

Enhancing capacity for conduct of Human clinical trials for COVID-19 Vaccine candidates

Request for Expression of Interest (REOI) : Enhancing capacity for conduct of Human clinical trials for COVID-19 Vaccine candidates

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)

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Section I - Program Overview – Mission COVID Suraksha

Funding agency

Department of Biotechnology (DBT)

Implementing agency

Biotechnology Industry Research Assistance Council (BIRAC)

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 Oct'20).

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, and other testing facilities to support COVID-19 vaccine development

To enable the above, this Request for Expression of Interest (REOI) is to seek EOI/ application only for : **Enhancing capacity for conduct of Human clinical trials for COVID-19 Vaccine candidates** as per the instructions given below. Other published REOIs on Vaccine Development, Immunogenicity lab establishment and Animal challenge facilities may be accessed through BIRAC website.

SECTION II : Details of REOI

REOI : Enhancing capacity for conduct of Human clinical trials for COVID-19 Vaccine candidates

1. Background

There are few vaccine candidates already in human clinical trials in India and several promising candidates in various stages of development. To ensure timely development of these multiple COVID-19 vaccine candidates, it is essential that sufficient trial capacity is available to coincide with vaccine readiness for testing. Over the next year, large-scale efficacy trial capacity would be required for candidates in early to late clinical stages towards which community and hospital-based sites would need to be established. To ensure that sites are prepared for fast tracking the trials, the Mission COVID Suraksha aims to bolster the existing trial capacity to meet the COVID-19 vaccine trial demand.

2. Objective

Ensure availability and access to Good Clinical Practice (GCP) compliant clinical trial sites to vaccine developers. The trial sites will be both for supporting hospital-based sites for performing early stage clinical trials and large scale Phase III clinical trials through access to community based healthy population.

3. Scope:

Funding may be considered for following but not limited to

Enhancing and strengthening the institutional capacity for conduct of Phase 1/2/3 clinical trials for COVID-19 vaccine candidates in terms of :

- i. Community-based site capabilities for Community outreach, community engagement and community-based data collection
- ii. Establishing collection and storage space for sample/specimen storage, handling, processing, and temperature monitoring.
- iii. Establishing Pharmacy to receive, store, manage inventory, dispense study product, and maintain accurate records with and cold-chain logistic support, staffed by a qualified pharmacist(s)
- iv. Establishing Biorepository for storage of samples collected from the recruitment sites and laboratories
- v. Capacity for Data entry and Management Capability
- vi. Building a trial administration team to support all activities required for effective implementation and management of the trial
- vii. Training on GCP and GPP for research team of Investigators/Co-investigators, physician, coordinators, nurses, lab technicians, and field workers relevant to conducting vaccine trials
- viii. Establish quality management systems
- ix. Conducting clinical trials for vaccine companies developing COVID-19 vaccine candidates

4. Pre-requisite

- The applicant is funded under BIRAC for community based or hospital based clinical trial sites, hospitals engaged in community based field trials (any therapeutic consortium) (listed in Annexure II)
OR
- The applicant has participated/participating/ready to participate in the COVID-19 vaccine clinical trial

Applicant site should have the following attributes

- Investigator and Co-investigator team should have members from at least one of the following departments: Internal Medicine, Pulmonology, Critical Care Medicine, Pharmacology or Anaesthesia or Paediatrics.
- Site should have DCGI registered Ethics Committee
- Access to space for counselling subjects, placement of required infrastructure and good internet connectivity for electronic data management
- Hospitals/emergency care facility in vicinity

Applicants should submit

- Declaration from the Head of the institution to provide adequate support for fulfilment of proposed objectives
- Site refurbishment plan with gap assessment of current infrastructure, details of refurbishments required and plans for strengthening and specific resources required
- Staff capacity building plan with staffing plan, training needs of existing staff and how training will be delivered, plans for mentoring new staff and providing continuing education/training, and training assessment

All personal data will be stored and used by or on behalf of DBT/BIRAC in accordance with the Indian Laws and confidentiality norms.

5. Expectations from the Applicants

1. Establish quality management systems. A quality management plan including GCP training and resources required for establishment of a robust quality management system
2. The site should be ready for signing service agreements with vaccine manufacturers for conduct of clinical trials
3. The sites should plan adequate steps to ensure timely recruitment of appropriate population. Strategy to ensure minimal loss to follow-up should also be developed by site Investigator.
4. The sites are expected to provide service to multiple vaccine developers
5. The data generated as an outcome of this grant should comply with ICH guidelines and suitable for submission to CDSCO for seeking relevant approvals
6. All the participants under the present Mission (the grantees and the partnering entities) shall enter into Mission COVID Suraksha Partnering Agreement with BIRAC. Please refer to guidelines.

