केंद्रीय आयुर्वेद अनुसंधान संस्थान

CENTRAL AYURVEDA RESEARCH INSTITUTE

(भारत सरकार, आयुष मंत्रालय, केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्)
(Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Govt. of India)
#12, उत्तरहल्ली मनवर्तेकावल, कनकपुर मेन रोड (तलघट्टपूरा पोस्ट), बेंगलुरु -560109
12, Uttarahalli Manavarthe Kaval, Kanakapura Main Road, Thalaghattapura post, Bengaluru-560109
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F. No. 6-82/2020/CARI/BNG/AMRA/945 Date: 31-07-23

विषय: केंद्रीय आयुर्वेद अनुसंधान परिषद्, आयुष मंत्रालय, भारत सरकार द्वारा प्रायोजित बहुकेंद्रित सहयोगात्मक नैदानिक अध्ययन AMRA की तीसरे पक्ष की निगरानी के लिए कोटेशन मंगाना।

Subject: Calling for quotations from eligible individuals for third party monitoring of a multicentric collaborative clinical study "A Double-blind, Double Dummy, Randomised Controlled Study to evaluate the efficacy of Classical Ayurvedic Management versus Methotrexate in Rheumatoid Arthritis (AMRA study)" sponsored by Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India.

Brief of the study

Presently this study is carried out at three centres namely Central Ayurveda Research Institute (CARI) Bengaluru, RRAP-CARI Mumbai and Arya Vaidya Pharmacy (AVP) Coimbatore. Fourth centre at Amrita school of Ayurveda, Kollam is likely to be added. The two year study involves 240 participants distributed at participating centres. To ensure maximum quality and uniformity of the trial, robust monitoring mechanism is needed. Therefore, for the selection of clinical study monitors, sealed quotations are invited as per the specifications given at Annexure –I.

निविदा के बारे में सामान्य जानकारी/General information about the tender.

a)	निविदा दस्तावेज/फाइल संख्या Tender Document/file No	6-82/2020/CARI/BNG/AMRA/945 Date: 31- 07-2023
b)	निविदा प्राप्त करने की अंतिम दिनांक एवं समय Last date & time for receipt of Tender	14 - 08-2023, 4 PM
c)	तकनीकी बोली खोलने की दिनांक Date of opening of Technical Bid	16 - 08-2023- 2023 at 3 PM
d)	वित्तीय बोली खोलने की दिनांक Date of opening of the Financial Bid	16 - 08-2023- 2023 at 3 PM
e)	आपूर्ति के लिए अनुमत समय Time allowed for supply	One week from issue of work order
h)	निविदाएं खोलने का स्थान Place of opening of Tender	Meeting room, CARI, No.12, Uttarahalli, Manavarthe kaval, Bangalore-560 109.

1. निविदा स्पष्ट रूप से मुहरबंद लिफाफे पर "नैदानिक अध्ययन मॉनिटर के लिए बोली" लिखकर प्रस्तुत करना चाहिए।मुहरबंद निविदाएं स्पीड/पंजीकृत डाक द्वारा या हाथ से उपरोक्त पते (क्रमांक 3) तक पहुंचने के लिए नियत दिनांक और समय तक प्रभारी सहायक निदेशक (आयु.), के.आ.अ.सं., #12, उत्तरहल्ली, मनावर्ते कवल, कनकपुरा रोड, बैंगलोर - 560 109 को भेजा जा सकता है।

   Tender shall be submitted clearly super scribing on the sealed envelope "Bid for study monitor ". The sealed Tenders may be sent by speed/registered post or delivered by hand to reach the above address (Sl. No.3) to the Assistant Director (Ay.) In-charge, CARI, No.12, Uttarahalli, Manavarthe kaval, Kanakapura Road, Bangalore-560 109 by due date and time.

2. निविदा में भाग लेनेवाले फर्मों को दो बोलियां अर्थात तकनीकी और वित्तीय बोली प्रस्तुत करना चाहिए।

   Persons participating in the Tender should submit two bids i.e. Technical and Financial bid.

