 24 months given the urgency of the global health situation unless TEC/Apex recommends more than 24 months considering the requirements of the project.**

A. 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), preferably with some (documented) commercially successful track record in relevant field.
- 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.

Investigators should have documented strong expertise in the R&D subject matter of the proposed area.

Application can be submitted by any of the above entities (a - c) either singly or in collaboration

Collaborations between institutes and between research and clinical teams are encouraged. Investigators are encouraged to work with hospitals that have access to patients.

B. FUNDING

The funding will be in the form Grant-in-Aid.

1. The Grant-in-Aid assistance support (hereafter referred to as Funding) will be subject to pre-acceptance of associated conditions and execution of Grant Agreement as prescribed by BIRAC.
2. The fund allocation into different budget heads and break-up into milestones will be done as per the recommendations of relevant committees

3. The Recurring cost includes small Equipment, Manpower, Consumables, Travel, Outsourcing towards CMO/Consultancy, Contingency. The Non-recurring component not to be more than 30% of the total project cost.

4. Outsourcing for activities to international labs may be considered only if the facility to perform the same is not available in India.

Depending on the nature of the applicant (academia or a Company/LLP), the funding will be made available by DBT or BIRAC. While academic organizations will be supported by DBT, companies/LLPs will receive support from BIRAC. If there is a collaboration between Industry/LLP & academia or academia & Industry/LLP, funding will be made available by BIRAC.

C. PROJECT DURATION: Up to 24 Months given the urgency of the global health situation unless SAG/Apex recommends more than 24 months considering the requirements of the project in rare exceptional scenario.

D. APPLICATION PROCESS

- (i) Proposals are required to be submitted online through BIRAC website only. Online proposal submission can be done by registered users. The RFP will be open for a period of 15 days. Process for submitting the proposals online is detailed below:
- (ii) Log on to 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.
- (viii) Applicants should fill-up and submit their applications early honouring 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.
- (ix) 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
- (x) Requests for changes in the proposal once submitted will not be entertained.
- (xi) Providing incorrect information or employing corrupt or fraudulent practices shall be viewed adversely.

Support Documents for Application:

- Letter of Agreement from key members of the technical team/engagement
- Formal Agreement/MoU/Letter of support from academic partners

- Formal Agreement or MoU between Academia and company
- Letter indicating the TRL of the proposed study
- Any other due diligence certificate requested by BIRAC/DBT

E. EVALUATION PROCESS

The process of evaluation broadly comprises the following steps:

- The screening of proposals will be a uniform evaluation process for all the applications received under the call. Proposals will be scrutinized at BIRAC. All proposals submitted by Academic Institutes will be transferred to DBT for further processing. However, the composition of Area Review Panel (ARP), Scientific Advisory Group (SAG), and Apex committee will be common for BIRAC and DBT processed proposals.
- All the proposals will be assigned to at least two Area Review panel experts for their detailed review and being lead discussants.
- ARP will meet through videoconferencing or in person to screen and perform technical evaluation for the “within scope” proposals to down select proposals.
- The SAG will meet through videoconferencing or in person to review the “ARP shortlisted” proposals. The SAG will review the audio embedded PowerPoint presentation slides from applicant explaining the objective, methods, deliverables, and budget through videoconferencing and applicant is invited on videoconference mode for defending the proposal and provide clarifications.
- The Apex committee will meet through videoconferencing or in person to screen the “SAG shortlisted” proposals for further review. The APEX will review the audio embedded PowerPoint presentation slides from applicant explaining the objective, methods, deliverables, budget and timelines along with the observations and recommendations of SAG presented by internal technical officer.

F. EVALUATION CRITERIA

The proposals will be evaluated on following criteria:

- a) Scientific Merit
- b) Technical strength of proposal
- c) Clarity of technical strategy
- d) Innovation level
- e) Investigator’s Credentials and/or collaborative team’s expertise.

