

Integrated approach to address/support COVID-19 vaccine induced immunity, related processes and facilities

RFP Document

2022

1. Introduction

It has been more than two years that India and the rest of the world are suffering from COVID 19. The development of COVID-19 vaccines was swift because of years of prior research on related viruses and speedier vaccine manufacturing methods, as well as massive funding.

The virus mutated several times giving rise to a number of variants that are proved to be more infectious than the wild type strain. At the onset of this disease, a lot of experimental therapies and drug repurposing were tried to mitigate this new viral disease. These included the use of antiviral medications (e.g., Remdesivir), anti-SARS-CoV-2 monoclonal antibodies (e.g., bamlanivimab/etesevimab, casirivimab/imdevimab), anti-inflammatory drugs (e.g., dexamethasone), immunomodulators (e.g., baricitinib, tocilizumab), convalescent plasma therapy, etc. During the course of the time, many of these were dropped by WHO indicating them to be ineffective.

The disease also saw a number of associated severe clinical indications such as Pulmonary Fibrosis, Cystic fibro Acute respiratory distress syndrome (ARDS), etc.

Today, vaccination has markedly reduced adverse outcomes of the disease, but it is unknown how long the COVID-19 vaccine will provide protection. Over time, it does seem that the ability of the vaccine-induced immunity to avoid the infection erodes. Similarly, the protection against serious illness also deteriorates over time. Hence, it is important to have integrated efforts to address the associated issues and support the vaccine induced immunity.

2. Scope of the call:

The Scope of the current call is development of treatments by accelerating pre-clinical & clinical development and development of processes/facilities for COVID associated conditions such as Pulmonary Fibrosis, Cystic fibrosis, Acute respiratory distress syndrome (ARDS), pro-thrombotic state and diffuse tissue injury, etc. This may focus on

- Development of treatment modalities
- Invitro assays and In vivo animal models for lead molecule development.
- Supporting capabilities for process development, cell line development and manufacturing of GMP batches for animal toxicology studies and clinical trials.

3. Expectation from the applicant:

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

4. Administrative Eligibility

Proposals can be submitted by Industry or Academia, individually or in collaboration with each other. The entities who are the applicants or the Collaborators shall be evaluated for eligibility criteria related to minimum resident Indian shareholding or ownership;

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

The below mentioned documents would be required

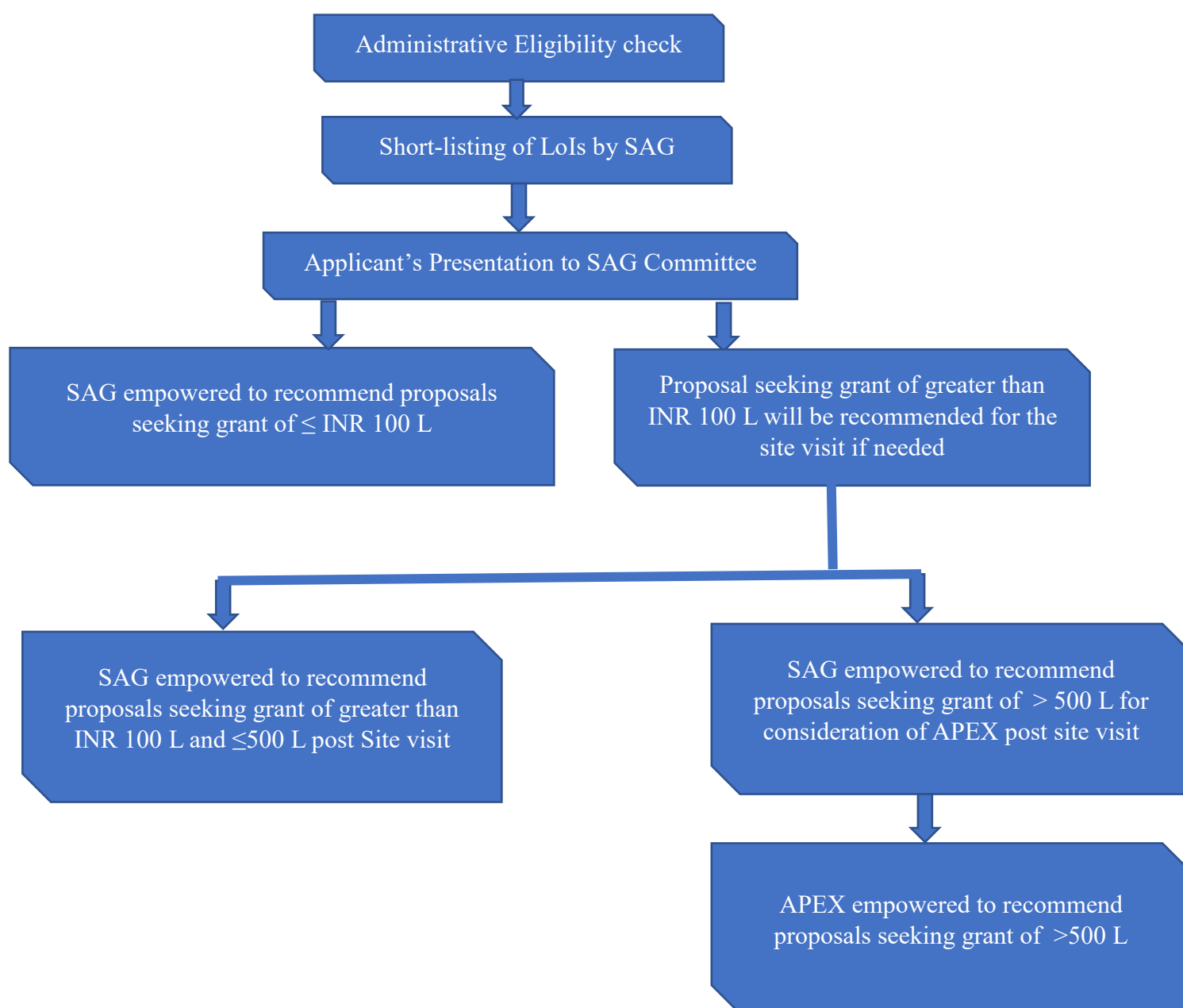
- a) Scanned copies uploaded by way of CA certified shareholding, Registration certificate, copy of self-attested Passport copy, establishment or incorporation documents and other relevant documents
- b) Applicant and Collaborator can submit Letter Of Intents (LOI), MOU or support letters as scanned copies executed on relevant Letter Heads to show the mutual arrangements. Detailed signed MoU would be needed before the project is sanctioned.
- c) Board Resolution requirement can be substituted by resolution signed by MD/CEO/ COO along with any other executive Director or Company Secretary. Letter of Authorization requirements shall be considered adequate if signed by the Head of the Institution/ Head of the Department/ Principle Investigator / Dean of the Institute.