7. The funding support shall be duly acknowledged when publishing/showcasing/presenting project particulars or outcomes
8. The sites should be available for planning and conduct of trials of companies supported by BIRAC/Indian Start-ups and MSMEs

6. Eligibility Criteria

- i. Company (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).
- ii. 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
- iii. 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
- iv. Non-profit organizations/ Society/ Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ which is a legal entity

NOTE: Funding is not available for Contract Research Organizations or Site Management Organization

7. Funding Mechanism

There will be an upper cap of the budget for one-year duration:

- INR 200 Lakhs for hospital sites for one year
- INR 250 Lakhs for field sites for one year

Projects must be budgeted on a milestone basis. Funding will be awarded for 12 months, subject to the applicant complying with agreed milestones. The Project Review and Monitoring Committee will assess the site performance in every 2 months. Fund disbursements may be influenced by the assessment report.

Allowable costs:

- **Non-Recurring:** Purchase of Laptops/desktops/tablets, proprietary software, servers, sim cards, laser printer, photocopier, scanner, recording equipment for audio-visual consent, weighing scale, patient resuscitation equipment such as crash cart, ECG machine and defibrillator, refurbishment, furniture, filling/storage cabinets, CCTV, cold storage (-80°C, -20°C, pharmacy-grade refrigerators), temperature monitoring system, data loggers, centrifuges, UPS, AC.
- **Recurring:**
 - Database: eDiaries, eTrial Master Files, Servers, relevant journal, and market reports subscription.
 - Manpower: Administrative/HR executive for field office, study coordinator, study investigator, data manager, pharmacist, QA staff, nursing staff, GIS manpower,

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- Census manpower, Station manager, statistician, project manager, lab technician, phlebotomist, field workers.
- IT manpower – Software developer/tester and technicians as applicable
- Consumables
 - Clinical consumables - thermometer, stethoscope, sphygmomanometer, weighing machines, stadiometer, measuring tapes, wipes, sanitizer, tissue roll cotton roll, alcohol (ethanol), disinfectant, etc.
 - Lab consumables – Viral transport media, nasopharyngeal swabs, centrifuge tubes, culture bottles, ice buckets, laboratory trays, vacutainer needles, vacutainers, microcentrifuge tubes, pipettes, pipette tips, cryovial container box, sample collection vials, syringes, cannulas, needles, kits, sample transportation packing/bags, microtiter plates, cuvettes, pH testing paper or pH testing probe, microslides, slide boxes, paraffin, Petri dishes, loops, Bio-specimen collection containers, test tube rack, etc.
 - Safety gear - disposable masks, N95 respirators, shoe covers, disposable gloves, lab coats, Eye Protection, eye goggles or face shield, etc.
 - IT accessories - computer accessories, software, printer cartridge, data logger, tablet bag, SIM cards (with data)
 - Expenses for equipment calibration and maintenance
 - General stationery including subject material
 - Communication expenses, scientific publication relevant to the funded project
- Subject reimbursement for participation
- Ethics Committee fees
- Travel: This may include local travel for staff for community engagement, investigator travel to field/site, meeting within the cluster, to BIRAC for review meetings and presentations, Vehicle rental and fuel charges
- Contingency and Overheads:
 - Insurance: Accidental
 - May include rentals including rentals to secure earmarked space from the hospitals/institution, for a guest house, rentals for servers, utilities like AC, telephone bills, electricity bills

Non-Allowable Costs:

- Civil Construction work
- Any Litigation/ Opposition/ Infringement cost.
- Any legal fees outside the purview of allowable cost.

Section III – Application Process and Instructions

Application Timelines:

Key Dates

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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 "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 EOI 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:

The 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?
- 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?

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- 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. Contact Information

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

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Annexure – I

In case of Companies:

1. Incorporation / Registration certificate.
2. 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). Copy of passports of the shareholders (in support of 51% eligibility criteria).
3. Research mandate/ details regarding in-house R&D facility, if any / Incubation agreement.
4. Audited Financial Statement for the last 3 years along with the Notes on Accounts & Auditor's Report (i.e. 2017-18, 2018-19, 2019-20).
5. Memorandum of Association (First Page, Object Clause and last Page)
6. Articles of Association (AOA)
7. List of directors with DIN(Company)
8. Index of Charges Registered with the ROC
9. Latest Six months operating bank's statement
10. GST
11. PAN

In case of LLP:

1. Incorporation / Registration certificate.
2. 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)
3. Research mandate/ details regarding in-house R&D facility, if any / Incubation agreement.
4. Audited Financial Statement for the last 3 years along with the Notes on Accounts & Auditor's Report (i.e. 2017-18, 2018-19, 2019-20).
5. Memorandum of Association (First Page, Object Clause and last Page)
6. Articles of Association (AOA)
7. List of Partners DIN
8. Index of Charges Registered with the ROC
9. Latest Six months operating bank's statement
10. GST
11. PAN

