

Guidelines for Ind-CEPI Mission program on
Epidemic preparedness through rapid vaccine
development

Process Flow and Terms

About the program

The Department of Biotechnology, Ministry of Science and Technology, Government of India is supporting the implementation of the Ind-CEPI Mission, *“Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)”*, through a dedicated Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC).

The Ind-CEPI Mission was approved on 27th March 2019 with a total cost INR312.92 crore.

Aim and Objectives

Ind-CEPI Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emergent infectious threats in India.

The objectives of the mission include:

1. Supporting the development of at least 2-3 new vaccines for potential outbreak threats up to phase 2 testing in five years.
2. Strengthening of infrastructure to support the needs of the vaccine development through an academia-industry interface.
3. Supporting capacity building and skill development.
4. Strengthening internal inter-ministerial co-ordination for rapid vaccine development and testing to address known and unknown infectious disease threats.
5. Strengthening of development frameworks, surveillance and logistics for use of new vaccines, where appropriate.

Operational Plan

Ind-CEPI Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emergent infectious threats in India.

Engagement with CEPI:

Role of CEPI:

- CEPI has already conducted a prioritization exercise in the past based on which it issued RFPs for Lassa, Nipah, MERS, RFV and Chikungunya vaccine candidates
- Guidance for call timelines and evaluation parameters while developing the RFPs will be sought from CEPI. In addition, strategic collaborations with CEPI on future RFPs of CEPI on priority pathogens/assays/strengthening of surveillance sites etc. will also be explored.
- Nomination of Experts from/by CEPI for the review and evaluation of proposals including SAG.
- The Ind-CEPI Mission will facilitate the studies through the provision of clearly defined criteria and pathways for vaccine assessment, which will be developed in consultation with CEPI. Also, participation of Experts from CEPI will be solicited in oversight or mentoring activities for accelerated development of vaccines and platform technologies.

Role of BIRAC in CEPI:

The progress against the grants administered will be coordinated on a regular basis by the PMU at BIRAC (InD CEPI) and the results shared with the SAG and Steering Committee annually. Individualized, hands-on technical, managerial and regulatory assistance will be provided by the PMU to the grantees through the duration of the projects. Disease specific Project Development Units (PDUs) may be constituted.

The scheme has two categories:

1. Calls announced from PMU, BIRAC under Ind-CEPI
2. Funding the Indian components of proposals considered by CEPI.

Operational Guidelines

Project Duration:

The funding is provided over a maximum period of 60 months in installments against agreed milestones.

Eligibility Criteria:

A) single or consortia of Indian Company (ies) - Small, Medium or Large. An Indian Company is defined as one which is registered under the Indian Companies Act, 2013 and Minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport (Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders) The proposals can be submitted:

- Solely by an Indian Company; or
- Jointly by an Indian Company and National R&D Organizations and Institutions;
or
- By a group of Indian Companies along with National Research Organizations etc.
- By a Not for profit groups, LLP or academic institutions working in vaccine R&D

B) Not for Profit Limited Liability Partnership (LLP) – which is incorporated under the Limited Liability Partnership Act, 2008 and Minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens

