Request for Expression of Interests (REOI):

Enhancement of Capacity to support COVID-19 vaccine development

Under
Mission COVID Suraksha

Of

Department of Biotechnology, Ministry of Science & Technology,
Government of India and

Biotechnology Industry Research Assistance Council (BIRAC)

(A Government of India Enterprise)

Call Opens	01 December 2020
Closure of Submission	20 December 2020, 5:00 PM

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Introduction

As a part of the Government of India's response to Covid -19 pandemic, the Department of Biotechnology (DBT), Ministry of Science and Technology, has been working with all stakeholders to address this urgent need for a COVID Vaccine. Biotechnology Industry Research Assistance Council (BIRAC) as a Government Enterprise has been identified by DBT to effectively implement Mission COVID Suraksha by setting up a Mission Implementation Unit (MIU).

COVID 19 pandemic is anticipated to lead to a loss of $2 trillion - $4.1 trillion -- 2.3% to 4.8% of the global gross domestic product. Recognizing its critical importance, rapid development and deployment of effective vaccines against COVID-19 is the need of the hour with ~66 candidates in clinical trials globally (data as per WHO compilation, accessed on 31st October 2020).

Vaccine development is a lengthy, expensive process, typically taking and an average of 10-15 years. But the current emergency does not provide this luxury of time. While the government efforts have helped quickly put together the best groups and encouraged them to accelerate the COVID vaccine development, it is now imperative that the COVID vaccine development and manufacture are taken up in a Mission mode and not in a project mode.

Therefore, to ensure a steady supply of vaccines in the next 12-18 months, DBT has established **Mission COVID Suraksha.** The focus of this mission is to consolidate and streamline available resources towards a warpath for accelerated vaccine development. This will be a National Mission working to bring to the citizens of the country a safe, efficacious, affordable, and accessible COVID vaccine at the earliest with a focus on Atma Nirbhar Bharat, and fulfil our commitment of serving not just the country but the entire globe.

It must be ensured that all vaccines being introduced through the Mission have preferred characteristics applicable for India and that is proposed to be achieved by strengthening the following functional domains:

- Accelerating the production of clinical trial material, and clinical development for licensure of COVID-19 vaccine candidates.
- Establishing clinical trial sites, immunoassay laboratories, central labs and suitable facilities for animal challenge studies, manufacturing facilities and other testing facilities to support COVID-19 vaccine development

To enable the above, this Request for Expression of Interest (REOI) is only to seek application for:

- **Enhancement of Capacity to support COVID-19 vaccine development.** The other REOIs on Vaccine development and Clinical trials site can be assessed on BIRAC's website

SECTION II : Details of REOI

REOI: Enhancement of Capacity to support COVID-19 vaccine development

1. **Background:**

Considering the number of vaccine candidates under development it is critical that harmonised processes are followed for appropriate comparisons of immune response elicited by each candidate. To enter efficacy trials, COVID-19 vaccine candidates need to be tested in animals demonstrating safety and efficacy, particularly against a challenge with SARS-CoV2. Several animal models of SARS-CoV2 have been developed including mice expressing ACE2, mouse models with mouse-adapted SARS-COV2 strains, ferrets, hamster and NHP models. Access to these animal facilities needs to be streamlined for generating high-quality data.

In addition to animals, a major source of variability is the assays for estimating immune responses. The assays required to measure immune response are complex, require BSL-3 facility and involve testing of antibody response, functional response using wild and Pseudovirus and Cell Mediated Immunity (CMI). It is critical to establish and standardise these assays in laboratories which will follow harmonized protocols to measure immunogenicity of various COVID 19 vaccine candidates.

2. **Objective:**

To upgrade /strengthen Service Facilities for conduct of animal studies and immunological assays that is available to COVID-19 vaccine developers. It will help in accelerating development of COVID-19 vaccines in the pipeline.

