Request for Proposals (RFP)

Under

NATIONAL BIOPHARMA MISSION

Funded by

Department of Biotechnology, Ministry of Science & Technology, Government of India

Co-funded through World Bank Loan Assistance

(Innovate in India for Inclusiveness Project)

Through Implementing Agency

Biotechnology Industry Research Assistance Council (BIRAC)

(A Government of India Enterprises)

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Section I - Program Overview - NBM

This is an Industry-Academia Collaborative Mission For Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation", also referred to as National Biopharma Mission (NBM).

Funding agency

Department of Biotechnology (DBT) (Program co-funded by World Bank loan)

Implementing agency

Biotechnology Industry Research Assistance Council (BIRAC)

Background [1]

Towards strengthening the emerging biotechnology enterprise in India, Department of Biotechnology (DBT), Ministry of Science & Technology, has initiated the Mission Program entitled - An Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals – *"**Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation**" ("Program").* Biotechnology Industry Research Assistance Council (BIRAC) setup by DBT is the Implementing Agency of *i3* Program (Program co-funded by World Bank loan) managed through a dedicated Program Management Unit (PMU).

The vision of the Program is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals including vaccines, biologics, medical devices and diagnostics to a level that will be globally competitive over the next decade.

This Request for Proposal (RFP) is to seek applications for the following:

RFP 1: Clinical Development of novel/new/next-generation vaccine candidate(s)

RFP 2: Translational Research Consortium (TRC)

[1] *For further details of the Program, see the National Biopharma Mission Document*

Section II – Application process, Instructions, Applicant eligibility criteria and other processes for the RFPs at Section III

1. Application Timelines:

Key Dates

Call Opens	**31st January 2020**
Last Date of Submission for RFP 1 (Vaccine Candidate)	**28th February 2020 (5:00 PM)**
Last Date of Submission for RFP 2 (TRC)	**13th March 2020 (5:00 PM)**

2. Application Guidelines and Process:

The Proposal can be submitted online as per the required format. The website will provide detailed user guide to facilitate the online proposal submission.

Process for submitting the proposals online is detailed below:

a. Go to BIRAC's website or Go the URL: https://www.birac.nic.in/nbm/
b. Click on the RFP on NBM link under Programs and the active call would be highlighted.
c. Click on the active call against which you wish to submit the proposal.
d. Further details on 'How to Submit a Proposal' would be available in the User Guide available on the website.
e. Log on to BIRAC website http://www.birac.nic.in
f. If you are a registered user, log-in using the credentials, else you need to register your company/organization by clicking on New User Registration.
g. In case of new user registration, a computer-generated link will be sent to the email-id provided at the time of registration to generate a password.
h. Once you login, you will be navigated to the proposal submission page under NBM link.

Instructions:

a. 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.

b. Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review. Applicants are advised to provide self-contained proposals with essential supporting materials provided as uploads.
c. Requests for changes in the proposal once submitted will not be entertained.
d. Providing incorrect information intentionally is viewed adversely.
e. Please read through this RFP in its entirety and ensure that your application, budget and organization are in compliance with the eligibility criteria provided. 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 of their quality. You are strongly encouraged to contact NBM, BIRAC if you are unsure about the eligibility of your project.
f. Proposed budget shall be made inclusive of all applicable taxes and shall be considered accordingly.
g. Information on all relevant pre-existing agreements/ MoUs in connection to the proposed technology, background IP, collaborations, outsourcing, consultancy, joint ventures, consortium partnerships, IP licensing, technology transfer, material transfer etc. should be provided at the time of proposal submission.
h. Risk management proposal for the project should be submitted after scrutiny of the execution aspects of the project.