5. Application Process

- A request for proposal document will be published on BIRAC's website. Proposals will be sought through an open call as Letter of Intent through BIRAC's on-line platform.
- Proposals submitted in hard copy or those submitted after the call closure will not be accepted.

6. Selection Process

- a. The screening of Letter of Intent (LOI) will be a uniform evaluation process for all the applications received under the call. Submitted LOIs will be screened for administrative eligibility internally by BIRAC. Eligible LOIs will be considered for further screening.
- b. A Scientific Advisory Group (SAG), and Apex committee will be constituted for evaluating the proposals. The SAG will meet through videoconferencing or in person to screen and perform technical evaluation for the “within scope” LOIs to down select LOIs.
- c. The shortlisted LOIs will be assigned to SAG experts for their detailed review and being lead discussants and the applicants will be invited to make a detailed presentation including objective, methods, deliverables, and budget to the SAG committee
- d. The Apex committee will screen the “SAG shortlisted” LOIs for further review.



7. Sanction of Fund Support

- a) Site visits for Technical Due Diligence will be conducted for proposals seeking grant greater than INR 100L. After the final recommendation of the relevant applicable committee, the applicant will have to revise the LOI based on the recommendations of the committee. The application will be proceeded further for financial concurrence, legal/IP concurrence and issuance of GLA as per BIRAC norms. Financial Due Diligence will be done as per BIRAC norms.
- b) After successful execution of the above documents and fulfilment of other formalities, fund disbursement will be initiated by BIRAC.

8. Funding Process

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 the final approving committee
3. The Recurring cost includes, Manpower, Consumables, Travel, outsourcing and contingency. Non-recurring component not to be more than 30% of the total project grant. However, if a specific project has a requirement for non-recurring grant of more than 30%, then the same can be considered based on the recommendations of the committee.
4. Outsourcing for activities to international labs may be considered if the facility to perform the same is not available in India.

Note: For industry, salary of Project co-ordinator and other manpower (Financial Clearance is required) may be included in the project cost based on the man hours towards the project. However, it has to be ensured that they are not availing the salary from any other sources and if they are technically involved in the project.

9. Fund Disbursement

1. Financial concurrence will be done on the LOI as per the recommendations of the approving Committee.
2. A no lien account will have to be opened for the project. In case where the company contribution is also there, the company will put in their contribution (into the same no-lien) for the milestone upfront.
3. The expenditure done after signing of the GLA should only be included in the project. All expenditure should be made as per the details mentioned in the GLA. The equipment list

should strictly match with those given in the GLA. All expenses (for both BIRAC and company) are to be done out of the no-lien account only.

4. The release for academia and non-profit entities shall be processed with the existing organizational accounts.
5. The GLA shall have specific undertakings with regard to the accommodation towards the first release provisions of Company/ LLP as applicable.
6. The fund disbursement will be milestone based (the duration, milestone and fund release schedule may be changed based on very specific recommendation of the committee). In most of the cases, if the project duration is less or equal to 12 months, the following will be milestones (and the fund release percentage):
 - a) Signing of the GLA and promoter contribution for the milestone upfront (30%)
 - b) Completion of first technical milestone (30%)
 - c) Completion of Second technical milestone (30%)
 - d) Completion of project (10%).

