Indian Institute of Integrative Medicine

(Formerly known as Regional Research Laboratory)

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TENDER NO: 12(291)/2020-P Date 22.09.2020

TENDER DOCUMENT

FOR

Selection of Independent Clinical Trial Auditors

INVITATION TO BID

File No. 12(291)/2020-P Date 22.09.2020

Dear Sirs/Madam,

Sub: Quotation for supply of "**Selection of Independent Clinical Trial Auditors**"

Ref: Our Enquiry No. 12(291)/2020-P dated: 22.09.2020

Director, CSIR – Indian Institute of Integrative Medicine herein after called as the **'Purchaser'** is interested in the purchase of below mentioned material (s).Kindly send your quotation so as to reach us on or before **06.10.2020 by 11:00 AM hrs. (IST).** Bids are to be submitted electronically only on **NIC portal/ etenders.gov.in**

Sr. NO.	Description of Item(S)
1.	**Selection of Independent Clinical Trial Auditors**

Detailed Specification:

Selection of Independent Clinical Trial Auditors

CSIR-Indian Institute of Integrative Medicine, Jammu
Council of Scientific & Industrial Research
Ministry of Science & Technology
Govt of India

Background

Council of Scientific & Industrial Research and Ministry of AYUSH, Govt. of India have taken various initiatives to address the COVID 19 pandemic in the country. Among many, these initiatives involve studying the impact of AYUSH based prophylactic interventions in high risk population and also studying impact of some Ayurvedic formulations as add on to standard care treatment options in mild and moderate stage COVID-19 patients.

The *Interdisciplinary AYUSH Research and Development Task Force* has formulated and designed clinical research protocols for prophylactic studies and add-on interventions in COVID-19 positive cases through thorough review and consultative process of experts of high repute from different organizations across the country for clinical validation of four different ayurvedic formulations.

A. List of AYUSH-CSIR clinical studies

S. N.	Study title	Estimated sample size and study sites (may vary)
1.	Ayurvedic formulation-1 for the Prophylaxis Against SARS-COV-2 in subjects with increased risk during the COVID 19 Pandemic: A comparison with Hydroxychloroquine/SOC in the health care providers	**Sample size:** 400 **study sites: 10**
2	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of	**Sample size**: 140 **study sites: 04**

	Ayurvedic formulation-2 as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients	
3.	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation-3 as an Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients	**Sample size**: 140 **study sites: 04**
4	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation-4 as an Adjunct Treatment to Standard of care for the management of Mild to Moderate COVID-19 Patients.	**Sample size**: 140 **study sites: 03**

These studies are being implemented through three CROs as follows.

Study No.1: M/s Cadila Pharmaceuticals Ltd – CRO Ahmedabad

Study No. 2 & 3: M/s Ardent Clinical Research Services, Pune

Study No. 4: M/s Target Institute of Medical Education and Research, Mumbai.

and monitored jointly by Council of Scientific & Industrial Research through CSIR-Indian Institute of Integrative Medicine Jammu and Ministry of AYUSH through Central Council for Research in Ayurvedic Sciences (CCRAS) as a nodal organizations.

CSIR-IIIM Jammu hereby invites applications from clinical trial auditors/auditing firms for conducting independent routine audits of aforesaid clinical trials sponsored by CSIR/Min. of AYUSH.

B. Types of Audits to be conducted

At a minimum, the following types of audits will have to be conducted, remotely and with at least one visit for each site, for each clinical trial, as part of the Sponsor's quality assurance program:

1. Investigator Site Audits
2. Trial Master File (TMF) Audit

The objectives of the investigator site audit are to:

- To evaluate clinical trial conduct and compliance with the protocol, standard operating procedures (SOPs), Good Clinical Practice guidelines issued by CDSCO, ICH, GCP and the applicable regulations.
- To evaluate completeness, quality and timeliness of data reported to the Sponsor.
- To evaluate reliability of trial data and protection of subject rights.

The objective of the TMF audit is:

- To evaluate the compliance and completeness of the essential documents contained within the TMF, against the SOPs, GCP Guidelines (CDSCO and ICH) and applicable regulations.

C. Qualification of Auditor – MBBS/ BDS/ BAMS/ BUMS/ BHMS etc as recognized by MCI, DCI, MoHFW 2003 and subsequent notifications for alternate systems of medicine plus degree / diploma having syllabus of procedures, laws for the conduct and monitoring of clinical trials in India.

D. Experience: At least three years of experience of having audited important multi-centric trials

that ensures:

i) **Knowledge** of necessary laws regulations guidelines, GCP, ethics, clinical and pharmaceutical knowledge, SOPs, computerized system validation.

ii) Skills of communication, writing, language

iii) Nature/attitude – tenacity, power of observation, analytical capability, sense of ethics, maturity.

