

National Biopharma Mission
for Accelerating Early Development of Biopharmaceuticals
Innovate in India (i3)

Establishing Clinical Trial Networks and Strengthening Clinical Trial Capacity

Frequently Asked Questions

1. Eligibility Criteria

What is the eligibility criteria for applying?

The proposals can be submitted:

- *Solely by Non-profit organizations OR Societies OR Trusts OR Foundation OR Associations OR R&D Organizations (Public) OR Government entities OR Institutes (Public or Private) OR Institutes established under Acts/statute OR Hospitals (Public or Private)*

OR

- *Jointly by Non-profit organizations OR Societies OR Trusts OR Foundation OR Associations OR R&D Organizations (Public) OR Government entities OR Institutes (Public or Private) OR Institutes established under Acts/statute OR Hospitals (Public or Private)*

Are private hospitals eligible to apply?

Yes, both public and private hospitals are eligible.

Private Hospitals may apply as Private Research Institutions and upload their MCI Registration in the additional information link. Further information regarding their legal eligibility will be sought at the time of legal eligibility check.

Whether companies and partnership firm can submit a proposal?

No. Companies and Partnership firms like LLP are ineligible to apply except hospitals which are registered under company's act

Can we submit a collaborative proposal that involves researchers from multiple institutions or universities?

For RFP 1 it is mandatory that each specialty Network (Diabetology network or Ophthalmology network or Rheumatology network or Oncology network) should have at least 6 sites with each site.

Sole applicants are ineligible to apply for RFP 1.

For RFP 2 and 3/4 proposals can be submitted Solely or Jointly. However the investigators have to be from the local institute and residing near the cohorts.

Can an institution submit more than one application? If yes, will the amount be restricted for each site or per application?

Yes. One institution can submit more than one application. However, one investigator or site will be a part of only one network. He/she cannot be a part of multiple networks or RFPs. The funding would be capped as per the respective RFP.

Can I apply if my institution is currently receiving funding from BIRAC under any other scheme?

Yes. Additional undertaking from the organization will be solicited declaring that 'robust and comprehensive risk management tools to ascertain proper fund utilization and financial reporting without duplication' will be undertaken.

Can a funded (from other Govt. of India agencies or venture capitalists) program seek funding through this program for specific milestones over the next 3 years that may not be covered in other grants?

Yes, if there is no overlap.

2. Relevant documents to be submitted at the time of LoI submission:

Applicant being an Indian academic scientist/ researcher/ clinician:

- a. Copy of passport (from academic scientists or researchers or clinicians) or self-declaration of Citizenship attested by a gazetted officer.*
- b. A declaration/ authorization in favour of applicant, issued by Host Organization (which states that the host organization is willing to give facilities to applicant for the project applied for).*

Indian institution/ universities/ public research organization:

- a. Affiliation/registration certificate or statute reference for establishment.*
- b. Details regarding in-house R&D facility, if any.*
- c. If the public research organization or institution (public or private) are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust.*

Society/ Trust/ NGO/ Foundation/ Association:

Society

- a. Society registration certificate and Byelaws*
- b. Details regarding in-house R&D facility, if any.*
- c. CA certificate (supporting the fact that more than 51% of the members of the*

society are Indian citizens)

Trust

- a. *Trust deed and Registration Certificate*
- b. *Details regarding in-house R&D facility, if any*
- c. *CA certificate (supporting the fact that more than 51% of the trustees are Indian citizens)*

NGO/ Foundation/ Association

- a. *Registration details/ certificate.*
- b. *Details regarding in-house R&D facility, if any.*
- c. *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.*

Hospital (Public or Private)

- a. *Medical Council of India (MCI) registration certificate*
- b. *Registration Certificate of the legal entity*

Is DSIR certification mandatory to apply?

No.

Can we submit a separate bio sketch? If a bio sketch is allowed, in what section of the proposal do we submit this information?

Institutional description and bio-sketch both are important requirements of the LoI/Proposal. Please see LoI/Proposal format, visible after registration on BIRAC website, for further clarity.

Can I submit additional documents in addition to the LOI?

Please submit only LoI as requested. Additional documents if needed for eligibility determination will be sought from the applicant.

