



Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR)

NÚM. EXPEDIENT: 2022-018 CRO SERVICES FOR (MuCCUA study / CRESCER Project)

**DOCUMENT OF TECHNICAL SPECIFICATIONS
NOT HARMONIZED TRADE – OPEN PROCEDURE**

SERVICE FOR HIRING A CRO SPECIALIZED IN THE MANAGEMENT OF PHASE I-IV CLINICAL TRIALS WHO IS IN CHARGE OF DATA MANAGEMENT, MEDICAL WRITING AND BIOSTATISCAL SERVICESFOR THE “MOTHER AND CHILD INTERVENTIONS FOR CHRONIC UNDERNUTRITION IN ANGOLA. A COMMUNITY CLUSTER AND COST-EFFECTIVENESS TRIAL” (MUCCUA STUDY) AS PART OF THE PROJECT “OPERATIVE RESEARCH AGAINST CHRONIC CHILD MALNUTRITION IN ANGOLA” (CRESCER PROJECT)-FED/2020/418-106 FROM FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON - INSTITUT DE RECERCA (VHIR).



Clause 1. Aim of the tender

The object of this tender procedure is the contracting of the service of a CRO specialized in the management of phase I-IV clinical trials, research training, capacity building and clinical trial auditing. for the data management, medical writing and biostatistical services for the study “Mother and Child interventions for Chronic Undernutrition in Angola. A community cluster and cost-effectiveness trial” (MuCCUA study) as part of the **project “Operative Research Against Chronic Child Malnutrition in Angola” (CRESCER project)**- of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR).

The selected CRO, which must have knowledge and experience with clinical trials, must be in charge of the data management, medical writing and biostatistical services of the referred community trial specifically the following tasks: development and management of the electronic Case Report Form (eCRF) and associated Completion Guidelines; final Statistical Analysis Report; and final study report.

Throughout this specification, the tasks included within the object of this contract are specifically described, as well as the scope of the proposed service.

Clause 2. Maximum budget of the tender.

In the present tender procedure, the maximum tender budget and the estimated value of the contract doesn't match.

The maximum total budget, corresponding to the total duration of the procedure, is **NINETY THOUSAND EUROS (€ 90.000,00)(*)** without VAT, plus EIGHTEEN THOUSAND NINE HUNDRED EUROS (€ 18.900,00) corresponding to VAT, which adds up to the amount of **ONE HUNDRED EIGHT THOUSAND NINE HUNDRED EUROS (€ 108.900,00)**.

(*) Price that the tenderer, will be able to improve in the ECONOMIC OFFER.

The estimated value for this tender is **ONE HUNDRED EIGHT THOUSAND EUROS (€ 108.000,00)**, plus the TWENTY-TWO THOUSAND SIX HUNDRED AND EIGHTY EUROS (€ 22.680,00) corresponding to VAT, a total of **ONE HUNDRED THIRTY THOUSAND SIX HUNDRED EIGHTY EUROS (€ 130.680,00)**.

| Concept | Price (VAT not included) |
|------------------------|---------------------------------|
| Maximum budget | 90.000,00 Euros |
| Possible modifications | 18.000,00 Euros |
| Possible extensions | 00,00 Euros |
| Total | 108.000,00 Euros |



Amount established for modifications

In accordance with article 204 of L9/2017, the possibility of modifying the contract, and up to 20% of the total maximum bidding budget given that the possibility of an increase in the price of licenses derived from the fluctuation of the market in the time of hiring. Amount that will be paid to the company in the same way and under the same conditions that regulate this specification, prior presentation by of the recipient of the invoice.

In no case will the estimate of the volume in the provision of the service be binding, the VHIR will pay the invoices for the service actually provided, detailing on the invoice the delivery note numbers duly signed.

*** The service must comply with all legal requirements at the time of the hiring, and throughout the term of the contract.

Clause 3. Duration of the contract.

The duration of the service object of this tender will coincide with the validity of the aforementioned project, which is until **February 14 of 2025**, the completion date of the project's "Operative Research Against Chronic Child Malnutrition in Angola" (CRESCER project).

However, if this project were to be found, for any of the reasons that are not now can foresee, subject to the request of a possible extension, the end date will be susceptible to being extended, at most to the one that is finally authorized.

Clause 4. Description of the service and scope of the object of the contract.

The CRO that provides data management, medical writing and biostatistical services to the community trial must be specialized in clinical trials. Experience in the preparation and management of related documentation will be valued.

STUDY INFORMATION:

The study is conceived as a community trial, controlled, open, randomized by conglomerates (cluster), with 3 intervention arms grouped by block, in 2 provinces of southern Angola: Huíla and Cunene.

- Standard Intervention
- 2 x Southern Angolan Provincial sites



- 720 female participants in Huila Province and 720 female participants in Cunene Province, Southern Angola i.e., a total of 1440 participants
- Study period from recruitment start to close-out visits of 33 months

EXPERIMENTAL INTERVENTIONS:

- **STANDARD INTERVENTION:** The Standard package includes a series of actions related by Community and Health Development Agents (ADECOS), which are characterized by having demonstrated in the scientific literature strong evidence of its effectiveness and are part of WHO and national health guidelines in different countries, including Angola.
- **STANDARD+NUT Arm:** Standard Intervention plus nutritional supplementation.
- **STANDARD+MT Arm:** Standard intervention plus money transfers.

NEXT ACTIVITIES:

- Recruitment and baseline visits;
- Entry of the first patient in the study;
- 50% of recruited patients;
- 100% of recruited patients;
- Close-out visits;
- Analysis and final report of the study;
- Publication.

Clause 5. General Conditions.