3. Evaluation Methodology:

a. PMU-NBM, BIRAC will screen the proposals for eligibility to all the specified administrative and procedural provisions required in the RFP. If the application is found to be incomplete or not complying to the provisions described in the RFP, the application will be considered ineligible.
b. Proposals that meet the eligibility criteria will be submitted for peer-review by national and/or international reviewers to assess the proposal merit. Reviewers will be checked for conflicts of interest and will sign confidentiality agreements. Information may also be shared with selected third parties for the purposes of independent audit, evaluation and assessment of activities.
c. The Scientific Advisory Group will collate the results of the reviews, make their own assessments and recommend shortlisted applications for further screening to the Technical Advisory Group.
d. 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.
e. Technical and financial due diligence process (site visits) of the shortlisted applications would be carried out by PMU-NBM, BIRAC as part of the review process.
f. A final decision on applications to be funded will be made by the Technical Advisory Group.

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

DBT/BIRAC reserves the right to not to process your proposal should you be ineligible to be a proponent or should the subject of your proposal not fall within the RFPs' remit. Mere consideration of the Proposal in no way implies that sanction of Grant-in Aid will be forthcoming unless other legal requirements are fulfilled.

4. Eligibility Criteria:

Who may apply?

The proposals can be submitted:

- Solely by Indian Company / Non-profit organizations/ LLP/ Society/ Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ which is a legal entity OR
- Jointly by Indian Companies/ Non-profit organizations / LLP/ Societies/ Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ OR
- By a consortium of Indian Companies/ Non-profit organizations/ LLP/ Societies/ Trusts/ Foundation/ Association/ Government entities/ Institutes/ R&D Organizations
- Indian Start-up companies in collaboration with Industry/Academia/research institutes/ are specially encouraged to apply.

Criteria Particulars for the Proponent entities:

Indian companies:

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].

Non-profit organizations/ Government entities/ Institutes/ R&D Organizations:

This will include Academic Research Institutes, Universities, Research Foundation, Medical Colleges and Institutes – both public and private who are valid legal entities such as Trust, Society or established under central or state statute.

Limited Liability Partnership:

A limited liability partnership is defined as one which is incorporated under the Limited Liability Partnership Act 2008. Minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens. [Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders].

Relevant documents for submission in the application:

Applicant being an Indian academic scientist and researcher:

a. Copy of passport (from academic scientists & researchers) or self-declaration of

Citizenship attested by a gazetted officer

b. Either incubation agreement; or letter of intent in favour of applicant, issued by Incubation centre (which states that the incubation centre is willing to give facilities to applicant for the project applied for)

Companies:

a. Incorporation certificate
b. Latest Share holding pattern as per BIRAC format only (For formats go to https://www.birac.nic.in/nbm/cms/page/resources and click Formats), certified by external CA and verified from MCA/ ROC records.
c. Details regarding in-house R&D facility, if any, or Incubation agreement
d. Audited financial details of last three financial years (i.e. 2016-17, 2017-18, 2018-19), if applicable
e. Copy of passports of the shareholders (in support of 51% eligibility criteria) or self-declaration of citizenship attested by a gazetted officer

Limited Liability Partnership:

a. Incorporation/Registration certificate.
b. Partnership deed; or list of subscribers which states that minimum half of the partners are Indian citizens.
c. Copy of passports of Indian partners/subscribers or self-declaration of citizenship attested by a gazetted officer.
d. Research mandate/ details regarding in-house R&D facility, if any, or Incubation agreement.
e. Audited financial details of last three financial years (i.e. 2016-17, 2017-18, 2018-19), if applicable.

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, or 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.

Society/ Trust/ NGO/ Foundation/ Association:

Society:

a. Society registration certificate.
b. Details regarding in-house R&D facility, if any, or Incubation agreement.
c. CA certificate (supporting the fact that half of the members of the society are Indian citizens)

Trust:

a. Trust deed.
b. Details regarding in-house R&D facility, if any / Incubation agreement.

c. CA certificate (supporting the fact that half of the members of the trustees are Indian citizens)

NGO/ Foundation/ Association:

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

5. Requisites for Funding:

Decision to fund will be as per sanction of the competent authority. Successful proponents shall enter into necessary funding agreements. The fund disbursement will be subject to completion of required formalities. The disbursement will be by way of Grant-in-aid assistance. The fund recipient shall be accountable for fund utilization as per the sanction. Re-appropriation of funds can be undertaken only after approval of BIRAC, within the same Budget Head.