E. Scope of Audit:

The scope of the investigator site audit should include audit of:

- The clinical trial conduct process
- Informed Consent Forms (ICFs)
- Ethics Committee, other essential documents
- Source data verification
- Investigational Medicinal Product (IMP)
- Laboratory Samples management
- Personnel and training
- Monitoring and site management

The scope of the TMF audit should include review of the TMF documents for quality and completeness.

F. Audit Report:

- A draft audit report for Study No. 1, 2 & 3 would be submitted to The Director, CSIR-Indian Institute of Integrative Medicine, Canal Road, Jammu and for study No. 4 to Director General, CCRAS, New Delhi within 15 working days of the completion of the audit/audit series.
- The final signed audit report and audit certificate would be submitted within 05 working days of the acceptance of the corrective and preventive actions from the auditee.

G. Application: Applicant should submit the following:

i. Proposal (Financial) for conducting the following audits for each of the four studies separately.
   - Investigator Site Audits
   - TMF Audits

ii. Proposed auditors' curriculum vitae specifying qualification and experience with documents that supports the requirement stated above.

iii. SOPs for conducting the audits.

Last Date for submission : 06-10-2020 up to 11.00AM. hrs. (IST)
Date of Opening : 07-10-2020 at 11.00AM hrs. (IST)

TERMS & CONDITIONS

1. The quotation must be in the form furnished by the Purchaser and should be free from corrections/erasures. In case there is any unavoidable correction it should be properly attested. If not the quotation will not be considered. Hand written Quotations will not be considered.

2. As per Govt. of India procurement policies,

   a. Only class-I Local Supplier and class-II Local Supplier defined under the Department of Promotion of Industry and Internal Trade (DPIIT) order date 4th June, 2020 shall be eligible to participate.

   b. The purchaser intends to give purchase preference to local suppliers* in case the cost of procurement is in the range of more than Rs 5.00 lakhs and up to Rs. 200.00 lakhs.

   c. The procuring entity intends to give purchase preference to products/goods manufactured by micro, small and medium enterprises.

   *"Local supplier" means a supplier or service provider whose product or service offered for procurement meets the minimum local content as prescribed in DIPP Order No.P-45021/2/2017-PP (BE-II) dated 29.05.2019 or by the competent Ministries/Departments in pursuance of this order.

   'Local content' means the amount of value added in India which shall, unless otherwise prescribed by the Nodal Ministry, be the total value of the items procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.

Model Clauses for Tenders

I. Any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with the Competent Authority.

II. "Bidder (including the term 'tenderer', 'consultant' or 'service provider' in certain contexts) means any person or firm or company, including any member of a consortium or joint venture (that is an association of several persons, or firms or companies), every artificial juridical person not falling in any of the descriptions of bidders stated hereinbefore, including any agency branch or office controlled by such person, participating in a procurement process.

III. "Bidder from a country which shares a land border with India" for the purpose of this Order means:-
   a. An entity incorporated, established or registered in a such a country; or
   b. A subsidiary of an entity incorporated, established or registered in a such a country; or
   c. An entity substantially controlled through entities incorporated, established or registered in a such a country; or
   d. An entity whose beneficial owner is suited in a such a country; or

e. An Indian (or other) agent of such an entity; or
f. A natural person who is a citizen of such a country; or
g. A consortium or joint venture where any member of the consortium or joint venture falls under any of the above

IV. The beneficial owner for the purpose of (iii) above will be as under:

1. In case of a company or limited Liability Partnership, the beneficial owner is the natural person(s), who, whether acting alone or together, or through one or more juridical person, has a controlling ownership interest or who exercises control through other means.
   Explanation----
   a. "Controlling ownership interest" means ownership of or entitlement to more than twenty-five percent of shares or capital or profits of the company;

   b. "Control" shall include the right to appoint majority of the directors or to control the management or policy decisions including by virtue of their shareholding or management rights or shareholders agreements or voting agreements;

2. In case of a partnership firm, the beneficial owner is the natural person(s) who, whether acting alone or together, or through one or more juridical person, has ownership of entitlement to more than fifteen percent of capital or profits of the partnership;

3. In case of an unincorporated association or body of individuals, the beneficial owner is the natural person(s), who, whether acting alone or together or through one or more juridical person, has ownership of or entitlement to more than fifteen percent of the property or capital or profits of such association or body of individuals;

4. Where no natural person is identified under (1) or (2) or (3) above, the beneficial owner is the relevant natural person who holds the position of senior managing official;

5. In case of a trust, the identification of beneficial owner(s) shall include identification of the author of the trust, the trustees, the beneficiaries with fifteen percent or more interest in the trust and any other natural person exercising ultimate effective control over the trust through a chain of control or ownership.