DATA MANAGEMENT

- DM protocol review
- eCRF development (two drafts, one final)
- Set-up and testing of the EDC platform
- Compilation of the following study documents (two drafts, one final and updates during study period, if required):
 - Data Management Plan
 - eCRF Completion Guidelines
 - Data Validation Plan including Edit Check Specifications
- Edit check programming
- Provision of EDC training
- Provision of user access to the EDC



- Setup of the Data Management Master File
- Project Management
- Data cleaning and validation (including query management)
- Maintenance of user access
- Maintenance of the Data Management Master File
- Monthly reporting
- EDC user support
- Ongoing maintenance and quality control of the EDC
- Database lock activities
- Database lock and data transfer to statistician
- Prepare DM files for archiving with Sponsor

BIostatistical Services

- Statistical analysis plan
- Final statistical analysis report
- Final Study Report / Publication

Medical Writing

- Final Study Report
- Publication

Clause 6. Billing and payment.

The contractor will invoice the service through its corresponding monthly invoice, which must be sent to the following email address: factures@vhir.org

Each invoice issued must detail the period to which it corresponds, the breakdown / description of expenses by concept, as well as indicate the references “**LICI-2022-018 CRO SERVICES FOR (MuCCUA study / CRESCER Project)**”.

The effective payment of the executed services will be made by bank transfer, with a maturity of 30 days / invoice date.

The contracting entity pays for the services once they have been carried out in part or in full and once the invoice has been entered in its register. According to this parameter, the advance payment of part or all of the contract price is not contemplated.

Under no circumstances will the contractor be entitled to a price review for any reason.



The VHIR will only pay the successful bidder for the services actually provided, without, in any case, the VHIR being obliged to exhaust the estimated value of the contract/bid budget.

Clause 7. Responsible for the contract.

The person in charge of the contract will be Israel Molina the Head of VHIR's Infectious Diseases Group, who will basically have the functions of management and supervision of the contracts and the billing; follow-up, control and provide instructions for the good execution of the agreements; determine whether the performance conforms to the prescriptions established for its execution, reception of the order after its completion and comply with the obligations assumed by VHIR

Clause 8. Location and Service Provision Hours.

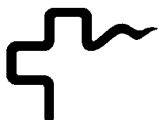
- The contractor will provide online services free of charge during business hours.
- Business hours are from 9:00 to 18:00, South Africa time. (the supervision of working hours will be carried out by the group responsible for the CRESCER project.).
- Travels can be performed upon the request of the investigational team.

Clause 9. Confidentiality, Protection of personal data and Intellectual and Industrial Property

Notwithstanding the provisions of the current legislation on intellectual property, protection of personal data and confidentiality, the companies awarded in this call for tenders will expressly commit to not giving the information and / or data provided by VHIR, or any use not provided in this bidding document, and / or expressly authorized by the Head of the Research Grants Office.

The company that awards the contract derived from this bidding will have to extend to their employees the obligations assumed by the awarded company, regarding confidentiality, intellectual property and protection of data.

All rights worldwide will be exclusively granted to VHIR for the maximum time established in applicable laws and / or international treaties for their exploitation through any format and / or exploitation modality, including the exploitation of any discovery, invention, creation, work, procedure, idea, technique, drawing, design, image or any other intellectual or industrial property right generated, raised or acquired as a consequence of the work carried out by the contracting company (hereinafter "Intellectual Property and / or Industrial"), which



derives directly or indirectly from the relationship between VHIR and the company awarded in this tender procedure.

The awarded company must inform VHIR of any discovery, creation, invention, idea or any other element that constitutes or is likely to constitute a right of Industrial and / or Intellectual Property partially or totally developed during the contract period.

In the event that the awarded company discovers or develops any creation of intellectual or industrial property, it will be understood that the discovery or development constitutes confidential information of VHIR.

The awarded company must sign all those public and / or private documents that are necessary, in VHIR's discretion, to allow the accreditation of the ownership of VHIR or the proper protection of the aforementioned Intellectual Property and / or Industrial rights in favor VHIR or any designated third party.

The awarded company authorizes VHIR for the transformation, modification, publication, public communication and exploitation by any means of the work resulting of the execution of the contract derived from this tender procedure.

Cláusula 10. Criterios de Valoración sometidos a Juicio de Valor.

Each bidder must provide a technical as well as a financial offer. The contracts will be awarded according to criteria based on an approach that meets the best relationship cost-effectiveness, a circumstance that will be evaluated according to the following criteria:

1. FINANCIAL OFFER..... up to 50 points.

It will be valued automatically, in accordance with the following formula:

$$P(N) = M \times (2 - N/B)$$

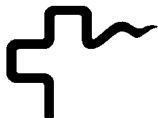
P(N): Score of offer N

M: Maximum possible score

B: Best offer submitted

N: Offer to be valued

If after having applied the automatic formula to a submitted offer, the resulting value is negative, zero (0) points will be assigned directly from the economic part. **P(N) = 0.*



The following criteria will be evaluated through value judgments. The award criteria for assessing the contents of envelope No. 2 are as follows:

2. TECHNICAL OFFERup to 50 points.

2.1 Drafting of work proposal..... (up to 40 points).

It must include:

- Activities plan.
- Timelines.
- Quality and control plan, which includes a system of indicators for the evaluation of partial results (follow-up of visits, drafting of reports summarizing the achievements, next steps, etc.)

2.2 Memory of experience.....(up to 10 points).

Bidders must present a report of experience explaining their participation in clinical trials.

- Memory of experience;
- CV of the responsible Project manager.

Barcelona, March 17 of 2022.

CONTRACTING ENTITY

Dr. Joan X. Comella Carnicé

Director

Fundació Hospital Universitari Vall Hebron– Institut de Recerca (VHIR)