3. Submission

Do I have to use the online application system?

Yes. The applications have to be submitted online only. Please follow the link below

https://www.birac.nic.in/nbm_proposal_submission.php?cid=28

LoI 1 for RFP 1 - Clinical Trial Network

LoI 2 for RFP 2–Epidemiology Study

LoI 3 for RFP 3–DSS/DHS site establishment

LoI 4 for RFP4 – Data Management platform

Can you critique a draft of my application?

You may write to BIRAC for specific clarifications on proposal submission.

Can I schedule a meeting with BIRAC - NBM staff to discuss projects and/or funding opportunities?

Yes, feel free to contact respective Manager if you need any information regarding the RFPs. For contact details please refer the RFP.

Is it possible to apply for multiple RFPs through a single project or a different project?

Separate LoI should be uploaded for different RFPs.

What will be the last date of submission?

<i>Last Date of Submission of Letter of Intent (LoI)</i>	<i>10th Oct 2019; 1400 hrs</i>
<i>Last Date of Submission of Full Proposal</i>	<i>Will be communicated through email to shortlisted applicants after screening of LoI</i>

What if there is an important reason we might miss the application deadline?

The proposal will not be considered after close of call.

Is future vision required to be included at the time of submission of LOI?

Yes. At the time of submission of LOI, the outcome at the end of three years should be clearly mentioned.

Can you give an example of a promising LoI/ Proposal?

A LoI/ Proposal would be favoured if it fulfils the eligibility criteria and aligns with the requirements as detailed in individual RFAs. There are no published examples.

What will be the Start date of the project/Funding?

From the day of execution of funding agreement, expenses will be considered for reimbursement/ disbursement.

When and how will we be notified if our application has been declined?

BIRAC official will notify the applicants regarding the status of the application. You will be intimated within 4-6 weeks through email if the LOI is not shortlisted.

When and how will we be notified if our LoI has been shortlisted or if BIRAC will be requesting a formal proposal?

BIRAC official will notify the applicants regarding the status of the application through email.

Is there a word limit to the LOI?

Yes, it has a word limit for every question. Options for uploading additional documents is given in few questions.

How much time will I have to submit the full proposal? And how will I come to know about it?

You will have about 4-6 weeks to submit the full proposal. You will be intimated through email if the LOI is shortlisted. The last date of submission of proposal will be communicated through email.

Does BIRAC provide feedback on proposals that are not selected for funding?

BIRAC expert committees provide feedback on proposals that are not selected for funding.

If I do not receive funding under this RFP, will there be another opportunity to apply?

BIRAC publishes calls for proposals on a regular basis. Please check BIRAC website for new calls.

4. Selection Process

What will be the process and criteria for selection/evaluation?

For Selection Process please refer Section 3 of RFP:

Proposals will be evaluated in two stages:

- *Stage I: Screening of Letter of Intent (s)*
- *Stage II: Evaluation of Full Proposal (only for shortlisted applicants)*

For Selection and/or Evaluation Criteria please refer Section 9 of the RFP.

Who shall be responsible for evaluation/selection of the proposals?

PMU-NBM, BIRAC will screen the proposal for responsiveness to all the specified administrative and procedural provisions required in the RFP. The Area Review Panel and Scientific Advisory Group would assess the merit and quality of research proposals and recommend the most appropriate applicants. Recommendation on proposals to be funded will be made by the Technical Advisory Group. A final approval on proposals to be funded will be made by the Competent Authority of BIRAC.

If not selected can it be reconsidered?

Reconsideration or representation is not possible. The decision of the committee is final.

5. Funding

How many sites are going to be funded via the proposal?

It is a competitive process. The Expert Committees will decide the number of projects to be recommended for funding.

What are the budget limits for each RFP?

RFP 1: The budget for establishing one clinical trial network is capped at 1600 lakhs for 03

years. The final approved budget will consider the number of sites proposed in each network.

RFP 2: The budget for one site is capped at 650 lakhs for 03 years.

RFP 3: The budget for one site is capped at 450 lakhs for 03 years.

RFP 4: The budget for this application is capped at 250 lakhs for 03 years.

