REQUEST FOR EXPRESSIONS OF INTEREST
(CONSULTING SERVICES – FIRMS SELECTION)

INDIA

Loan No: 8751 IN

Assignment Title: Clinical Trial Regulatory Advisory and data safety consultancy

Reference No. (as per Procurement Plan): 02

1. BACKGROUND

The Department of Biotechnology has received financing from the World Bank toward the cost of the Industry-Academia Collaborative Mission For Accelerating Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation" (Hereinafter referred to as i3 Program or National Biopharma Mission or NBM) and intends to apply part of the proceeds for consulting services.

The vision of the i3 Program is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals (including vaccines, biologics, devices and diagnostics) to a level that will be globally competitive over the next decade.

Please Note: Also refer to the associated Terms of Reference (TOR) for details on the scope and activities, technical and financial requirements and other particulars of REOI.

2. CONSULTING SERVICES ("THE SERVICES") INCLUDE:

The Clinical Trial Regulatory Advisory and data safety consultant will support the PMU in fulfilling the expectation of monitoring/auditing/ review of safety data of clinical trials and will covers all the five basic processes of Clinical trial Planning, Clinical trial Initiation, Clinical trial Execution, Data safety Monitoring and controlling deviations and Analysis and reporting.

The scope of work (SoW) of the present Consulting Services include the following:-

i. **Scientific Review of Clinical Trial Related documents:** To judge for appropriateness of Background/Significance of the trial, Study Design, Study

Population, Risk Vs Benefit etc. Review of Study Protocol, Informed Consent documents, DSMB charter and other documents and accordingly advise PMU.

ii. **Quality Management Assurance:** To assure the PMU that the Clinical Trial processes followed by different sponsors adhere to the expected quality practices of documentation associated with clinical research activities.

iii. **Evaluation of the trial sites before initiation and during the trial:** To ensure the feasibility of trial conduct at selected trial sites by the study sponsor

iv. **Monitoring of trials:** To ensure that all systems followed during study conduct are adequate which include but not limited to ethics clearance, compliance with ethics approval terms, adherence to investigational product management, randomization Procedures, Seeking Informed consent, recruitment process, Protocol deviations recording as per the regulations, Data Safety Monitoring board meetings & reports, Safety reporting and Premature Termination or Suspension of Trial, Issues related to compensation and processes to be followed for site visit closure.

v. **Safety data monitoring:** Review of safety data including DSMB comments and comprehensive safety and medical monitoring through review of relevant documents.

vi. **Regulatory Advise:** To advise PMU on the approvals and regulatory pathway for product development of Medical devices and diagnostics, vaccines, biosimilars and novel cell lines.

vii. Review of Immunogenicity assays validation process and data.

viii. Any other associated activity in furtherance of effective Risk management of Clinical Research and Validation Management Framework components under i3 program.

3. The BIRAC (Biotechnology Industry Research Assistance Council) implementing agency of the Program, has established a dedicated Program Management Unit (PMU) .The PMU now invites eligible consulting firms to indicate their interest in providing services, interested consultants should provide information demonstrating that they have required qualification and experience for which they have to provide brief technical proposal **(The brief Technical Proposal should provide particulars of proponents experience related to the basic processes of the present Consultancy's SoW)** to perform the services.

The shortlisting criteria are:

- **Clinical trial Monitor:** Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 3-5 yrs in monitoring clinical trials.
- **Senior Clinical trial monitor**: Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 6-8 yrs in monitoring clinical trials.
- **Medical Monitor:** MBBS/MD: with experience of 6-10 yrs in Medical Monitoring/ pharmacovigilance/ safety data review.
- **Medical Writer:** MBBS/MD/PhD: with experience of 8-10 yrs in developing essential documents for clinical trials.
- **Quality Assurance expert:** Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 8-10 yrs in performing audits of trial sites and clinical laboratories supporting trials and identifying gaps in the clinical trial processes.
- **Regulatory expert:** Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 8-10 yrs in defining product development pathway of devices and diagnostics.
- **Regulatory expert:** Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 8-10 yrs in defining product development pathway of Biologicals.
- And Experience of the firm demonstrating:

– Performing the activities mentioned above for trial conduct, trial management, regulatory advisory and safety data monitoring.

– Management of multicentric clinical trials.

– Atleast 2 long term (minimum 6 months) projects in last 3 years providing **Clinical Trial Regulatory Advisory and data safety consultancy to** public research institutions, the private sector, Government and/or civil society organizations working within the space of clinical trial conduct for regulatory submission.

Note:- The attention of interested Consultants is drawn to paragraph 1.9 of the World Bank's *Guidelines: Selection and Employment of Consultants [under IBRD Loans and IDA Credits & Grants] by World Bank Borrowers* [("Consultant Guidelines"), setting forth the World Bank's policy on conflict of interest.

Consultant's may associate with other firms in the form of a joint venture or a sub-consultancy to enhance their qualifications but are subject to the following eligibility criteria:

- The Consultant should be legal entity (Company or LLP incorporated or a JV having legal entity as members/Society/Not-for profit legal entity).
- The Bank permits consultants (firms, including Joint Ventures and their individual members) from all countries to offer consulting services for Bank-financed projects
- Furthermore, it is the Consultant's responsibility to ensure that its Experts, joint venture members, service providers, suppliers and/or their employees meet the eligibility requirements as established by the Bank in the Applicable Guidelines.

A Consultant will be selected in accordance with the FBS method set out in the Consultant Guidelines (Cannot exceed INR 5 crores for the duration of Five Years (3+2) from the Effective date of the engagement), by BIRAC from among the Shortlisted EoI(s).

Further information can be obtained at the address below during office hours [*i.e. 1000 to 1700 hours*].

Expressions of interest must be delivered in a written form to the address below and soft copy by email by **25th February 2019**

Office of – Dr. Kavita Singh

Mission Director

NBM-PMU, Biotechnology Industry Research Assistance Council "BIRAC",

A Government of India Enterprise,

1st Floor , MTNL Building,9, CGO Complex,

Lodhi Road, New Delhi-110003

E-mail address: technical.birac@gov.in

Phone:+91-11-24389600; Fax: +91-11-24389611