



Department of Biotechnology (DBT)

&

Biotechnology Industry Research Assistance Council
(BIRAC)

announce

CALL FOR PROPOSALS

on

Anti- SARS-CoV-2 /nCoV-2 Virus Studies using Botanical Ingredients and Traditional Formulations

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It was first identified in December 2019 in Wuhan, China, and has since spread globally, resulting in an ongoing pandemic. As of 13 May 2020, more than 4.26 million cases have been reported across 187 countries and territories, resulting in more than 291,000 deaths.

SARS-CoV-2 is an envelope, positive-sense, single-stranded RNA β -corona virus and shown similarity with severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) viruses. So far as its entry and pathogenicity is concerned, SARS-CoV-2 enters into cells through binding of its spike proteins with host cell receptors, Angiotensin converting enzyme 2 (ACE2) and leads to down regulation of the ACE2 receptor. This leads to viral entry and replication, as well as severe lung injury. The occurrence of COVID-19 elevated intense attention not only within India but internationally. No specific therapeutics is available, and current management includes travel restrictions, lockdown, patient isolation, and supportive medical care. Therefore, there is an urgent need for its management and prevention.

There is no specific treatment except managing the symptoms of SARI (Severe Acute Respiratory Infection). In some countries anti-HIV drugs are being tried while in India antimalarial drug HCQ (Hydroxy Chloroquine) is given as prophylaxis to high risk Health Care

Personnel. The available data suggests that there is no specific treatment in modern medicine. Health supplements like Vitamin C, Zinc etc., are being used for the immunity boosting.

Some traditional medicines appear to be effective in treating viral infection by enhancing the immunity of the body against virus. Also, they are a potential source of antiviral drugs and various bioactive compounds. Randomized clinical trials suggest the possibility to obtain natural product to treat viral infections and its complications from traditional medicinal plants. It is a remarkable effort to isolate active principles from plants with a confirmed antiviral activity that leads to explore their mechanism of action and, lastly, to develop a conventional dosage form design that not only controls viral infections but also reduces the associated complications.

The rapid increase in patients of COVID-19 during the last few weeks is posing tremendous challenge for the healthcare systems across the world including India. Effective strategies for prophylaxis and holistic management are of paramount importance in curtailing the progress of the disease and reducing burden on hospitals.

To manage COVID-19 pandemic through the application of medicinal and aromatic plants, project proposals are solicited by Industry/Academia/ Industry-Academia in following research areas:

- (a) Development of experimental models for evaluation of anti-viral activity of extracts, fractions and phytochemical constituents from medicinal and aromatic plants**
 - (i) *In vitro* anti-viral activity (nCoV2, non-infective, pseudo-RNA virus)
 - (ii) Antiviral (anti-nCoV-2) efficacy in animal model
 - (iii) MTT / PI / CCK8 assay for cell toxicity

- (b) Screening of extracts, fractions, phytochemical constituents and traditional formulations from medicinal and aromatic plant against SARS-CoV2**
 - (i) Development of research lead candidates based on screening to take forward towards developing phytopharmaceuticals.
 - (ii) Development of phytopharmaceuticals for prevention, co-administration and mainstay therapy
 - (iii) Development of herbal products for prevention against COVID-19 – Proof-of efficacy, pre-clinical and clinical.

- (c) Studies on extracts, fractions and phytochemical constituents from medicinal & aromatic plants**
 - (i) Immunomodulatory and anti-inflammatory activity (PBMC, Neutrophils, Th1/Th2 driven T-cell responses, antigen presentation)
 - (ii) Effect if any on obesity, diabetes, lung fibrosis and
 - (iii) Drug-drug interaction studies (CYP450 studies)
 - (iv) Essential oils compounds inhibitory to SARS-COV-2 proteins & infections

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).
- 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

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

B. FUNDING

- Funding Support would be in the form of Grant-in-aid
- The extent of funding will depend on the proposed activities. However, under no circumstances the total project cost would exceed Rs. 100 lakhs.

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 the project involves only industry/LLP then the financial support from BIRAC would be restricted to a maximum of 50% of the total approved Project cost. The remaining 50% cost would be borne by the Applicant company/LLP subject.
- If the project involves only academia, the entire cost would be borne by DBT
- If the project involves both industry/LLP and an academic partner, financial support from BIRAC to the industrial/LLP partners would not exceed more than 50% of the total budget of the industrial/LLP partners. The remaining 50% cost would be borne by the Applicant company/LLP subject. However, the entire cost to the academic partner/s would be borne by DBT.