V. An Agent is a person employed to do any act for another, or to represent another in dealings with third person.

VI. [To be inserted in tenders for Works contracts, including Turnkey contacts] The successful bidder shall not be allowed to sub-contract works to any contractor from a country which shares a land border with India unless such contractor is registered with the Competent Authority.

Model Certificate for Tenders (for transitional cases as stated in para 3 of this Order

"I have read the clause regarding restrictions on procurement from a bidder of a country which shares a land border with India; I hereby certify that this bidder is not from such a country and is eligible to be considered."

3. **Origin of the each item should be mentioned by the bidders.**

4. It may kindly be noted that your bid should

   A) be in ***Single part bidding***
   B) accompany No Bid Security

4. Each quotation must be sent electronically in single cover through e-procurement portal (etenders.gov.in)

5. The acceptance of the quotation will rest with the competent authority of Indian Institute Of Integrative Medicine Jammu, who does not bind himself to accept the lowest quotation and reserves the right to himself to reject, or partially accept any or all the quotations received without assigning any reason.

6. Price quoted should be net and valid for a minimum period of 120 days from the date of opening of the quotation.

7. Participation in this tender is by invitation only and is limited to the selected Purchaser's registered suppliers. Unsolicited offers are liable to be ignored. However, suppliers who desire to participate in such tenders in future may bring it to the notice of the purchaser and apply for registration as per procedure. It may be noted that Conditional/Unsigned tenders shall not be considered

8. The bidder must submit the applicable Price Schedule Form as Annexed to the tender document available on the website.

9. **Complete specification with manufacturer's name and address should be given while quoting. Literature/Pamphlets should also be enclosed wherever applicable.**

10. Prices are required to be quoted in units indicated in the enquiry. When quotations are given in terms of other units, relationship between two sets of units should be furnished. Quantity discounts, if any should also be indicated. The items should be quoted indicating the serial No. of our RFQ.

10**.** In cases of agents quoting on behalf of their foreign manufacturers, one agent cannot represent two manufacturers or quote on their behalf in a particular tender enquiry. One manufacturer can also authorize only one agent/dealer. There can be only one bid from the following:

   1. The foreign manufacturer directly or through one Indian agent on his behalf; or
   2. Indian/foreign agent on behalf of only one principal.

11. Please indicate the name and address of the agents in India if any, the details of service to be rendered by them & the percentage of commission payable to them. **Agency commission payable to the Indian Agent should be clearly indicated**. The Agency commission would be payable only in Indian Rupees after acceptance.
12. This lab/Instt Is registered with Dept. of Scientific & Industrial Research, Govt. of India and concessional customs duty and GST & IGST are leviable vide notification no. 54/2002-Customs on all imports covered under notification No.51/96-Customs dated 23.07.1996,

Notification No.47/2017-Integrated Tax (Rate) and Notification No.45/2017-Central Tax (Rate) both dated 14th November, 2017.

13. The mode of dispatch/transportation of the items must be by ***Air/Sea/Rail/Road only. (Retain one only).***
14. In case the items in the enquiry are covered by any rate contract or running contract finalized by any other state or central Government, it should be specified in your quotation and accepted contract rates should also be mentioned.
15. Delivery period required for supplying the material should be invariably specified in the quotation. The offered delivery period shall have to be strictly adhered to in case an order is placed.
16. Liquidated Damages Clause for delays: The applicable rate is 0.5% per week and maximum deduction is 10% of the contract price.
17. If the deliveries are not maintained and due to that account the purchaser is forced to buy the material at your risk and cost from elsewhere, the loss or damage that may be sustained there by will be recovered from the defaulting supplier.
18. All supplies are subject to inspection and approval before acceptance. Manufacturer warranty certificates and manufacturer/Government approved lab test certificate shall be furnished along with the supply, wherever applicable.
19. TDS would be recovered as per rules in case of Fabrication/ Servicing/ Maintenance jobs/Installation charges etc.
20. Kindly furnish your PAN & GST Number etc. in your quotation for our records.
21. Our normal payment terms are 100% (hundred percent) within 30 (thirty) days on receipt and acceptance of material at our site in good condition. Please inform your Bank details for RTGS payment.
22. All disputes shall be settled in the courts of Jammu (J&K) Jurisdiction only.
23. Tender conditions (printed on the reverse), if any, or otherwise sent along with the tender shall not be binding on us.
24. All the above instructions and our standard terms and conditions must be complied failing which your offer may be liable for rejection.
25. Instructions to Bidders, General Conditions of Contract applicable to limited tenders originating from S&P Division along with different formats can be viewed on our website http://www.iiim.res.in under the heading tenders.

Yours faithfully,

Sd/-

Store & Purchase Officer