EXPRESSION OF INTEREST (EOI)

FOR

SHORTLISTING OF CONTRACT RESEARCH ORGANIZATIONS (CROs)

FOR CLINICAL TRIALS SERVICES

EOI No: BDG/EOI/2024/001

CSIR INDIAN INSTITUTE OF INTEGRATIVE MEDICINE
(**BDG/CEC**)
Canal Road, Jammu Tawi
Jammu- 180001, India

Email: **rmbd@iiim.ac.in**

About the Organization

Indian Institute of Integrative Medicine (IIIM), Jammu, established in 1941, is a constituent laboratory of Council of Scientific and Industrial Research (CSIR), New Delhi. With its expertise in Natural Product Chemistry and Medicinal Chemistry, and Pharmacology, it provides solutions to challenges faced by Industry, Government Departments and Entrepreneurs through basic and applied research and process development. It is internationally recognized for its contributions to chemistry research and is an ideal place for bringing ideas to commercialization through state-of-the-art research and development.

CSIR-IIIM, during its yesteryears journey, has made its mark as a dynamic, innovative and result oriented R&D organization. The clientele spans all corners of the globe. In India, the CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM) is one of the oldest National Laboratories and a reliable destination for Natural & medicinal chemistry and biotech industries.

CSIR-IIIM is a leading research organization for phytopharmaceutical and NCE drugs. Some of our leads are in the advanced stage of drug development. With a view to taking these leads to the clinical development stage, we are looking to hire contract research organizations that have experience in providing services related to various aspects of clinical trials and all the matters related to clinical trials. Therefore, an expression of interest is sought from the interested CROs with the following terms and conditions.

INSTRUCTION TO TENDERERS

Shortlisting of Contract Research Organizations

(Invitation for Expression of Interest)

1. Director, Indian Institute of Integrative Medicine, Jammu, invites Expression of Interest (EOI) for short listing Contract Research Organizations (CROs) to provide various services related to clinical trials for CSIR-IIIM for two years. The nature of services to be provided by the CROs will include but are not limited to, the preparation of clinical trial protocol, study document development, selection of investigators, site identification and screening, ethics committee submissions and approvals, study initiation, medical writing, data management and analysis, project management, vendor management and conducting clinical trials for various drug leads of CSIR-IIIM.

   The scope of services would also include dossier preparation, getting all requisite regulatory approvals from the regulatory authorities and timely reporting of all safety data to the Ethics Committee and CSIR-IIIM. Anything incidental to the basic purpose would also be deemed to be included in the scope of the work irrespective of the fact that the same is listed specifically in the document or not.

2. Eligibility Criteria for Selection of CRO:

   a. The CRO should have at least five years working experience in clinical trials of drugs on human subjects

   b. They should have the capability to cater services throughout the country across states, including UTs, with adequate Human Resources and Infrastructure. **(Necessary documentary evidence to be enclosed)**

   c. The average annual turnover of the CRO during the last three financial years should be above Rs. 5.0 Crores from clinical research services-related activities **(audited balance sheet and profit & loss account) of the relevant period, duly authenticated by a Chartered Accountant should be enclosed.**

   d. The party should not have incurred loss during the preceding five years and not have been declared as insolvent. The party shall attach a solvency certificate from any scheduled bank for an amount of 2.0 crores. Or equivalent to the award value. **ITR and audited balance sheet of last 5 years must also be enclosed.**

   e. Confidentiality of the study data should be maintained with utmost care and Non-disclosure agreement will have to signed

   f. The firm should have carried out clinical trial studies for Govt. Institutions like CSIR, ICMR, DBT, & DST etc., AND/OR for reputed pharmaceutical industries. **(Documentary evidence must be enclosed)**

g. Should have carried out **05** or more clinical trial studies successfully **(Necessary documentary evidence to be enclosed)** during the last ten years.

h. Details of the major past inspection activities by Health Authorities/ Regulatory Authorities for GCP activities should be mentioned. Past three-year audit reports on the GCP compliance by the CRO should be submitted.