3. तकनीकी बोली (लिफाफा ए) और वित्तीय बोली (लिफाफा बी) को अलग-अलग मुहरबंद लिफाफों में रखना चाहिए और इन दोनों (ए और बी) को एक (01) लिफाफे में "नैदानिक अध्ययन मॉनिटर के लिए बोली" लिखना चाहिए। बोली में वाणिज्यिक नियमों और शर्तों के साथ आपूर्ति किए जाने वाले उपकरणों के सभी तकनीकी विवरण होना चाहिए। बोली में कोई ओवरराइटिंग या सुधार की अनुमति नहीं है।

   Technical Bid (Envelop A) and financial Bid (Envelop B) should be kept separately in the sealed envelopes and both these (A&B) should be kept in one (01) envelop super scribing "study monitor". Technical Bid should contain all qualification and experience details of study monitor along with supporting documents in the prescribed format. No overwriting or correction in the bid is permitted.

4. निविदा दस्तावेज सीसीआरएएस वेबसाइट www.ccras.nic.in से डाउनलोड किया जा सकता है या इस कार्यालय से कार्य दिवसों के दौरान पूर्वाह्न 10.00 बजे से अपराह्न 04 बजे तक प्राप्त किया जा सकता है।

   The tender document can be downloaded from www.cari.gov.in or www.ccras.nic.in or can be collected from this office during the working days from 10.00 a.m. to 04 p.m.

5. लिफाफे में निम्नलिखित दस्तावेज होना चाहिए/Envelope should also contain the following documents:

- A covering letter, properly filled in check list, supporting documents such as PAN, qualification and experience certificates etc.
- The undertaking clearly mentioning the following shall be furnished. (Annexure- IV)
  a) All the terms and conditions mentioned in the tender are acceptable to the bidder.
  b) The participant would abide as per the specifications prescribed by this office vide Annexure-II.

6. The tenderer should also submit a separate proposal containing their execution and monitoring plan.

7. नैदानिक अध्ययन मॉनिटर की आपूर्ति के लिए वित्तीय बोली (लिफाफा बी) संलग्नक - II के प्रारूप में प्रस्तुत करना चाहिए और प्रत्येक पृष्ठ पर मुहर लगानी चाहिए। कोई भी कॉलम खाली नहीं चोदना चाहिए। यदि किसी मद के लिए कोई दर नहीं भरी गई है तो इसे काटना चाहिए लिफाफा बी तभी खोला जाएगा जब क्रय समिति तकनीकी बोली से संतुष्ट हो।

   The financial bid (Envelope B) for study monitor should be submitted in the format at Annexure – II with stamp and signature on each page. No column should be left blank. It

should be struck off if no rate has been filled in for any item. Envelope B will be opened only if the purchase committee is satisfied with technical bid.

8. यह जनहित में प्रायोजित केंद्र सरकार की परियोजना है अतः ।कोटेशन दर उचित होनी चाहिए
   Quote should be reasonable in consideration that it is a central government project sponsored in public interest.
9. भुगतान प्रत्येक दौरे के पूरा होने के बाद और रिपोर्ट की स्वीकृति के लिए प्रायोजक से उचित अनुमोदन के साथ किया जाएगा। यदि अन्य कोई खर्च हुआ तो बिल निपटाने के लिए सहायक दस्तावेजों के साथ बिल जमा किया जा सकता है।
   The payment will be made after completion of each visit and with due approval from the sponsorer for acceptance of the report. Bill may be submitted for other periodic expenses, if incurred, with supporting documents for settling the bills.
10. उद्धृत राशि पूरे अध्ययन के दौरान लागू होगी और कोई वृद्धि की अनुमति नहीं होगी।
    Quoted amount would be applicable throughout the study and no enhancement shall be permissible.
11. निविदाकर्ता को यह कार्य किसी अन्य व्यक्ति/फ़र्म(यों) को नहीं सौंपना चाहिए।
    The tenderer should not handover this work to any other person/firm(s); it will amount to cancellation of order.

i. निविदाएं दिनांक 16 - 08- 2023 at 3 PM को अपराह्न 3 बजे संस्थान की क्रय समिति के उपस्थिति में खोला जाएगा। निविदाकर्ता या उनके प्रतिनिधि इस संस्थान के बैठक कक्ष (प्रशासनिक भवन) में निविदा खोलने में भाग ले सकते हैं।
   The Tenders will be opened on 16 - 08-2023 at 3 PM at 03 PM in the presence of Purchase Committee of the Institute. The Tenderers or their representative may participate in the tender opening in the Meeting Room (Administrative Building) of this Institute.

ii. प्रभारी सहायक निदेशक (आयु.) को बिना कोई कारण बताए किसी भी बोली को अस्वीकार/स्वीकार करने का पूरा अधिकार है।
   The Assistant Director (Ay.) In-charge has every right to cancel/reject/accept any bid without assigning any reason.

