

Development of COVID-19 vaccine candidate(s)

Request for Expression of Interest (REOI):
Development of COVID-19 vaccine candidate(s)

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
First closure of Submission	15 December 2020, 5:00 PM
Second closure of submission	15 January 2021, 5:00 PM

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Section I - [Program Overview – Mission COVID Suraksha](#)

Introduction to Mission COVID Suraksha

As part of the Government of India's response to the COVID 19 Pandemic, the Department of Biotechnology (DBT), Ministry of Science and Technology, has been working with all stakeholders to address the urgent need of COVID 19 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 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: **Development of COVID-19 vaccine candidate(s)** other REOIs published for CT sites, immunoassay labs and suitable facilities for animal challenge studies may be accessed through BIRAC website.

SECTION II: Details of REOI

REOI: Development of COVID-19 vaccine candidate(s)

1. Background:

As part of the Government of India's response to the COVID 19 Pandemic, COVID Suraksha is being initiated. The purpose of this REOI is to accelerate COVID 19 vaccine development at global scale to counter the pandemic.

2. Objective:

To ensure accelerated development of a vaccine for COVID-19, the objective of this REOI is to support Regulatory toxicology studies, manufacturing clinical trial material, and clinical development for licensure of COVID-19 vaccine candidates, and other activities to ensure accelerated development of vaccine candidates such that within the next 12 months they are closer to licensure and introduction in the market.

3. Scope:

The call seeks proposals for the development of COVID-19 vaccine candidates for the following:

3a. Regulatory toxicology studies:

PCT application to RCGM ready to be filed/or filed

3b. Clinical development

Funding may be considered for:

- i. Clinical trials for the demonstration of safety, immunogenicity and efficacy for the most promising vaccine candidates. This includes funding for preparatory activities, trial conduct, sample collection, clinical assays, data management and final report submission to regulatory.
- ii. Scale-up and manufacturing of material for conduct of clinical trials till market authorization.
- iii. Comparative/ bridging trials for introduction into the National immunisation program.
- iv. In-licensing of vaccine candidates and further clinical development in India may be considered with appropriate justification provided for in-licensing

NOTE:

- No new research for developing proof of concept towards vaccine development will be supported under this REOI
- The applicants are encouraged to use DBT/BIRAC/NBM established Clinical trial networks for large scale randomized trials. This established network is equipped with infrastructure, and have access to the target population, GCP trained personal, registered ethics committee, defined processes and quality assurance systems to enable to conduct Phase 1,2 or 3 clinical trials.
- In case, the applicant wishes to use the external facility/sites not supported by DBT/ BIRAC/NBM for trials may provide detailed justification.

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- Recommended that sites selected for the clinical trial also submit separate application to BIRAC so as to directly receive funds under the REOI 3 of Clinical Trial sites. Applicant should also advise their preferred CT sites to apply through a dedicated published REOI to directly get funded under the mission

For details regarding the clinical sites and facilities funded under National Biopharma Mission, BIRAC, please click the link below:

<https://birac.nic.in/nbm/cms/page/clinical-trial-network - For field sites>

<https://birac.nic.in/nbm/cms/page/clinical-trial-network - For facilities>

4. Pre-requisite for applying

The proposal should include previously conducted studies and available supporting data to be submitted depending on the stage of development as described below:

- i. **Regulatory toxicology studies**
 - a. Proof-of-concept studies such as functional in vitro assays
 - b. Animal immunogenicity studies
 - c. Batch consistency and stability data
- ii. **Clinical Development:** Submit data related to
 - Proof-of-concept studies such as functional in vitro assays
 - Animal immunogenicity studies
 - Toxicology studies
 - Manufacturability and stability of the vaccine candidate
 - Previously conducted clinical trials in India or globally

5. Expectations from the Applicants:

- i. The proposal should have a clearly defined product development plan with details of proposed activities, specific milestones & timelines, and the budget estimates depending on the stage of development.
- ii. If seeking support for clinical development, then following to be submitted:
 - Clinical assay development plan: Details of clinical assays, selected facilities or partners for conduct of assays.
 - Manufacturing strategies: Details of expression platforms, cell lines, analytical assays, formulation strategy.
 - Clinical trial strategy: Details of the clinical development plan, sites
 - Regulatory plan.
- iii. The proposal should indicate the feasibility of advancing the candidate from the current readiness state of technology (stage of development) by providing a clear understanding and articulation of risks proposed solutions to these challenges (most significant technical, regulatory & IP risks).
- iv. The data generated as an outcome of this grant should comply with ICH guidelines and suitable for submission to CDSCO for seeking relevant approvals.

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- v. The proposal should indicate a plan for interactions/consultations with global and national experts, regulatory agencies/NTAGI to ensure compliance with regulatory authorities and expectations of the decision-makers of Target Product Profile (TPP) of the final vaccine.
- vi. The project will be a Nationally important project and it may have specific terms of global access, licensing, pricing or March-in rights for the purpose of public interest/ demand of Government of India as will be recommended by the Apex Committee.
- vii. For the products being funded, the Global Access obligations to ensure that the products being developed are affordable and accessible for the target population is a must.
- viii. All the participants under the present mission (the grantees and the partnering entities) shall enter into Mission COVID Suraksha Partnering Agreement with BIRAC.
- ix. The funding support shall be duly acknowledged when publishing/showcasing/ presenting project particulars or outcomes/commercializing the Product in the manner as prescribed by BIRAC.

6. Eligibility Criteria: The proposals can be submitted by any one of the following:

- i. Company (Start-up, Small, Medium, or Large), LLP 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).
- ii. 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
- iii. 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 12 months, subject to the applicant complying with agreed milestones.

The call will not fund:

- Development of new adjuvants
- Fundamental/ basic research
- Preclinical material generation and Preclinical studies
- Projects without proof of concept data
- Funding for procuring instruments and equipment not to exceed 50% of the Grant.
- Activities related to commercialization
- Civil construction to set-up large manufacturing facilities
- Any Litigation/ Opposition/ Infringement cost.
- Any legal fees outside the purview of allowable cost.

Section III – Application Process and Instructions

Application Timelines:

Key Dates

Call Opens	1 December 2020
First closure of Submission	15 December 2020, 5:00 PM
Second closure of submission	15 January 2021, 5:00 PM

There will be a rolling review and approval process for funding. Considering finite amount of funds, we strongly encourage early submissions of Expression of Interest.

1. Application Guidelines and Process:

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 "**Mission 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.

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- 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 REOI. 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 REOI, 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 REOI?
- Does the Proposal demonstrate preliminary work useful for the proposed scope of work?

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- 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. Intellectual Property:

- The applicant team should have the legal interests and the freedom to operate as related to IP, including consent from others where applicable.
- IP developed through this grant will be owned by and will be the responsibility of the applicant (unless stated otherwise) subject to pre-existing legal arrangements. The Mission to make affordable products shall be embraced by the Grantees.

5. 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.

6. 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

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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

7. Contact Information

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

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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