In addition to signing of agreement between all the concerned parties, following requirements need to be completed before the first instalment can be released:

a. A letter of authorization by the Head of the Academia and/or A Board Resolution from the Company Partner for acceptance of the Grant-in-Aid under NBM
b. Opening up a No-Lien Account with a scheduled/nationalized Bank
c. MoU with collaborator(s) (if applicable)/letter of support from contributors
d. Commitment to comply with Clinical Research Validation and Management Framework (CRVMF) https://www.birac.nic.in/nbm/uploads/2019/08/crvmf.pdf
e. Commitment to obtain all applicable environmental authorizations, prior to the commencement of product development/ research activities.
f. Inclusion of qualified environmental / EHS engineer in the team for implementation of Environment and Health Risk Management Plan (EHRMP) and comply with Environmental Management Framework (EMF) requirements during all stages. Requirements on Environmental aspects may be found at https://www.birac.nic.in/nbm/uploads/2019/08/emf.pdf
g. Adhere to the Project Risk Management Plan during all stages of execution. (For formats go to https://www.birac.nic.in/nbm/cms/page/resources and click Formats)
h. Submission of documents related to conveyance of interests in the background technology/IP

6. Program Monitoring Mechanism:

Project Monitoring Committee (PMC)

The projects shall also be monitored and mentored regularly by a Project Monitoring Committee (PMC) constituted by PMU-NBM, BIRAC for each project. The PMC is

responsible to monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives contained in the Agreement.

Based on the foregoing, PMC will assess and recommend:

a. Release of next instalment or part release thereof by BIRAC
b. Revision of project duration
c. Closing or dropping or modifying any of the components of the Project within the overall approved objectives, budget and time-frame
d. Mentor(s) to overcome any technological problem faced in the Project implementation
e. To advise on issues related to securing of IPR
f. To advise on any other matter as referred to it by BIRAC and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of proposed Scheme

7. Reporting of Progress:

a. On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format
b. The MCR will be assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget will be released
c. The Applicant will have to submit a duly certified Statement of Expenditure for every 30th September and 31st March
d. Format for MCR, Utilization Certificate and Statement of Expenditure will be made available as per requirement
e. Compliance to the Project Risk Management plan

8. Funding Mechanisms:

Project must be budgeted on a milestone basis. Funding will be awarded for maximum up-to **30 months** depending on the objectives. Fund disbursements will be subject to the project team attaining the proposed milestones. The primary applicant and the proposed collaborators should specify the funding requirement for their corresponding milestones. The funds will be disbursed to them separately subject to the achievement of milestone and reporting of progress.

a. ***Allowable costs include***

- *Personnel*: All personnel working for the development of the product *only* are allowed to claim costs. Researchers and PIs who receive a salary from the host institution as permanent or fixed term staff members may NOT claim salary reimbursement from BIRAC grants
- *Technology Consultants*: These may include both national and/or foreign consultants who provide a service and capability that is not available among the project partners.
- Equipment

- Supplies and consumables for the equipment to be used for the project
- Travel & accommodation: Must be directly related to the execution of the project or travel related to seeking technology transfer
- Institutional overheads (maximum 8% of recurring budget)
- IP protection (Project related) – Upto Rs 2 Lakhs
- Conduct of pre-clinical/clinical studies, provisions for which are currently not feasible in the country. *Appropriate justification for the need to be submitted*

b. ***Non-allowable costs include***

- Purchase or construction of a building/ space/ land
- Rental costs for space
- Recruitment costs for staff
- Attendance at conferences
- Legal fees
- Setting up large scale manufacturing facilities
- Commercialization
- Any trials or tests conducted outside India, unless the service is not available in India.

9. Intellectual Property:

- The applicant team should have freedom to operate as related to IP, including consent from others where applicable.
- Intellectual Property developed under the BIRAC funding through this grant will be owned by and will be the responsibility of the applicant (unless stated otherwise).