The applicant Company/LLP should either: -

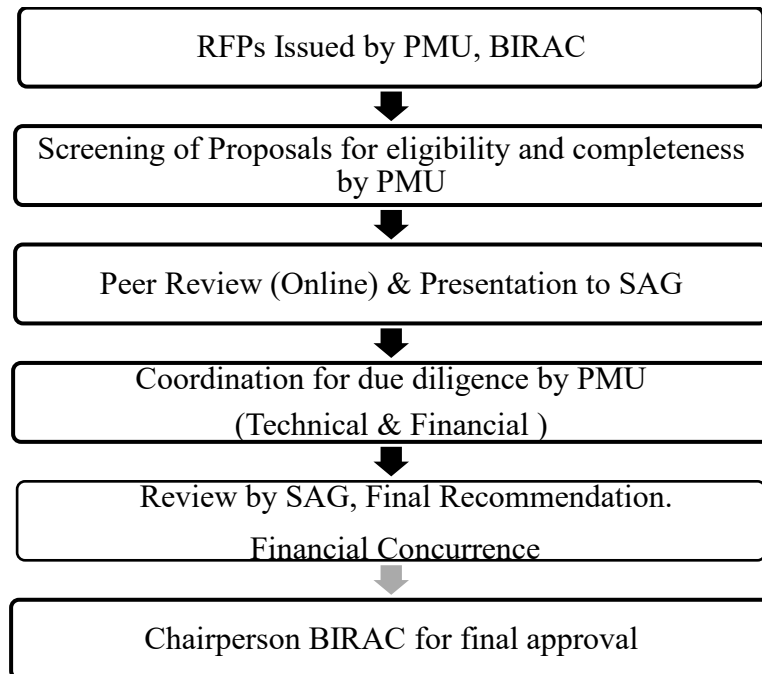
- i) Have adequate in-house facility to address the project implementation (which shall be evaluated during the site visit) or
- ii) Incubation with any of the recognized Incubation Facility.

How and when to submit proposal?

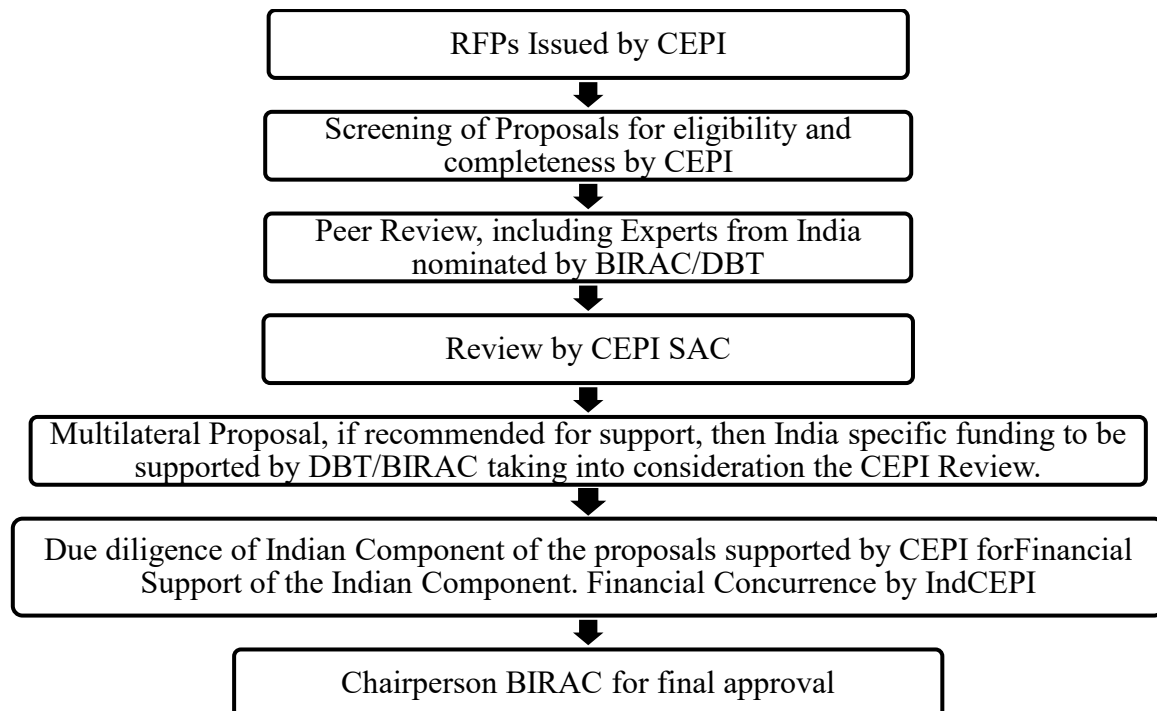
Proposals are required to be submitted online only. Online proposal submission can be done only during an active call.

Process flow for Calls and Review of Proposals:

1. For Calls from PMU, BIRAC under Ind-CEPI*



2. Funding the Indian components of proposals considered by CEPI *



*Proposed Mechanism subject to variation on case-to-case basis, considering in principle approval of Chairperson BIRAC.

