Terms of Reference

Name of the assignment:
Consultancy Services for Innovate in India program entitled "Industry-Academia Collaborative Mission for Accelerating Early Development for Biopharmaceuticals-Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation".

Introduction:

Department of Biotechnology, (DBT) Ministry of Science &Technology has initiated the above-mentioned mission in partnership with co-funding through a World Bank loan. The program known as i3 program aims to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals (including vaccines, biologics) to a level that will be globally competitive over the next decade.

This scientifically driven enterprise, aims to support development of specific affordable biotechnology products, bridging critical gaps in skill and infrastructure, enhancing clinical capacity, promoting product oriented development, building functional institutional framework for inter-disciplinary and inter/intra institutional collaborations within and across academia and industry involving national and global experts.

The program is being implemented by a National Biophamra Mission, Project Management Unit (PMU) of Biotechnology Industry Research Assistance Council (BIRAC), a govt of India enterprise.

Objective and Scope of the Services:

BIRAC intends to seek a Clinical Trial Regulatory Advisory and data safety consultancy firm which will support the Project Management Unit in Clinical Trial activity and oversight.

The Clinical Trial Regulatory Advisory and data safety consultancy firm will support the PMU in fulfilling the expectation of monitoring/auditing of clinical trial conduct and will covers all the five basic processes:

1. Clinical trial Planning
2. Clinical trial Initiation
3. Clinical trial Execution
4. Data safety Monitoring and controlling deviations
5. Analysis and reporting

The proposed scrutiny and assessment system will ensure that clinical trials and trial sites being supported under national biopharma mission prevent any adverse social impact. It will involve careful identification and definition of factors that have potential predictive value for noncompliance at the program level, the study level and the site investigator level.

Specific Tasks to be undertaken by Clinical Trial Regulatory Advisory and data safety consultancy firm:

1. **Scientific Review of 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.

2. **Quality Management Assurance:** To assure the PMU that the Clinical Trial processes followed by different sponsors and the GCLP labs associated with trials adhere to the expected quality practices of documentation associated with clinical research and good clinical lab practices.

3. **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

4. **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.

5. **Safety data monitoring:** Review of safety data including DSMB comments and comprehensive safety and medical monitoring through review of relevant documents and advise PMU on the safety status of the ongoing trials.

6. **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.

7. **Training:** Training on GCP for BIRAC and as per the need of trial sites. Issuance of certificate on GCP training from an authorised trainer

8. **Validation of Immunoassays:** Review of validation data of various immunogenicity assays under GCLP lab settings

Expected Outcomes:

Clinical Trial Regulatory Advisory and data safety consultancy firm will assure PMU of National Biopharma Mission on the adequacy of the processes of different sponsors and appropriateness of scientific design of the clinical trials through:

1. **Site visits:** To confirm the suitability of the trials site and monitoring the trial to ensure processes being followed are as per applicable GCP guidelines
2. **Review of essential documents of clinical trial**
3. **Medical and safety data Monitoring**
4. **Review of Regulatory strategy**
5. **Review of immunoassay validation data**

Selection Method:- The manner of the Clinical Trial Regulatory Advisory and data safety consultancy firm shall be on Fixed budget selection which cannot exceed INR 5 crores for the duration of Five Years (3+2) from the Effective date of the engagement.

Eligibility Criteria for Consultants:

The proponent must possess below mentioned experiences and capabilities:

The team composition should have resources with background of Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees. The team should exhibit multi-disciplinary capabilities with prior experience in conduct and management of regulatory compliant clinical trials.

Technical requirements:

The team should possess relevant technical expertise and be familiar with Indian regulatory requirements and ICH GCP guidelines for conduct of clinical trials and clinical evaluation for regulatory submission. The experience expectations of the team and the expected time commitment for each of the required expertise is mentioned below

- **Clinical trial Monitor:** Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 3-5 yrs in monitoring clinical trials and evaluating trial sites. The expected time commitment is about 6-8 days in a month
- **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 including community based field studies. The expected time commitment is about 3-4 days in a month.
- **Medical Monitor:** MBBS/MD: with experience of 6-10 yrs in Medical Monitoring/ pharmacovigilance/ safety data review. The expected time commitment is about 2-3 days in a month
- **Medical Writer:** MBBS/MD/PhD: with experience of 8-10 yrs in developing essential documents for clinical trials. The expected time commitment is about 2-3 days in a month
- **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. The expected time commitment is about 2-3 days in a month.

- **Bioassays Validation expert:** Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 8-10 yrs in performing validation of assays as per ICH guidelines. The expected time commitment is about 2-3 days in a month.
- **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. The expected time commitment is about 3-4 days in a month
- **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. The expected time commitment is about 1-2 days in a month
- **Biostatistician:** Biostatistics postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 8-10 yrs as a biostatistician handling analysis of clinical trial data, generating tables, listings and graphs. About 1-2 days in a month
- **GCP Trainer:** Life Science Graduates / Life Science postgraduates/MBBS/PhDs/ higher equivalent degrees with experience of 6-10 yrs in GCP and training. The expected time commitment is about 2-3 days in a month

The Organization/Team should have the following experience (within the boundaries of the technical areas defined above):

- Have active linkages and be engaged as partners with public research institutions or the private sector, Government, and/or civil society organizations working for conduct of clinical trials
- Experience in planning of clinical trials, conduct of multicentric trials as per ICH GCP guidelines and data analysis and report preparation and submission to regulatory authorities
- The firm should be willing to provide for 'references', or contacts in client organizations willing to vouch for a bidder's performance upon request

Financial Requirement:

The Proponent should not have incurred any loss during the preceding two financial years. Please submit relevant balance sheets for reference.

- **The Legal Entity requirements:**

The REOI provides for the required legal requirements and evaluation parameters and are to be referred to.

- **Governing Contract:**

The consultancy services under the i3 will be governed in terms of the time based contract format of the World Bank.

- **GOVERNING LAW**

The RFP and the Time Based Contract /Agreement shall be deemed to be a contract made under, governed by and construed in accordance with the laws of India subject to exclusive jurisdiction of courts of Delhi. TKP shall ensure full compliance of all applicable Indian/its own resident Laws and statutory regulations at its own cost for executing the present scope of work.