Proposals are thus invited for establishing (i) facilities and conducting challenge studies in animals and/or (ii) laboratory for performing Clinical Immunogenicity assays

3. **Scope:**

a. For establishing facilities and conducting challenge studies in animals:

Funding may be considered for:

i. Strengthening facilities for demonstrating efficacy of COVID-19 vaccines through animal challenge studies with SARS-CoV2. Animals models can include but not limited to
   - ACE2 transgenic mice
   - Mouse models with mouse-adapted SARS-COV2 strains
   - Syrian hamsters
   - NHPs (preferably Rhesus macaque)
   - Ferrets

ii. Facility to upgrade capacity through:
   - Enhancing infrastructure and capacity for animal holding
   - Upgrading Virus handling capabilities specifically SARS-CoV2 virus that includes BSL-3 facility and any of the following:
     - Environment controlled room with Specific Pathogen Free (SPF) conditions
     - Individually Ventilated Caging (IVC) systems
     - The facility would have veterinary and technical manpower for animal handling and experimentation

- Ensure establishment of Quality Management System (QMS) through agencies and consultants.

b. For establishing laboratory and performing Clinical Immunogenicity assays

Funding may be considered for:

i. The laboratory to validate and conduct either of the following assays to support immunogenicity assessment for clinical trial testing of COVID-19 vaccine candidates. The assays including but not limited to:
   - ELISA/CLIA: High Throughput assays
   - Neutralization assays using wildtype Virus/ Pseudovirus
   - Assessing cell mediated immunity (CMI) responses e.g. antigen specific memory T-cell differentiation and long-term protective response by immuno-phenotyping and immunogenicity assays, measuring T-cell proliferation, identification of specific cytokines/ chemokines in response to infection/ vaccination as a measure of T cell response, inhibition of viral replication.

ii. To assess and adsorb assay technology transfer from National and Global reference labs, research institutes etc. The laboratory to adsorb new high-throughput immunological assessment assays.

iii. To utilize advanced technology platforms such as Luminex, Meso Scale Delivery (MSD), which allows minimum sample and maximum data.

iv. To establish, evaluate and document the validation of assays as per ICH Guideline on Validation of Analytical Procedures Q2 (R1).
   - The laboratory to establish systems for filing towards accreditation under the National Accreditation Board for Testing and Calibration Laboratories (NABL).
   - Ensure establishment of Quality Management System (QMS) through agencies and consultants.

4. <u>Pre-requisite for applying</u>

a. For establishing facilities and conducting challenge studies in animals:

i. Facility must be a Govt national research lab or a Govt autonomous institute.
   OR
   Facility must be previously funded under NBM for animal facility /analytical facility/manufacturing facility/immunoassay lab

ii. Applicant organization should have BSL3 facility and have demonstrated prior experience conducting animal studies preferably for assessing efficacy of any vaccine candidate.

iii. Applicant must demonstrate systems to provide fee-for-service

iv. Applicant organization should preferably have done any COVID product related testing

v. Applicant organization should preferably have access to Biorepository of COVID-19 samples

b. For establishing laboratory and performing Clinical Immunogenicity assays

i. Facility must be a Govt national research lab or a Govt autonomous institute.
OR
Facility must be previously funded under NBM for animal facility /analytical facility/manufacturing facility/immunoassay lab

ii. Applicant organization should preferably have demonstrated prior experience conducting COVID 19 serology/ diagnostic testing

iii. Applicant must demonstrate systems to provide fee-for-service

iv. Applicant organization should preferably have BSL3 facility which can be further strengthened

v. Applicant organization should preferably have done any COVID-19 product related testing

vi. Applicant organization should preferably have access to Biorepository of COVID- 19 samples

5. Expectations from the facility

a. For establishing facilities and conducting challenge studies in animals:

i. Should function as a fee-for-service model and work towards obtaining accreditation within 12 months

ii. Should build a Project Management support to ensure coordination with vaccine developers/ manufacturers

iii. Should provide study reports appropriate for submission to regulatory authorities

iv. Should develop a well-established rehabilitation plan for animals

v. Should have access to Institutional Research Board for seeking clearance on conducting animal studies

b. For establishing laboratory and performing Clinical Immunogenicity assays

i. Should function as a fee-for-service model and work towards obtaining ISO 15189:2012 or 17025 accreditations and GCLP compliance.

ii. Should demonstrate prior experience of performing humoral immunogenicity assays.

iii. Should agree to be linked to or be mentored by globally recognized Key opinion Leader (KoL) and for transfer of assays

iv. Should plan participation in external quality assessment programs and will be subjected to assessment by vaccine manufacturers for adequacy.

v. Should adhere to the processing timelines as per the clinical development program to get the results within accepted timeframes.

vi. Should have proactive involvement and compliance in terms of budgets and legal agreements discussions, as well as policies on publication of data.

vii. Logistically the laboratory should be well connected (preferably by air).

viii. The laboratory is expected to provide service to multiple vaccine developers. The laboratory should demonstrate capabilities to expand further if there is a need.

