Expression of Interest (EoI)

for

Shortlisting of Contract Research Organizations (CROs)

For Preclinical Toxicology Studies

EOI No: BDG/EOI/2025/001

CSIR-Indian Institute of Integrative Medicine, Jammu

(BDG/CEC)

Canal Road, Jammu Tawi

Jammu- 180001, India

Contact Email id: rmbd@iiim.ac.in

About the Organization

Background: Indian Institute of Integrative Medicine (IIIM) is a constituent laboratory of the Council of Scientific & Industrial Research. The institute works in the area of natural products-driven drug discovery and development for various diseases. The institute is actively involved in the phytopharmaceuticals drug development. The institute would like to invite the EOI for shortlisiting the reputed CRO for the **90-days repeated dose toxicity in rats and rabbits for its phytopharmaceutical leads under GLP conditions as per new drugs CT Rules 2019 of CDSCO**

INSTRUCTION TO TENDERERS

Shortlisting of Contract Research Organizations
(Invitation for Expression of Interest)

Director, Indian Institute of Integrative Medicine, Jammu, invites Expression of Interest (EOI) for short listing Contract Research Organizations (CROs) for performing 90 days pre-clinical toxicity testing in rats and rabbits, as per the details given in the work item document enclosed.

A. Eligibility criteria for shortlisting of CRO/Institutions:

1. The CROs/Institutions should have at least five years of working experience in regulatory GLP toxicology studies.
2. The CRO/Institution should have a Valid GLP certificate for conducting regulatory toxicology studies/Safety studies.
3. They should have the capability to cater services throughout the country across states and UTs with adequate Human Resources and Infrastructural facilities. . (Necessary documentary evidence to be enclosed)
4. The confidentiality of the study data must be maintained with utmost care.
5. A Memorandum of Understanding (MoU) will be executed between CSIR-IIIM and CRO/Institution. CDA to be signed by the CRO/Institution before executing MOU with CSIR-IIIM.
6. Director, CSIR-IIIM Jammu reserves the right to award or not to award any study or part thereof without assigning any reason therefor.
7. Should have carried out 5 or more preclinical- efficacy/toxicity/safety studies in which at least three will be in AYUSH mode product/Phytopharmaceuticals/NCEs. **(Necessary documentary evidence to be enclosed)**
8. The quoting firm should submit a detailed study design.

9. The average annual turnover of the firm during the last three financial year should be above Rs 5.0 crores (audited balance sheet and profit & loss account) of the relevant period, duly authenticated by a Chartered Accountant should be enclosed.
10. 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 submitted.**
11. Details of the major past inspection activities by Authorities/ Regulatory Authorities for GLP activities should be mentioned. Past three-year audit reports on the GLP compliance should be submitted. **(Documentary evidence must be enclosed)**

B. Other Requirements

1. Interested parties meeting the eligibility criteria are requested to fill up annexure A & B appended at the end of the document and submit along the application.
2. All interested parties are requested to submit their EOI. The last date for submission of EOI is **23.01.2025 (11:30 A.M).** The Subsequent amendment/changes if any will be published on our website
3. 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.
4. 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.
5. 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.

6. 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.
7. 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.
8. Evaluation: The evaluation will be carried out by a Technical committee/CEC 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.
9. Director CSIR-IIIM reserves the right to reject any or all bids either in part of in full without assigning any reason.
10. 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/ email to **rmbd@iiim.ac.in**
On or before **23.01.2025 (11:30 AM)**

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 Pre-clinical work:

6. Number of pre-clinical studies 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 Studies Done In Last Five Years

Sl. No.	Study Title	Name and Address of the Sponsor	Details of the study		Other Details	Remarks
			Type	Testing Leads (NCE/Phytopharmaceutical/AYUSH etc)		