Role and Responsibility of the Reviewer and Expert Member

Specific role of the Expert Reviewer of different panels is to:

- i. Review the project online and give a detailed evaluation based on the established criteria.
- ii. Shortlist proposals based on Review score for a detailed presentation.
- iii. Assess proposals based on the interaction during the presentation and shortlist for an on-site visit.
- iv. Technical Due diligence during on-site visit after detailed interaction with Applicant.
- v. Recommend proposals for support under IndCEPI after SAG Committee discussion.
- vi. Assist PMU-BIRAC in Monitoring the Project.

The reviewers evaluate the proposal based on review criteria and allot scores for each defined parameter and sub parameters in the prescribed format. The reviewers would maintain complete confidentiality about the proposals. The reviewers are generally given two weeks for proposal evaluation and submission of report. The evaluations of the reviewers are then discussed by the SAG. The coordinator of each of the Review Panel would serve as the moderator for that area and would discuss and normalize scores for the proposals for which there is a significant variation in the scores allotted by the reviewers. The Technical Committee then discusses each proposal finally after moderating. The SAG shortlists proposals for next round of screening i.e. Presentation. During the presentation a detailed discussion is held and proposals are evaluated for the following:

- a. Level of innovation
- b. Advanced technology of great promise
- c. Level of risk

Guidelines to Reviewers regarding Confidentiality and Conflict of Interest

- In discharging their duties as Panel members, all Panel members must observe the Code of Conduct, Conflict of Interest and Confidential Information requirements set out below.
- These guidelines apply equally to everyone involved in the assessment of applications – including, but not limited to Panel members and Reviewer.

Confidentiality and Transparency

An effort has been made to ensure complete transparency in the proposal submission and evaluation. An important feature of the Ind-CEPI process is the high level of confidentiality which is maintained throughout the proposal decision making process. The review panels and technical committees are comprised of senior technical experts and eminent scientists from research institutions, academia and public sector. Each member signs a confidentiality certificate before having access to any document related to Ind-CEPI proposals. Issues related to conflict of interest are specially taken care of and each reviewer declares a no conflict before they can access any documents. The entire process is online. BIRAC receives applications under Ind-CEPI in confidence and is responsible for protecting the confidentiality of their submission and contents. For this reason, confidentiality must be maintained; therefore, DO NOT copy, quote, or

otherwise use material from this summary application. When you have completed the review, please destroy all printed and electronic materials related to the Application and maintain its confidentiality. If you are unable to review, please do not accept the Membership online. You can click on Not Available or state Conflict of Interest when it asks for your consent and destroy all printed and electronic materials related to the application, and maintain its confidentiality.

Any panel member can self-reveal the fact that he/she served on the panel, but CAN NOT reveal the composition of the panel or any of the discussions during the panel meeting or during the entire review processes.

Conflict of Interest: These guidelines are designed to ensure that all such conflicts are:

1. Identified and disclosed;
2. Recorded; and
3. Managed in a rigorous and transparent way that promotes public confidence in the integrity, legitimacy, impartiality and fairness of the Panel's decision-making process.

What is a Conflict of Interest?

A conflict of interest usually involves a conflict between the public duty and the private interests of a member, in which the member has private interests which could improperly influence the performance of their official duties and responsibilities.

These guidelines apply not only to actual conflicts of interest but also to "apparent" or "perceived" conflicts of interest. This kind of conflict of interest arises when it appears that the member has private interests which could improperly influence the performance of their official duties and responsibilities.

These guidelines also apply to "potential" conflicts of interest. This kind of conflict is one which may not have yet occurred but if the Panel member were to become involved in certain relevant activities an actual or apparent conflict could arise.

Conflict of interest may arise in respect of a particular application in the following situations (this list is indicative and not exhaustive):

- The involvement of a Panel member in any current application – e.g. as an applicant for funding or as the supervisor of an applicant;
- Membership of a Panel member in an organization involved in any current submitted application under the programme; or
- ownership of shares by an Advisory Panel member in a company involved in any current, established or submitted application, or if the future of the company will be significantly affected by the success of the application.