6. Eligibility Criteria

- 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).
- 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
- 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
- Non-profit organizations/ Society/ Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ which is a legal entity

7. Funding Mechanism

Projects must be budgeted on a milestone basis. Funding will be awarded for 1 year, subject to the applicant complying with agreed milestones.

Allowable costs include:

- *Personnel*: Researchers and PIs who receive a salary from the host institution as permanent or fixed term staff members may NOT claim salary reimbursement from BIRAC grants.
- *Consultants*: These may include both national and/or foreign consultants who provide a service and capability that is not available among the project partners. Preference should be given to national service providers. Quality Management consultants to also be considered
- *Supplies and consumables:* Reagents from international repositories and supplies to also be considered in addition to all other consumables for providing services.
- *Travel & accommodation*: Must be directly related to the execution of the project or travel related to seeking technology transfer.
- *Institutional overhead/Contingency*
- *Infrastructure*: Partial Maintenance of Infrastructure of the facilities pertaining to varied services including analytical work area, specimen collection room, waste disposal facility, fire safety equipment.

Non-allowable costs:

- Civil construction work
- Attendance at conferences
- Any Litigation/ Opposition/ Infringement cost.
- Any legal fees outside the purview of allowable cost.

SECTION III

1. Application Guidelines and Process:

Key Dates

Call Opens	01 December 2020
Closure of Submission	20 December 2020**,** 5:00 PM

The Expression of Interest can be submitted online as per the required format. The website will provide a detailed user guide to facilitate the online proposal submission.

The process for submitting the proposals online is detailed below:

i. Go to BIRAC's website **https://www.birac.nic.in**

ii. Click on the Call for Proposal and then-current call tab in order to view the call detailed description.

iii. Click on the active call against which you wish to submit the Proposal.

iv. Further details on 'How to Submit a Proposal' would also be available in BIRAC 3i Portal.

v. If you are already a registered user, then kindly enter your login credential at the below link in order to submit proposal: **https://birac.nic.in/login.php**

vi. If you are a new user and your company/organization is not listed in the drop-down on the registration page, then you need to register your company/organization by clicking on link: **https://birac.nic.in/desc_new.php?id=327**

vii. Once you register your company/organization, then your organization will be activated within 24 hrs. After activation, please create your login credential by browsing the same link : **https://birac.nic.in/desc_new.php?id=327** . After registration, you will receive an auto-generated link on the registered email id entered at the time of registration.

viii. Once you login into https://birac.nic.in by using login credentials, then kindly click on "COVID Suraksha" on the dashboard to submit the proposal.

ix. Applicants are advised to fill-up and submit their applications early without waiting for the last date in order to avoid any last-minute contingencies. The system stops accepting applications automatically after 5:00 PM of the last date of submission.

x. In case of any query may please drop an email at **pmubmgf5@birac.nic.in** without any delay.

xi. Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review (Refer Annexure 1).

xii. Applicants are advised to provide self-contained proposals with essential supporting materials provided as uploads.

xiii. Requests for changes in the REOI once submitted will not be entertained.

xiv. Please read through this REOI in its entirety and ensure that your technical details, budget, and organization details are in compliance with the eligibility criteria provided. The Applicants should read the guidelines for clear instruction and other details for comprehensive preparation of

EOI. Proposals for projects that do not meet the eligibility criteria and/or do not directly respond to the call area will not be reviewed, regardless other parameters.

xv. The proposed budget shall be made **INCLUSIVE** of all applicable taxes and shall be considered accordingly. The commitment of the applicant to put in its resources as part of the Project will be specified distinctly.

xvi. Information on all relevant pre-existing agreements/ MoUs in connection to the proposed technology, background IP, outsourcing, consultancy, IP licensing, technology transfer, material transfer, etc. should be provided at the time of proposal submission.

2. Evaluation Methodology:

Mission Implementation Unit (MIU) will screen the proposals for eligibility. If the application is found to be incomplete or not complying to the provisions described in the EOI, the application will be considered ineligible.

Proposals that meet the eligibility criteria will be submitted to Scientific Advisory Group (SAG) for review.