10. Evaluation and Decision-Making Criteria:

a. **Proposal Merit:**

- Does the proposal's approach align with the objective of RFP?
- Does the proposal demonstrate preliminary work of the identified product which will be useful for the proposed scope of work?
- Has the Primary applicant provided an adequate description of the existing manpower and infrastructure to understand their present capabilities?
- Are the objectives, activities and milestones well defined?
- Does the proposal identify project objectives with the Mission's mandate?

b. **Team/Applicant:**

- Is the Primary applicant competent to ensure effective conduct of the proposed work?
- Does the applicant team have relevant capabilities and appropriate experience for the same?

- Have the collaborations established have adequate technical expertise and background experience to achieve the objective of the RFP?
- 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?

c. **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 and benchmarks? Do they seem feasible in the given time frame?
- Have the resources (technical and management people, equipment, collaboration, outsourcing needs etc.) required over the time frame been comprehensively mapped?
- Has the applicant anticipated difficulties/risks that may be encountered? Have alternative tactics and mitigation plans been considered in case of failure?

d. **Business Strategy (if applicable):**

- Has the applicant provided any market surveillance details for the said product?
- Has the applicant provided any details on cost effectiveness of the product vis-à-vis existing products in the market?
- Has the applicant considered affordability on account of availing the Mission's funding?
- Has the applicant identified any specific clients or business opportunity for the product after development?

e. **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?

Note: We welcome potential applicants contacting the mission before submitting applications to clarify any questions or discuss their ideas with us. Kindly submit the application at least a few days before the deadline to avoid technical difficulties in submission of proposal at the last hour.

Contact Information

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

Contact Person:

Dr. Kavita Singh, Mission Director, PMU- National Biopharma Mission

Email: technical.birac@gov.in

Dr. Shikha T. Malik, Programme Manager, PMU- National Biopharma Mission

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Section III – RFP 1: Clinical Development of novel/new/next-generation vaccine candidates

Background:

Vaccines are one of the most cost-effective means available for managing infectious diseases, many of which, such as pertussis, measles, mumps, rubella and polio, had been principal causes of mortality and morbidity in the past. Additionally, past 20 years have seen a rejuvenation of innovation in vaccines.

There are many existing preventable infectious and emerging/ re-emerging diseases that impact Indian population. Despite public health importance, they are not prioritized by Global policy makers, research and pharma companies. To address this, it becomes important that novel/ new/ next generation vaccines are developed that are appropriate for Indian population and align with Indian public health needs.

Objective:

Vaccine candidates for many of the diseases relevant to India exist in early development stages in the portfolio of Indian companies. The Mission thus aims to facilitate clinical development of promising novel/new/next-generation vaccine candidates by the Indian industry by de-risking clinical development. This call seeks proposals that would benefit acceleration of cost effective, safe and efficacious vaccines through direct funding of clinical trials and providing access to a group of experts from industry and academia with relevant expertise that would help define and streamline clinical development pathway for efficient and quicker product development.

Proposals are thus invited by applicants who have vaccine candidate(s) in clinical development stage and are interested in seeking support in accelerating its development.

Scope of the Call:

- The call seeks proposals for development of novel/new/next-generation vaccine candidates that are either currently in clinical stage of development or clinical trials are about to be commenced (completion of pre-clinical studies by March 2020).
- The vaccine should be developed for disease with high burden in India, with clear economic and public health need and for diseases with potential of outbreak.
- In-licensing of vaccine candidates and further clinical development in country may be considered with appropriate justification provided for in-licensing.
- The call will fund activities related to design and conduct of clinical trials in India including:
    - Clinical assay development.
    - Design and conduct of Phase I, II, and/or III clinical trials.

  - Evaluating possible laboratory correlates of immune protection in the context of Phase IIb/III clinical trials that demonstrate significant vaccine efficacy.
  - Manufacturing and scale-up of Pilot Scale and large-scale clinical trial batches.
- This call will not support:
  - Development of new adjuvants, formulations.
  - Fundamental/ basic research.
  - Projects that have not completed preclinical studies by March 2020.
  - Funding for procuring instruments and equipment
  - Activities related to commercialization.
  - Setting up large scale manufacturing facilities.
  - Candidates for diseases where similar vaccines are available in market by other Indian companies.