C. PROJECT DURATION: up to 18 months

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 21 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:

- (i) Eligibility check of mandatory legal parameters
- (ii) Review of proposals by Area Review Panel (ARP) experts: The Area Review Panel (ARP) will consist of eminent domain experts which is constituted with the requisite approval. The experts have to sign a no-conflict-of interest and confidentiality agreement after the proposals are assigned to them. The full proposals will be evaluated by the panel and shortlisted for further screening.

- (iii) Presentation by applicant of selected proposals to Technical Expert Committee (TEC) comprising of eminent domain experts
- (iv) Final recommendations by the Apex committee comprising technical experts from relevant research areas and representatives from DBT and BIRAC. The Apex committee would be the governing body to assign the projects to the implementing agency as per the scope of the work and type of applicant.

In certain cases, at its discretion, the TEC may recommend site visit of shortlisted proposals after presentation.

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

G. FINANCIAL CONCURRENCE AND RELEASE OF GOVERNING AGREEMENT BY DBT/BIRAC

For Industry applicants, detailed financial due diligence for the company will be done by BIRAC as per existing guidelines.

Financial concurrence would be taken by each implementing agency (DBT/BIRAC) as per their existing guidelines. After receiving technical/ regulatory/ IP/ legal/ financial clearances, the GLA would be issued by the implementing agency to the applicant with final milestones and budget as per their existing guidelines.

H (i) SCOPE OF INTELLECTUAL PROPERTY GENERATED DURING THE DURATION OF THE PROJECT FUNDED BY BIRAC

- a) The New Intellectual Property (IP) rights belong to the recipient of funds, in a joint manner unless mutually agreed otherwise.
- b) It will be the responsibility of the Fund Recipients to protect the New Intellectual Property (New IP).

H (ii) SCOPE OF INTELLECTUAL PROPERTY GENERATED DURING THE DURATION OF THE PROJECT FUNDED BY DBT

New IP generated by the fund recipient shall be governed as per the funding agreement entered with DBT.

(NOTE: For the purpose of the 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 the GLA and any IP generated outside the scope of the GLA even during the term of this GLA).

I. 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.

J. FUND DISBURSEMENT

- The funding support offered will be in the form of grant-in-aid.
- The fund disbursement will be milestone based i.e. 4 instalments for 12 months project and 5 instalments for >12 months project. First instalment (30%) on sanction of the project & last instalment on completion of the project and submission of the project report (~ 10%). The remaining instalment with 20%+ 20%+20% or 30%+30% would be release depending upon the duration of project and satisfactory completion of the respective technical milestone. The releases will be done based on recommendation of project monitoring committee from DBT/BIRAC and UC- SOE submitted by the applicant. No extension of project duration will be considered, and will be closed on "as is" basis when the duration is completed.

K. 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.

L. PROJECT MONITORING & MENTORING

a. Project Monitoring Committee (PMC)

The projects shall be monitored/and mentored regularly by an Expert Committee constituted by BIRAC & DBT for each project. Site visits shall be conducted by specially constituted

Expert Committees comprising of Technical experts (2 or more depending on the requirement of the project) and financial expert.

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 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.

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.

M. 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 their implementing agency: 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 agency: DBT/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 DBT/BIRAC
- iv. MoUs related to IP arrangements/collaborations/outsourcing, etc needs to be in place.
- v. Royalty agreement signed by the industry applicant (Company/LLP) would be executed at BIRAC by the competent authority.

N. 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.

O. CALL DURATION

The call for proposals would be announced on June 12, 2020 and the last date for submission of proposals would July 03, 2020.

P. CONTACT

Further information can be obtained on **BIRAC Website:** www.birac.nic.in and **DBT Website:** <http://dbtindia.gov.in>

Q. CONTACT PERSONS (FOR QUERIES/COMPLAINTS/FEEDBACK)

- Dr Prachi Kaushik, Manager (Investment), BIRAC: pkaushik.birac@nic.in
- Dr Sanjay Saxena, GM & Head (Investment), BIRAC: investment.birac@gov.in
- Dr. Manoj K. Modi, Scientist ‘E’ DBT: manoj.modi@nic.in