If the project duration is more than 12 months, the following will be the milestones (and the fund release percentage):

- a) Signing of the GLA and promoter contribution for the milestone upfront Signing of agreement (30%)
- b) Completion of first technical milestone (20%)
- c) Completion of second technical milestone (20%)
- d) Completion of Third technical milestone (20%)
- e) Completion of Project (10%).

For infrastructure projects, the duration, milestone and fund release schedule will be based on very specific recommendation of the committee.

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

10. Governance, Monitoring & Reviewing

1. The process implementation shall be governed by the funding agreement. The governance for project implementation for all purposes shall be in terms of the respective agreement that will be entered between BIRAC and the Fund Recipient.
2. Review shall be conducted through the committees which will be formed for the projects. If need be, an online interaction/site visit shall be conducted during the course of the project or at completion.

11. Intellectual Property Governing Framework

A. SCOPE OF IP GENERATED DURING THE CONDUCT OF THE PROJECT

- a. The New Intellectual Property (IP) rights belong to the recipient of funds, in a joint manner unless mutually agreed otherwise. Provided, this Project is not determined as a “Nationally Important Project” to be governed through specific „Order of BIRAC“. Such cases of “Nationally Important Project” shall have specific terms of licensing, pricing or March-in-rights for the purposes of public interest/ demand of Government of India.
- b. It is the responsibility of the Fund Recipients to protect the New Intellectual Property (New IP). They shall bear the expenditure involved in protecting the New IP.

B. GLOBAL ACCESS

The Fund Recipient(s) jointly and severally agree to conduct and manage the Project and the resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, “Product”) and any IP that arises (New IP) in the manner that ensures “Global Access.”

Global Access requires that

- a. The knowledge and information gained from the Project be promptly and broadly disseminated or published.
- b. Project Developments and/or New IP are made available and accessible at an affordable price to people most in need within developing countries.
- c. In this regard, ensure Global Access in all present and future research and development agreements in a suitable form.

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.

12. Foreclosure and Termination

- i. In case, during the Project Duration, if it is found that the Project or any Project component is not likely to lead to successful completion, BIRAC may decide to foreclose the Project or the Project component as warranted. The decision of the BIRAC shall be final in all respects. The Fund Recipient shall submit detailed accounts of funds received and utilized. The Company shall immediately refund any grant-in-aid unutilized out of BIRAC’s disbursements to BIRAC, BIRAC, at its discretion, allow deduction of, the future committed expenses to third party vendors on pro-rata basis according to the quantum of BIRAC’s funding. If the Fund Recipient likes to continue the Project at its own cost, it would be able to do so without restrictions from BIRAC after complying with these provisions.
- ii. The fund recipients may, before the completion of the project, terminate the agreement by giving three months’ notice in writing to BIRAC. BIRAC may also terminate the agreement by written notice in the event of committing breach of terms of the agreement and either not rectifying it to the satisfaction of BIRAC or not satisfying BIRAC about its inevitability within a Specified period. In the event of termination of the agreement, no further disbursement shall be made by BIRAC. The fund recipients

- shall be liable to return immediately the amount of Grant-in-aid already availed of from BIRAC with additional simple interest at the rate of 12 (Twelve) percent annum within 30 (thirty) days of termination of the agreement, Interest on the quantum of funding assistance shall accrue from the date of release of the Grant-in-aid assistance. In case of failure to repay, without prejudice to any other rights under the agreement, the amount can be recovered by initiating any procedure available in Law.
- iii. Breach of terms, unjustified delay in project progress, failure to bring own contribution, unjustified delay/ non-submission of UC/SOE/SOA, progress report as required for final closure etc. shall also be grounds for termination.

13. Extension in the duration of the project

Extension of projects is DISCOURAGED. Request for extension of project on account of Change in Coordinator/Principal Investigator, delay in purchase of equipment, hiring of manpower, submission of Milestone Completion Reports, Statement of Expenditure (SoE), Utilization Certificate (UC), or any other financial/technical document by the company/collaborator necessary for release of funds by BIRAC will NOT BE ENTERTAINED.

Request for extension of milestone/project can be considered (without any additional financial implications) only in selective cases where accomplishment of technical milestone is prolonged due to delay in securing regulatory approvals, or where the relevant committee feels that some additional studies are needed to take the project to a logical conclusion/product development or due to any other technical reasons not envisaged at the time of submission of proposal. However, such request must be communicated to BIRAC at least TWO MONTHS before the scheduled date of completion of milestone/project with proper justification.

13. National Importance

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.

14. Call duration

The call for proposals will be announced on 13th October 2022. The last date for proposal submission is 3rd November 2022.

For any queries, please contact

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