What would be the nature of funding association? Equity/Soft Loan/Grant?

This is totally a grant-based program.

What cannot be funded? Where can I find additional guidance on allowable vs. not allowable costs?

Please refer Section 8: Funding Mechanisms of RFP for information on allowable and non-allowable costs.

How specific should we be in the budget?

Please fill the details as per the format to the extent possible.

What will be the bindings for the applicants through this grant?

Agreement with the Grantees would be undertaken to ensure alignment with the end goals of the Program. These binding requirements would be variable based on the type and nature of the RFP.

Is the applicant also required to give monitory contribution in the proposal?

No. Applicant contribution is not mandatory.

6. Agreement

What is the Grant agreement to be signed?

Grant-In-Aid-Letter agreement (GLA) will have to be signed between BIRAC and applicant with specific terms and conditions. For RFP1 GLA will be signed with each PI/collaborator.

What is the Funding Mechanism?

Project budget must be milestone-based. Funding will be awarded for maximum of 03 years and depending on the objectives. Fund disbursements will be subject to the project team attaining the committed milestones. The primary applicant and the proposed collaborators (if any) should specify their respective budgets and their corresponding milestones. The funds will be disbursed to them separately subject to the achievement of milestone/s and satisfactory reporting of progress.

Will we be able to negotiate any of BIRAC's standard contract terms and conditions if selected?

No. These are non-negotiable.

Questions specific to RFP 1: Clinical Trial Networks (CTNs)

Who can be Principal Investigator (PI) of the network? Can more than one investigator be involved from one site?

For RFP 1 – One Principle key investigator (PI) who is the lead applicant and applicant team members

- *5 more collaborators i.e. Key investigators from different sites and collaborator team members. Assigning the title of Principal key Investigator is at the discretion of the network.*

A minimum of six or more investigators, representing different geographical locations are required per network.

Is prior experience of conducting a clinical trial necessary for applying?

At least any one investigator should have prior experience of conducting a regulatory compliant trial. New sites with no experience should be part of the network.

Is the grant only for creation of a network or the trials will also be supported?

The grant is only for establishing clinical trial network. No trials will be supported through this grant.

Can one apply simultaneously for multiple RFPs?

One investigator or site will be a part of only one network. He/she cannot be a part of multiple networks or RFPs. However, more than one application may be submitted from an institute.

If I have the experience and I wish to apply for clinical trial network, but I do not have the required 6 number of sites. Can I still apply?

NO. Investigators are expected to reach out and identify other sites and investigators in the same speciality and apply as a network.

Questions specific to RFP 2/3: Epidemiology studies/DHS Site establishment

I am already doing a clinical study on Dengue / Chikungunya. How should this be reflected in the application?

Please give details in the LoI.

Under RFP 3, does one applicant has to establish one or more sites?

One applicant should propose to establish only 01 site.

Do we need to submit a formal consent from the local Government entity?

Any document confirming liasoning in community (e.g. MoU with state govt. and/or district health authorities) for past activities may be submitted.

Is there a word limit to the application?

There is a respective word limit for each question in the LoI.

Can the awarded funds be used to purchase data management systems?

A separate RFP has been published (RFP 4) which will ensure that uniform data management tools are available at all grantee sites.

Currently our institute is working on the registration of IEC with CDSCO, will this prevent my application from going forward?

No. This would not affect your application to go forward. However, over time you would be expected to get your EC registered.

Is it mandatory for the institute to have its own ethics committee? Or, an access to an independent ethics committee acceptable?

Access to an independent ethics committee is acceptable.

Questions specific to RFP 4: Data Management Platform

Are companies eligible to submit the LoI?

No. Companies are not eligible to apply.

Will the applicant own the data collected at different site?

Each site will own the data collected at their site. Data collated from all sites will be submitted to the Department of Biotechnology (DBT), Govt. of India and owned by DBT and not by the platform developer.

Is previous experience of development of a software mandatory for submitting the LoI?

Yes, it is mandatory that the applicant has relevant experience of developing software. The software developed for a similar purpose should be existing and be deployed at atleast one site.

The support of installing and maintaining the software through dedicated manpower is expected by DBT? During the grant or even after that?

The support is expected during the grant period.