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

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

1. Affiliation/registration certificate.
2. Details regarding in-house R&D facility, if any/ Incubation agreement
3. 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 .
4. Latest Six months operating bank's statement
5. PAN
6. KYC of savings account
7. Bye Laws

In case of Society

1. Society registration certificate / Trust deed / Registration certificate.
2. Details regarding in-house R&D facility, if any / Incubation agreement
3. CA certificate (supporting the fact that half of the members of the society are Indian)
4. Latest Six months operating bank's statement
5. PAN
6. KYC of savings account
7. Bye Laws

In case of Trust

1. Trust deed
2. Details regarding in-house R&D facility, if any / Incubation agreement
3. CA certificate (supporting the fact that half of the members of the trustees are Indian)
4. Latest Six months operating bank's statement
5. PAN
6. KYC of savings account
7. Bye Laws

In case of NGO/ Foundation/ Association

1. Registration certificate.
2. Details regarding in-house R&D facility, if any / Incubation agreement
3. if the NGO/Foundation/Association are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust.
4. Latest Six months operating bank's statement
5. PAN
6. KYC of savings account
7. Bye Laws

Annexure – II – List of sites funded under BIRAC

S. No.	Name of the Institute	
1	Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)	Pondichery
2	All India Institute of Medical Sciences (AIIMS),	Rishikesh, Uttarakhand
3	Amala Cancer Hospital Society (ACHS)	Thrissur, Kerala
4	Christian Medical College (CMC),	Ludhiana
5	Meenakshi Mission Hospital and Research Centre, (MMHRC)	Madurai, Tamil Nadu
6	Institute of Medical Sciences and SUM Hospital	Bhubaneswar, Odisha
7	MS Ramaiah Medical College and Hospital (MSRMCH)	Bangalore
8	Victoria Hospital, Bangalore Medical College & Research Institute (BMCRI)	Bangalore
9	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS)	Shillong, Meghalaya
10	Institute of Post Graduate Medical Education and Research, SSKM Hospital	Kolkata
11	Sri Guru Ram Das University of Health Sciences	Amritsar, Punjab
12	NIMS Medicity, Kerala	Cochin, Kerala
13	SRM Institutes of Medical Science	Chennai
14	Medanta Institute of Education and Research, Delhi	Gurgaon, Haryana
15	Mahatma Gandhi Institute of Medical Sciences (MGIMS)	Wardha, Gujrat
16	Post Graduate Institute of Medical Education and Research (PGIMER)	Chandigarh
17	Centre for Arthritis and Rheumatism Excellence (CARE)	Cochin, Kerala
18	St. John's National Academy of Health Sciences	Bangalore
19	Kusum Dhirjai Hospital	Ahmedabad
20	Amrita Institute of Medical Sciences	Cochin, Kerala
21	Regional Institute of Ophthalmology (RIO)	Patna, Bihar
22	Regional Institute of Ophthalmology (RIO)	Trivandrum
23	Adityajyot Eye Hospital Private Limited, Mumbai	Mumbai
24	Sri Sankara Deva Nethralaya	Guwahati, Assam
25	Shri Sadguru Seva Sangh Trust,	Chitrakoot, Madhya Pradesh
26	Tata Memorial Centre	Mumbai
27	Advanced Centre for Treatment, Research and Education in Cancer (ACTREC)	Mumbai
28	Dr. Bhubaneswar Borooah Cancer Institute	Guwahati, Assam
29	Homi Bhabha Cancer Hospital	Varanasi
30	Cancer Institute	Wadayar, Tamilnadu
31	Malabar Cancer centre	Kannur, Kerala
32	Max Super Speciality Hospital, Saket	Delhi
33	Regional cancer centre	Trivanrdrum

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34	Christian Medical College, Vellore Association	Vellore
35	Cachar Cancer Hospital Society	Silchar, Assam

Field sites

S. No.	Site	City
1	Society for Health Allied Research and Education	Hyderabad, Telangana
2	Christian Medical College Vellore Association	Vellore, TN
3	ICMR- National Institute of Epidemiology	Chennai, TN
4	The INCLEN Trust International	Palwal, Haryana
5	KEM Hospital Research Centre	Vadu, MH
6	Pondicherry Institute of Medical Sciences	Pondicherry, Tamil Nadu
7	Maulana Azad Medical College	New Delhi
8	Society for Applied Studies	New Delhi
9	ICMR-Regional Medical Research Center	Bhubaneswar
10	Andhra Medical College	Vishakhapatnam
11	The INCLEN Trust International	Shillong, Meghalya
12	The INCLEN Trust International	Delhi