You must disqualify yourself as a reviewer of an application if you have had any conflict of interest in the project including the following:

- a. Had a consulting/financial arrangement or other conflict of interest in the past 3 years, including receiving compensation of any type (e.g., money, goods, or services)
- b. Have a known family relationship such as a spouse, child, sibling, or parent, or other relationship, such as a close personal friendship, that you think might affect your

judgment or
be seen as doing so by a reasonable person familiar with the relationship.

Financial concurrence and release of Governing Agreement by DBT/BIRAC

Subsequent to SAG recommendation, financial concurrence will be taken by BIRAC followed by approval of MD- BIRAC and Secretary-DBT. Sanction Order will be issued by PMU-BIRAC with final milestones and budget. Further BIRAC will process Grant-in-aid Letter Agreement (GLA) with the grantee.

Funding

The funding support offered will be in the form of grant-in-aid. There is no cap on funding but budget proposed should be commensurate with activities and as per allowable cost.

The fund disbursement will be undertaken after due execution of the GLA and further release shall be milestone based. PI will define the budget heads with due diligence and justification.

Post Sanction

The releases and milestone-based achievement will be monitored and recommended by project monitoring committee/SAG duly constituted for the project. The fund recipient shall submit technical milestone attainment report and UC-SoE periodically. No extension of project duration will be considered, and will be closed on “as is” basis when the duration is completed.

Acknowledgement

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

Other Formalities

Fund releases for the project will be subject to fulfilment of certain formalities such as opening of no lien account by the company, submission of Board resolution by the company, submission of letter of authorisation by the academia etc. and regulatory approvals as applicable.

Allowable/Non-Allowable Cost

- The funding assistance will be in the form of grant-in-aid without the obligation of payment of Royalty.

- Appropriate Grant Award Letter will be issued by BIRAC for the funds disbursed providing for the governing terms and conditions and these will be accepted by the fund recipient(s) within the time period of four (4) weeks from the date of issue.
- In cases where support is restricted to equipment cost only, the first instalment would be released when 80% of the civil/construction work has been completed.

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.

Nationally Important Projects

If Apex Committee recommends certain Projects as nationally important Projects, then BIRAC will issue a specific “Order” to make the following provisions applicable;

A. In such cases of national importance BIRAC shall retain a royalty-free, non-exclusive, irrevocable licence to the Product developed with the funding support of BIRAC with right to sub-license for the purposes of public interest/Government of India and/or as decided by the Apex committee. The licensor of such Product will ensure that where the Product has been produced in collaboration with entities not in receipt of BIRAC’s Grant-in-aid, such collaborators will also grant license to BIRAC in the same way.

B. Nationally Important Projects shall mean such Projects that will serve specific purposes notified by Government of India in public interest.

C. In cases of national importance, if BIRAC determines that such –

(a) Action is necessary because the Fund Recipient or licensee/s has not taken, within the period of four (4) years from the date of completion of the Project, effective steps to commercialize the Product in such field of use;

(b) Action is necessary to meet requirements for public use or national interest and such requirements are not reasonably satisfied by the Fund Recipient or licensee/s;

Then, March-in-rights are applicable whereby;

- i. BIRAC along with retainment of royalty-free, non-exclusive, irrevocable license to the Product BIRAC, after taking into consideration the fund recipient's requirement for reasonable expansion and the demand supply gap at the appropriate time, shall have the right to require the Fund Recipient to transfer the technical know-how of the Product developed under the Project to other entrepreneur(s) and train them, on such terms and conditions as may be mutually agreed among BIRAC, the fund recipient and such other entrepreneur(s). Provided, BIRAC shall reserve its right to require that the Product must be manufactured and sold in India.
- ii. If the fund recipient (s) does not agree with the terms of above sub section (i), then BIRAC shall require that all rights and interests associated with the Product including Intellectual Property (IP) Rights to be assigned to BIRAC. The Fund Recipient(s) and co-owners of the IP shall undertake all necessary actions to affect the assignment.