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
3. Project which is at planning stage or without any PoC established.
4. Projects below TRL 4 (please check the definition of TRLs at BIRAC website)

G. THE SANCTION OF FUNDING SHALL FOLLOW THE PROCESS GIVEN HEREUNDER

1. No site visits for Technical Due Diligence however certified infrastructure pictures to be provided by the applicant to BIRAC as and when required.
2. Financial Due Diligence will be done on case-specific requirements as per BIRAC norms.
3. After, the final recommendation of the relevant applicable committee, application will be proceeded further for financial concurrence, legal concurrence and issuance of Agreement as per DBT/BIRAC norms.
4. After successful execution of the above documents and fulfillment of other formalities, fund disbursement will be initiated by DBT/BIRAC.
5. All the proposals which will be funded under BIRAC will have a royalty clause as per BIRAC norms.
6. A royalty-free license will be applicable if the proposal is recommended as National important project by the relevant Committee.

H. ROYALTY GUIDELINES FOR BIRAC FUND RECIPIENTS

The industrial applicant (Company/LLP) assigned to BIRAC shall pay royalty to BIRAC at the rate of 5 (five) per cent on annual Net Sales of the product(s) developed with BIRAC's assistance. Payment of royalty shall fall due beginning with the first sale of the product(s) and the liability to pay royalty will terminate upon the first of any of the following two events to occur: (a) 5% royalty has been paid to BIRAC till the royalty amount paid becomes equal to the amount of the Grant-In-Aid disbursed and that was not returned to BIRAC as unutilized funds; or (b) in case of Foreclosure or Termination of Project as per the terms of GLA.

I. FUND DISBURSEMENT

1. Financial concurrence will be done on the proposal as per the recommendations of the Apex Committee.
2. The release for Company/ LLP or the Collaborator shall be processed to the No-lien bank account only.
3. The release for academia and non-profit entities shall be processed with the existing organizational accounts.
4. Funding will be milestone based. If the project duration is less or equal to six months, the following will be milestones, a) Signing of the agreement (70%) and Completion of project (30%). If the project duration is more than six months and up to 24 months, the following will be the milestones, a) Signing of agreement (40%), b) Completion of first technical milestone (25%), C) Completion of second technical milestone (25%) and d) Completion of Project (10%).

Except above, any other funding assistance condition very pertinent to a Project shall be considered on approval of competent authority.

J. 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.

The Project Monitoring Committee (PMC) would be 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:
 - The release of next instalment or part release thereof by the DBT/BIRAC.
 - revision of project duration
 - closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
 - inclusion of additional industrial/institutional partner(s), if the applicant requests involvement of such partner(s), in the overall interest of the Project,
 - mentor(s) to overcome any technological problem faced in the Project implementation; and
 - 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/DBT and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of proposed Scheme.

K. TERMS & CONDITIONS AND REQUISITES FOR FUND DISBURSEMENT

a. Agreement of funding

Due execution of funding Agreement with DBT/BIRAC.

b. Other requisites for funds disbursements

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

- i. A Board Resolution needs to be passed for acceptance of the Grant-in-aid offer by the implementing Company:
- 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/Society/Trust in the prescribed format of DBT/BIRAC
- iv. MoUs related to IP arrangements/collaborations/outsourcing, etc needs to be in place.

- v. Royalty agreement should be executed by the grant recipient (Company/LLP) with BIRAC

L. National Importance

Since the Projects that will be supported under this special call are to deliver and to give nationally important outcomes, in addition to the Global Access. Accordingly every Project shall have a national/global commitment based on the expected results that will be part of the considered recommendations of the relevant Committee.

M. ACKNOWLEDGEMENT

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

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.

N. CALL DURATION

The call for proposals would be announced on **15th October, 2020** and the last date for submission of proposals would be **31st October, 2020**.

O. CONTACT PERSON (FOR QUERIES/COMPLAINTS/FEEDBACK)

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