Expectations from the Applicants:

1. Proposal should include substantial justification for significance of the disease and the need of the proposed vaccine.
2. Proposed candidate should align with Target Product Profile (TPP), if available from WHO or NTAGI.
3. Proposal should include previously conducted studies and available supporting data to substantiate readiness of the vaccine candidate to enter clinical development such as (but not limited to):
   - Data from proof-of-concept studies such as functional *in vitro* assays and animal studies.
   - Toxicology study data.
   - Data on manufacturability and stability of the vaccine candidate.
   - Data from previously conducted clinical trials in India or globally.
4. Proposal should have clearly defined product development plan with details of proposed activities, specific milestones & timelines and the budget estimates depending on the stage of development such as:
   - Detailed study design for clinical trials.
   - Clinical assay development plan: Details of clinical assays, facilities or partners for conduct of assays.
   - Manufacturing strategies: Details of expression platforms, cell lines, analytical assays, formulation strategy.
   - Regulatory plan.
   - Proposal should indicate the feasibility of advancing the candidate from current readiness state of technology (stage of development) by providing clear understanding and articulation of risks and reasonableness of proposed solutions to these challenges (most significant technical, regulatory & IP risks).
5. The data generated as an outcome of this grant should comply with ICH guidelines and suitable for submission to DCGI for seeking relevant approvals.

6. Proposal should indicate a plan for interactions/consultations with global and national experts, regulatory agencies/health technology assessment bodies to ensure compliance with regulatory authorities and expectations of the decision makers of TPP of the final vaccine.
7. The proposals are not for early, pre-competitive research but for development of processes towards commercialization and for clinical trials (in India) etc. Therefore, applications if submitted with academia / industrial collaborations should demonstrate that the partnership will move rapidly forward the proposal towards the end goal.

Section III – RFP 2: Translational Research Consortium (TRC)

Background:

Vaccines have been one of the most successful cost-effective interventions in global health. Majority of the current successful vaccines have been developed empirically through an 'isolate, inactivate, attenuate or subunit approach'.

However, traditional vaccine development has proven insufficient to deal with some pathogens. Additionally, in recent times, many vaccine candidates have failed in Phase II/III clinical trials. They yielded less than optimal results and efficacy despite promising preclinical efficacy data. These late-stage failures render the time and resources spent towards the vaccine development futile.

The hurdles in developing effective vaccines against important pathogens have been many, such as identifying conserved epitopes, identifying early markers of vaccine efficacy, defining correlates of protection and analyzing mechanisms of long lasting protective immune response. Understanding the human immune system as it responds to infection, vaccination, and other antigenic challenges, is essential for establishing a robust pipeline of vaccine candidates. But, immunoprofilling is highly complex, and its elucidation requires understanding of multiple disciplines of biology.

However, rapid emergence of high-throughput technology platforms in biology and the use of systems-based approaches to analyze large and varied sets of 'omics' data have led to broader and deeper understanding of complex immune response pathways. With major advances in platform technologies that include cell phenotyping, genomics, epigenomics, transcriptomics, metabolomics and proteomics, it is now possible to rapidly characterize various types of immune cells.

Results of such immunoprofilling studies using well established endemic cohorts or challenge models where possible, will create a foundation to identify potential targets for development of new vaccines, establish key gate-criteria for advancing candidates to next step, predict vaccine usefulness in different populations well in advance of efficacy studies, develop correlates of vaccine efficacy, and signatures to detect adverse events triggered by vaccination.

Objective:

The purpose of this RFP is to stimulate discovery, and/or early translational research to enable and accelerate the development of novel vaccine candidates. Cross-fertilization of ideas and collaboration among clinicians, immunologists, molecular and cell biologists, protein chemists, bioinformaticians capable of big data analytics, structural biologists and other domain experts is highly encouraged. To enable this, the National Biopharma Mission plans to establish **Translational Research Consortium (TRC)** in each of the disease focus areas as mentioned below.

Applications are hence solicited from multi-disciplinary teams to apply for establishment of a Translational Research Consortium.