प्रभारी सहायक निदेशक (आयु.)

Annexure-I

TECHNICAL BID

M/s.

_____

_____

(Name, Address landline and Mobile Nos. of the tenderer individual bidder)

Sl. No.	Documents to be kept in the Technical Bid envelope.	Whether enclosed (The tenderer would Write (Yes) or (No) in the respective Columns
01	Copy of PAN/ Aadhar	
02	Biodata	
03	Qualification certificates	
04	Valid GCP training certificate	
04	Proof of work experience – clinical research and clinical study monitoring	
05	Declaration (as per Annexure –IV)	
06	Other relevant certificates/documents if any	

It is hereby declared that the terms & conditions of CARI, Bengaluru – 560 109 as per the letter dated _____ are fully acceptable to the tenderer.

_____

(To be signed by the authorized signatory with name and sign and seal of the tenderer)

Place: Bengaluru
Date:

Note: For any specific technical query you may contact Dr. Shubhashree M.N. (Ph. 9448016968) (only during office hours and working days)

Annexure – II

तकनीकी निर्देश/Technical specifications:

Study Medical Monitor: Essential Qualifications and Experience

1. Minimum qualification of MBBS, MD or BAMS, MD
2. 10 years of clinical research experience
3. Experience of monitoring minimum two clinical studies

Study Medical Monitor: Roles and Responsibilities

The Study Monitor is expected to visit all the study centres once in 3-4 months to assess the study progress.

- The purposes of trial monitoring are to verify that:

a) The rights and well-being of human subjects are protected.
b) The reported trial data are accurate, complete, and verifiable from source documents.
c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

- The monitor(s) in accordance with the sponsor's requirements should ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site:

a) Acting as a line of communication between the sponsor and the investigator.
b) Verifying that the investigator has adequate qualifications and resources and remain adequate throughout the trial period, that facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period.

- Verifying, for the investigational product(s):

a) That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.
b) That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).
c) That subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).
d) That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.
e) That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor.

- Verifying that the investigator follows the approved protocol and all approved amendment(s), if any
- Verifying that written informed consent was obtained before each subject's participation in the trial and after all approved amendments.
- Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).
- Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.
- Verifying that the investigator and the investigator's trial staff are performing the specified trial functions in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

- Verifying that the investigator is enrolling appropriate, eligible subjects.
- Reporting the subject recruitment rate.
- Verifying that source documents and other trial records are accurate, complete, kept up-to-date and maintained.
- Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.
- Checking the accuracy and completeness of the CRF entries, source documents and other trial-related records against each other. The monitor specifically should verify that:

a) The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents.
b) Any dose and/or therapy modifications are well documented for each of the trial subjects.
c) Adverse events, concomitant medications and intercurrent illnesses are reported in accordance with the protocol on the CRFs.
d) Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are reported as such on the CRFs.
e) All withdrawals and dropouts of enrolled subjects from the trial are reported on the CRFs.

- Informing the investigator of any CRF entry error, omission, or illegibility. The monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialled by the investigator or by a member of the investigator's trial staff who is authorized to initial CRF changes for the investigator. This authorization should be documented.
- Determining whether all adverse events (AEs) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s).
- Determining whether the investigator is maintaining the essential documents.
- Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

Annexure – III

वित्तीय बोली/Financial bid for : For study monitor

Sl. No.	Visit wise break up details (approximately 3 to 4 visits per centre in two years)	Quote in Rs.	Justification/remarks
1.	Consultancy Charges		
2.	Transport Allowance		
3.	Hotel Charges (food and stay)		
4.	Office expenses		
5.	Online monitoring		
6.	Stationery/ consumables		
7.	Others if any		
8.	Total		

स्थान/Place:
दिनांक/Date:

निविदाकर्ता के हस्ताक्षर और मुहर
Sign and Seal of Tenderer

Annexure – IV

UNDERTAKING

I/We

.....

.....do hereby declare that we have carefully read all the conditions of the tender schedule of Central Ayurveda Research Institute, Bengaluru for third party monitoring of AMRA project for two years or till the project completion or as per the decision of the competent authority. I shall abide by all the conditions set therein. I/we also declare that the details furnished above are true and if found to be false I/we shall be liable to disqualification.

Signature of the tenderer

Name:

Seal: