EXPRESSION OF INTEREST (EOI)

FOR

EMPANELMENT OF CONTRACT RESEARCH ORGANIZATIONS

(CROs) FOR CONDUCTING CLINICAL TRIALS

EOI No: 01/2021
Dt. 05.11.2021

CSIR INDIAN INSTITUTE OF INTEGRATIVE MEDICINE
(**Business Development Group**)
Canal Road, Jammu Tawi ,
Jammu- 180001, India
Email: Purchase@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, 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 taking 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, CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM) is one of the oldest National Laboratories and the reliable destination of Natural & medicinal chemistry and biotech industries.

CSIR-IIIM has pioneered in process technology of Favipiravir and Fluoxamine which are being repurposed for the treatment of Covid-19 and is also working closely with Pharma industries. CSIR-IIIM has several projects in hand, carried out in-house or in collaborative mode, with premier academic and research institutions in the country and abroad.

INSTRUCTION TO TENDERERS

Empanelment of Clinical research organization for various clinical trials

1. Expression of Interest (EOI) for empanelling Contract Research Organizations (CROs) is invited for conducting various clinical trials for CSIR-IIIM. The nature of services to be provided by the CROs will include, but not limited to 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 and vendor management.

   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 Ethics Committee and CSIR-IIIM.

2. Eligibility Criteria for selection of CRO:

   - The CRO should have at least five years working experience in clinical trials of drugs on human subjects
   - They should have capability to cater services throughout the country across states including UTs with adequate Human Resources and Infrastructure.
   - The average annual turnover of the CRO during the last three financial years should be above Rs.15.0 Crores from clinical research services related activities (audited balance sheet and profit & loss account) of the relevant period, duly authenticated by a Chartered Accountant/Cost Accountant in India or equivalent in relevant countries)
   - 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.
   - Confidentiality of the study data should be maintained with utmost care
   - The firm should have preferably carried out clinical trial studies for govt. institutions like CSIR, ICMR, DBT, & DST etc., and for reputed pharma industries.
   - Should have carried out 10 or more clinical trial studies
   - 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 is desirable.
   - Rates with regard to clinical investigations should be as per CGHS norms.

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

- Training on Protocol and GCP of the study staff including investigators and Research Fellows (CRO)
- Ethics committee approval shall be ensured by CRO
- CRO would execute a tripartite agreement involving sponsor, CRO and each site.
- CTRI registration should be done by CRO and updated as trial progresses on monthly basis.
- Data collection and data management from site/hospital, data cleaning/biostatistics, preparation of final report and submission to sponsor.
- All adverse event management including reporting (AE & SAE)
- Clinical trial management at site till study completion.
- CRO should indemnify CSIR-IIIM for any harm liability and causality.
- Compilation of entire clinical trials data and submission of the dossier to DCGI and
- Attending to 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 in CSIR-IIIM.

5. All interested parties are requested to submit their EOI for the empanelment process. The last date for submission of EOI is **18.11.2021 (11:30 A.M)**.The EOI will be opened on **19.11.2021 (11:30 A.M)**. The Subsequent amendment / changes if any will be published in our website also.

7. The short listing shall be valid for a period of three 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. Bid Submission method: Interested parties are requested to fill up all the Annexures enclosed and submit the bid with all the necessary supporting documents. The EOI shall be submitted **online** on or before **19.11.2021 (11:30 A.M)**.

10. 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 CSIR-IIIM at the address given.

11. 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.

12. 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 will not be accepted.

13. 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 empanelment 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 shall be shortlisted for the activities.

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

15. **Arbitration:** Any dispute arising out of this Agreement, the same shall be referred to the arbitration of 3 (three) arbitrators, one to be appointed by each party to the dispute, and the third and presiding arbitrator shall be nominated by the said two arbitrators before entering into any reference. The decision of the majority of arbitrators shall be final and binding on both parties. The venue of arbitration shall be at Jammu and the arbitration proceedings shall take place under the provisions of Indian Arbitration and Conciliation Act, 1996.

E-copy of the EoI, complete in all respects with the copies of the documents may please be submitted online on or before 19.11.2021 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 Certificate of Registration.

Sign & seal of the tenderer

Annexure B

DETAILS OF CLINICAL TRIALS CONDUCTED IN LAST FIVE YEARS

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