3. List of activities proposed to be carried out by CRO for clinical trials

a) Training on Protocol and GCP of the study staff, including investigators and Research Fellows (CRO) and other staff as required.

b) Ethics committee approval shall be ensured by CRO

c) CRO would execute a tripartite agreement involving the sponsor, CRO and each site.

d) CTRI registration should be done by CRO and updated as the trial progresses on a monthly basis.

e) Data collection and data management from site/hospital, data cleaning/biostatistics, preparation of final report and submission to sponsor.

f) All adverse event management, including reporting (AE & SAE)

g) Clinical trial management at the site till study completion.

h) CRO should indemnify CSIR-IIIM for any harm liability and causality.

i) Compilation of entire clinical trials data and submission of the dossier to DCGI.

j) Attending queries post-submission of the dossier.

4. Interested parties meeting the eligibility criteria are requested to fill up **annexures A & B** appended at the end of the document and submit along the application.

5. All interested parties are requested to submit their EOI. The last date for submission of EOI is **17.01.2025 (11:30 A.M)**. The Subsequent amendment/changes if any will be published on our website

7. The shortlisting shall be valid for a period of two years, and all requirements that may arise during the period shall be tendered among the shortlisted parties separately.

8. CSIR-IIIM may, at its discretion, extend this deadline for submission of EOI by amending the Bid Documents or any other reasons, in which case all rights and obligations of the CSIR-IIIM and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

9. EOI will be opened in the presence of bidder's representative(s) who choose to attend on the specified date and time at the office of the CSIR-IIIM at the address given.

10. In the event of the date specified for bid receipt and opening being declared as a closed holiday for CSIR-IIIM, the due date for submission of EOI and opening of EOI will be the following working day at the specified times as given above.

11. CSIR-IIIM will not be held responsible for delay, if any, in the submission of the bidding document or the non-receipt of the same. EOI sent by Telex/Fax/Telegraph/mail will not be accepted, and only online EOI shall be entertained.

12. Evaluation: The evaluation will be carried out by a Technical committee constituted by the competent authority of CSIR-IIIM. CSIR-IIIM may decide not to continue with the shortlisting and cancel the notice of inviting EOI either full or in part at its discretion. The committee shall check the documents attached to the tender as asked for in the qualification requirement. The committee may ask the parties to come for a discussion/presentation if required. All the parties who meet the requirements of the tender may be shortlisted for the activities.

13. Director CSIR-IIIM reserves the right to reject any or all bids either in part of in full without assigning any reason.

14. **Arbitration:** In the event of any question /dispute/difference arising out of this agreement the same shall be referred to the Delhi International Arbitration Centre for appointment of Arbitrator to adjudicate the dispute. The award of the Arbitrator shall be final and binding on the parties. The Arbitrator may give interim award(s) and /or directions, as may be required. Subject to the aforesaid provision, the arbitration and conciliation act, 1996 and the rules made hereunder and any modification thereof from time to time being in force shall be deemed to apply to the Arbitration proceedings under this clause."

E-copy of the EOI, complete in all respects with the copies of the documents may please be submitted online on or before 17.01.2025 upto 11:30 A.M.

Annexure A

GENERAL INFORMATION

1. Names of the firm: …….

2. Legal Status of the Firm: Individual/Association/Joint Venture/Consortium

3. Registered Address, telephone, Tele-fax.

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4. Contact Person, Designation and address including email id

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5. Number of years in Clinical Research:

6. Number of clinical trials conducted in last five years:

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7. Details of certificates and accreditations (documents to be attached):

8. Details of major regulatory bodies inspection and audits (documents to be attached):

9. Attach an attested photocopy of the Certificate of Registration.

Sign & seal of the tenderer

Annexure B

DETAILS OF CLINICAL TRIALS CONDUCTED IN LAST Ten YEARS

Sl. No.	Study Title	Name and address of the Sponsor	Details of the study		Indication	Remarks
			Phase	Study Design		
