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 **Technical Knowledge Partner (TKP)** to be centralized, knowledge hub that links with the PMU and empowers the Scientific Advisory Group (SAG) and Technical Advisory Groups (TAG) of this mission.

TKP would not only aim and address but also facilitate through conducting various activities to ensure quality, effectiveness and maximum impact of program mentioned below:

- Facilitate shared learning and good practices to reduce isolation and increase credibility
- Define effective responses to complex realities of product development
- Enhance visibility of concerns and issues and provide solutions to mitigate risks
- Foster creativity and innovation
- Increase access to knowledge, experience, resources, and connections

Specific Tasks to be undertaken by the TKP

TECHCNIAL

i. Knowledge partner should be able to leverage in-house scientific capabilities derived from different domains to strategically analyse the available knowledge and expert views to identify needs and potential barriers in product development continuum for development of vaccines and bio therapeutics followed by three stages: i) **Preclinical development** (includes accurate assessment of candidate suitability and product characterization including proof of concept establishment, immunogenicity/safety/stability studies etc. ii) **Clinical Stages** (target population identification, assays requires for clinical evaluation etc. iii) **Regulatory pathway clarity**.

ii. Recommend initiatives that would guide thinking for strengthening and enhancing capacity within current ecosystem (setting up accessible and suitable facility like training required by staff, technologies/infrastructure needs, global and Indian linkages to be formed).

iii. Provide candid, non-biased, experience-based partner insights. Arrange for meeting and discussions with experts

iv. Provide well-researched, thoroughly analysed structured evidence including the market opportunity, industry analytics and competitive intelligence to aid in making appropriate and timely knowledge based strategic decisions.

v. Provide support to the PMU and assist TAG and SAG in generation and application of knowledge towards ensuring quality and effectiveness of the program

PROJECT MANAGEMENT

vi. Support PMU in identifying experts for various proposals to review progress and provide mentoring.

vii. Support includes Organizing meetings/ conferences/ working group meeting / brain storming sessions with identified area experts. Preparing materials for arranging the meeting, developing synopsis / minutes of brainstorming sessions. and inputs from these meetings.

viii. Establishment of Product development Units as per the need.

ix. Preparation of project management and monitoring tools

IMPACT ANALYSIS

x. Studying financial and biopharma environment Impact of i3 program under various activities of i3 and preparing appropriate communication material.

Expected Outcomes:

Comprehensive research reports, papers, presentations, that could serve in aligning various stakeholders and identification of technical requirements that would enable SAGs in developing relevant Request for Proposals and partner selection,

Competitive intelligence to aid in making appropriate and timely knowledge based strategic decisions for development of product.

A knowledge library which would offer a means for members to get resources they need to carry out their main activities more efficiently and effectively, such as information on new technologies and tools available as Continuous technical support to BIRAC's PMU.

Activity timeline- The specific activities as mentioned above shall be of continuing nature and will be spread out through the initial engagement period of 3 (Three) years and the further extension period of 2 (Two) years if considered. Certain specific activity timeline include the following;

- Arranging discussion sessions and forums for both Vaccines and Biotherapeutics (biosimilars and facilities) to discuss potential areas of additional activities to be undertaken by NBM. At least 2 International and 2 National experts will be invited for each segment discussion in consultation with NBM. All arrangement for inviting these experts, paying honorarium and logistics will need to be made by TKP. (Plan one session each for vaccines and biotherapeutics in the first year and second year). The meeting will include participation of TAG & respective SAG members. Objective of this session will be evaluation of the ongoing mission program, its processes, scope of improvement and continuous improvisation in the scientific content.

- Support NBM in holding round table discussions and sessions with relevant stakeholders and experts to develop RFPs (four such sessions in first and second year). The TKP will be responsible for preparing the concept note, developing questionnaires, identifying experts and preparing final recommendations and minutes of the meeting after discussions with NBM.

- From year 2 onward studying the impact assessment through a well-defined matrix for product development (biotherapeutics, vaccines and devices) and capacity enhancement once every year.

Selection Method:- The manner of the TKP shall be on Fixed budget selection which cannot exceed INR 5 crores for the duration of Five Years 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 MBBS/PhDs/MBAs/higher equivalent degrees. The team should exhibit multi-disciplinary capabilities with prior experience in vaccine and biotherapeutics product development and project management.

- **Technical requirements**:

  The team should possess relevant technical expertise and be familiar with pathway of product development, issues and gaps across product development (includes translational research, clinical validation, regulatory knowledge) regarding vaccine and bio therapeutics in alignment with regional priorities.

  Support to be made available for minimum 15 working days in a month. Experience expectations from key experts is as follows:

- **Vaccine expert:** MBBS/PhD with experience of minimum 10 years in vaccine clinical development pathways for different vaccines and is aware of latest technologies being pursued in vaccine development efforts.
- **Biotherapeutics experts:** MBBS/PhD with experience of minimum 10 years in biotherapeutics development and is technically updated in the field of biosimilars and /or production of biosimilars.
- **Project Management expert:** Graduate/PG and experience of 5- 8 years in handling projects in the healthcare product development sector.

- **Program Management requirements**:

  Experience in conceptualization and coordination of innovative programs, implementing and managing multisectoral, multidisciplinary and multiregional collaborations to bridge systematic gaps across academia-industry, clinic-lab, research-programs in partnership with the Government of India, scientific and research institutions, industry partners and global centres' of excellence other than BIRAC.

  Experience of at least 2 long term (minimum 6 months) projects in last 3 years as Lead Consultant/Consultant/Knowledge Partner for Central/State Governments or their agencies other than BIRAC. (Experience to be supported with documentary evidence of engagement).

  Support to be made available for minimum 10 working days in a month

- **Impact Analysis requirements**:

  Support to be made available for minimum 03 - 04 working 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 engaged as partners with public research institutions, the private sector, Government, and/or civil society organizations working within the vaccines, biotherapeutics/ development and implementation space
- Convened diverse stakeholders in a non-competitive environment (workshops, consultations etc.) developed symbiotic relationships and facilitated knowledge sharing towards identifying gaps and devising probable solutions to strengthen India's product development capability (for development of vaccines, biotherapeutics) and accelerate innovation
- Should mention the terms with regards to partnerships / consortia with international firms.
- Ensured creation of globally relevant and effective national programs and translation of evidence into action through conceptualization
- Enhanced and developed capabilities within the country that promote innovation in product development for vaccines, biotherapeutics.
- Implemented and managed multi-sectoral, multidisciplinary and multiregional collaborations to bridge systemic gaps across academia-industry, clinic-lab, research-programs
- Engaged with or as a Product Development Partnership (PDP) (within the vaccines, biotherapeutics space) and has know-how required to structure and manage a PDP.
- 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.