Scope:

A. Depending on the maturity of research and the product pipeline landscape of vaccines against Respiratory Syncytial Virus (RSV), Hepatitis E Virus and *Plasmodium spp*, the respective consortium's scientific research question should focus on the following:

1. **Epitope identification and validation using concepts of Rational Vaccine Design** like novel technologies for deep, high-throughput analysis of human immune responses in disease cohorts or cohorts from challenge trials that can clearly define protected individuals, advances in structural biology and protein design resulting in structure-guided immunogen design and development of better fit-for-purpose animal models such as humanized mice capable of mimicking human responses etc.

   Examples of research questions include, but not limited to:

   i. *Identifying neutralizing epitopes through in silico analysis and experimental evaluation based on MHC and antibody binding.*
   ii. *Predicting epitopes through docking and modelling studies based on structures of viral proteins/ antigens, antibody-antigen complexes.*
   iii. *Identifying sequences through bioinformatics approach that should be excluded due to risk of autoimmune responses.*

And/Or

2. **Candidate prioritization to further the development of vaccine candidate**

   Example of research questions include, but not limited to:

   i. *Developing and utilizing functional assays to assess immunogenicity of the vaccine candidate.*
   ii. *Evaluation of the developability of the vaccine construct to down-select potential vaccine candidates.*

B. This Call would support collaborative proposals that combine complementary and synergistic research strengths for establishment of Translational Research Consortium for **any one** of the above-mentioned pathogens (i.e. Respiratory Syncytial Virus (RSV), Hepatitis E virus or *Plasmodium spp.)*

C. The following will **not** be supported for the consortia:

- Sole applicant
- Consortia focused on disease areas other than the prioritized diseases in the scope
- Proposals focusing only on knowledge generation or blue-sky research without clearly defined impact on product development
- Large equipment for any lab

- Mice based immunogenicity studies for *Plasmodium* except use of transgenic mice with humanized immune systems or mice infected with transgenic *P. berghei/ P. falciparum* chimeras expressing *P. falciparum* pre-erythrocytic antigens.

Expectations from the Applicants:

- Each Key Investigator (Principal or Collaborator) should preferably be part of only one consortium and submit only one proposal.
- The proposal should provide justification of the research question and expected impact in alignment with global research and product pipeline for the relevant disease.
- Investigators who are not currently a part of previously funded consortia under NBM (Dengue and Chikungunya TRC) will be preferred.
- Principal Key Investigator of the applicant organization should have prior experience in the relevant disease (RSV or Hepatitis E or Malaria), demonstrated through publications in peer reviewed journals and data published from their respective labs/ institutes.
- Key Investigators should have prior experience in the respective domain technology.
- Specifically, each consortium should consist of the following three types of Key Investigators:
  a) Clinicians as Principal/Collaborator Key Investigators for building cohorts of patients. (maximum 2 investigators)
  b) Research Groups as Principal/Collaborator Key Investigators (maximum 04 investigators) with domain expertise as Molecular biologist, Immunologist, Structural Biologist, Protein Chemist, or any other domain as per the need of the respective consortium.
  c) Consortium Coordinator Collaborator (maximum 1 investigators). The role of unit would be:
     - Management of the consortium. Coordinator will coordinate with all the other partners ensuring effective implementation and management of the overall consortium's scientific activities.
     - Submit regular reports and other documentation on behalf of the Consortium
     - Coordinate with National Biopharma Mission, BIRAC for holding quarterly review meetings and collation of reports.
- Establish an External Advisory Committee of maximum 5 advisors for guidance (mix of national and international experts).
- The collaborators in the consortium should demonstrate the ability to fulfil the outlined Research questions and objectives of the proposal.
- Immunogenicity assays related to RSV can be outsourced to the Clinical immunogenicity lab established under NBM at Interactive Research School for Health Affairs, Bhartiya Vidyapeeth, Pune.
- Consortium should have access to relevant infrastructure and equipment to conduct the research activities. e.g. flow cytometers, high content imaging, next generation sequencing, RNAseq, mass spectrometers, microarrays.

- Consortium should have access to an established animal facility if animal experimentation is part of research question. Animal facilities that are already supported under NBM will be preferred.

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