The SAG will, make assessments and recommend shortlisted applications for further evaluation to the Apex Committee.

Grantees may also be invited for interaction or sought written clarifications when it is felt beneficial to ensure that any outstanding questions are resolved prior to concluding the full review.

Technical and financial due diligence process (site visits) of the shortlisted applications would be carried out by MIU as applicable.

A final decision on applications to be funded will be made by the Competent authority based on the recommendations of the Apex Committee.

3. Evaluation and Decision-Making Criteria:

3.1 Proposal Merit:

- Does the Proposal's approach align with the objective of EOI?
- Does the Proposal demonstrate preliminary work useful for the proposed scope of work?
- Has the applicant provided an adequate description of the existing manpower and infrastructure to understand their present capabilities?
- Are the objectives, activities and milestones well defined?

3.2 Team/Applicant:

- Is the applicant competent to ensure the effective conduct of the proposed work?
- Does the applicant team have relevant capabilities and appropriate experience for the same?
- Does the applicant have any prior regulatory experience?
- Has the applicant provided letters of support/agreements with any third party they would like to engage with during the different stages of product development?

3.3 Implementation:

- Has the implementation methodology and work plan adequately detailed and realistic?

- Has the applicant provided clear metrics for monitoring project progress, including milestones and outputs expected timelines, budget?
- Have the resources (technical and management people, equipment, outsourcing needs, etc.) required over the time frame been comprehensively mapped?
- Has the applicant anticipated difficulties/risks that may be encountered? Have mitigation plans been considered in case of failure?

3.4 **Budget Estimates:**

- Is the proposed budget reasonable in light of the defined scope of work? Have reliable references been provided for justification?
- Is the resource allocation across various stages, sufficient and appropriate?

4. Requisites for Funding:

- Successful proponents shall enter into necessary funding agreements. The fund disbursement will be subject to completion of required formalities by way of Grant-in-aid assistance and associated documentation. The fund recipient shall be accountable for fund utilization as per the sanction.

5. Program Monitoring Mechanism:

Project Review and Monitoring Committee (PRMC)

The projects shall also be monitored and mentored regularly by a Project Review and Monitoring Committee (PRMC) constituted by MIU for each project.

Reporting of Progress:

On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format

The MCR will be assessed by the PMRC/ SAG for its completion. On recommendation of the PMRC/SAG/VEC, the next Milestone budget will be released

6. C**ontact Information**

Further information can be obtained at BIRAC website. www.birac.nic.in

Contact Person:

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Annexure – I

List of documents to be enclosed for fulfilling Legal Eligibility as applicable

In case of **Companies/ LLP:**

a. Incorporation / Registration certificate.

b. Share holding pattern as per BIRAC format / Partnership deed **or** list of subscribers which states that minimum half of the partners are Indian citizens along with copy of passports of Indian partners/subscribers .

c. Research mandate/ details regarding in-house R&D facility, if any / Incubation agreement.

d. Audited financial details of last three financial years (i.e. 2017-18, 2018-19, 2019-20).

In case of **Indian institution/ universities/ public research organization:**

a. Affiliation/registration certificate.

b. Research mandate/ details regarding in-house R&D facility, if any / Incubation agreement.

c. If the institution/public research organization are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust.

In case of **Society/ Trust/ NGO/ Foundation/ Association:**

a. Society registration certificate / Trust deed / Registration certificate.

b. Research mandate/ details regarding in-house R&D facility, if any / Incubation agreement.

c. CA certificate (supporting the fact that half of the members of the society/trustees are Indian).

List of Financial Documents to be enclosed :

1. Memorandum of Association, AOA/Bye Laws/Partnership Deed/Trust Deed
2. Certificate of Incorporation
3. List of Directors with DoB, DIN and PAN
4. Index of Charges Registered with the ROC
5. Latest Six months operating bank's statement
6. PAN, TAN, ST-2 etc.
7 Details of R & D Facility/Incubation agreement
8. ***CA/CS Certified Shareholding Pattern indicating nationality of the shareholders*** (if shares are held by other Body Corporates then attach the CA/CS certified shareholding pattern of that body corporate also which indicates the nationality of the shareholders).
9. Audited Financial Statement for the last 3 years along with the Notes on Accounts & Auditor's Report.
10. KYC of savings account in case of institutes/academia/trusts/society