



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

Record N°: 2024-072 CRO SERVICES FOR (MuCCUA study / CRESCER Project)

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

SERVICE FOR A CRO SPECIALIZED IN THE MANAGEMENT OF PHASE I-IV CLINICAL TRIALS WHO IS IN CHARGE OF DATA MANAGEMENT, MEDICAL WRITING AND BIOSTATISCAL SERVICES FOR 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).



**Funded by
the European Union**

Clause 1. Aim.

The purpose 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 and Data Management; final Statistical Analysis Report (SAR); final Clinical Study Report (CSR); and Publication.

The division of the object of the contract into lots is not considered convenient, since given the technical characteristics of the service, the division into lots would make the execution of the contract excessively difficult from the technical and quality control points of view, and the need to coordinate the different contractors for the different lots could entail the risk of jeopardizing the adequate execution of the contract according to the international standards for clinical trials.

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.

The estimated value and maximum budget for this tender are not the same.

The maximum total budget, corresponding to the total duration of the procedure, is set at **"FIFTY THOUSAND EUROS" (50.000,00 €) (*)**, which, if we add the amount corresponding to VAT, "TEN THOUSAND FIVE HUNDRED EUROS" (10.500,00 €), makes a total of **"SIXTY THOUSAND FIVE HUNDRED EUROS" (60.500,00 €)**.

(*) Prices that the tenderer may improve in its economic offer – [Envelope number 3](#)

Therefore, the estimated value of the contract is established at **"SIXTY THOUSAND EUROS" (60.000,00 €)**, which, if we add the amount corresponding to VAT, "TWELVE THOUSAND SIX HUNDRED EUROS" (12.600,00 €), makes a total of **"SEVENTY-TWO THOUSAND SIX HUNDRED EUROS" (72.600,00 €)**.

Concept	Price (VAT not included)
Maximum budget	50.000,00 euros
Possible modifications	10.000,00 euros
Possible extensions	00,00 euros
Total	60.000,00 euros

Amount established for modifications:

In accordance with article 204 of the L9/2017, the possibility is established of modifying the contract upwards, and up to 20% of the maximum total tender budget. This amount will be paid to the company in the same way and under the same conditions that regulate the present specifications.

The reasons foreseen for carrying out the modification are the following:

- Significant increase in the number of VHIR's employees.
- Development of new ad-hoc modules

In no case will the maximum tender budget be binding, but the VHIR will pay the invoices for the services actually carried out on the basis of the unit prices finally awarded.

Clause 3. Duration of the contract.

The term of this service shall coincide with the term of the above-mentioned project, i.e., until July 15th, 2026.

In the case that the extension is agreed by the contracting entity, it will be obligatory for the contractor, in accordance with the provisions of Article 29 of the LCSP.

The initiation of the contract shall be on the day following the date of formalization of the contract.

Clause 4. Technical characteristics of the service.

The CRO that provides data management, medical writing and biostatistical services to the community trial must be specialized in clinical trials.

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 36 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 (control arm).
- **STANDARD+MT Arm:** Standard intervention plus money transfers.

NEXT ACTIVITIES:

- Follow-up visits;
- Close-out visits;
- Analysis and final report (CSR) of the study;
- Publication.

DATA MANAGEMENT

- DM protocol regular reviews
- eCRF maintenance
- Update/Review of the following study documents/systems):
 - 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
- 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
- Statistical analysis
- Final Statistical Analysis Report
- Final Clinical Study Report (two drafts; one final version in English)
- Publication (two drafts; one final version in English accepted by an international journal in accordance with VHIR recommendations)

MEDICAL WRITING

- Final Clinical Study Report (two drafts; one final version in English)
- Publication (two drafts; one final version in English accepted by an international journal in accordance with VHIR recommendations)

Clause 5. Location and Schedule

Location:

The service will be carried out telematically and communication with the company will be maintained via email and telephone calls.

Timetable:

The service will be provided from Monday to Friday from 9am to 5pm.

Clause 6. Billing and payment

According to Law 25/2013, of December 27, 2013, on the promotion of electronic invoicing and the creation of the accounting registry of invoices in the Public Sector, in its Article 4, *"All suppliers who have delivered goods or provided services to the public administration may issue and send electronic invoices. In any case, they will be obliged to use the electronic invoice and to submit it through the corresponding general entry point..."*.

The awarded company will invoice electronically the services actually performed. The DIR3 codes to be able to issue the invoice are the following:

DIR3	ACCOUNTING OFFICE	DIR3	MANAGING BODY	DIR3	PROCESSING UNIT
A09006467	Fundació Hospital Universitari Vall d'Hebron- Institut de Recerca (HUVH IR)	A09006467	Fundació Hospital Universitari Vall d'Hebron- Institut de Recerca (HUVH IR)	A09006467	Fundació Hospital Universitari Vall d'Hebron- Institut de Recerca (HUVH IR)

The invoice will be issued monthly. In no case will the maximum amount be binding on the VHIR, but only the supply and service actually provided will be paid based on the prices finally awarded.

Each invoice issued must detail the period to which it corresponds, the breakdown/description of expenses by concept and the internal account that should be charged, as well as indicate the references **"L 2024-072"**.

In the event that the issuance of the electronic invoice is not feasible for exceptional reasons, the contractor will invoice each service rendered through its corresponding invoice, which must be sent to the following e-mail address: factures@vhir.org

The effective payment of the executed services will be performed by bank transfer, due 30 days / invoice date.

The contracting institution will make the payment of the supplies once they have been fully performed and once the invoice has been entered into its registry. In accordance with this paragraph, advance payment of part or all of the contract price is not contemplated.

In no case, the contractor will have the right to the revision of prices pertaining to any concept.

Therefore, the contracting entity will make the payment of the invoices using the currency conversion according to the common practices that the entity carries out in this type of case, so said payment will be made at the time of payment of the invoice.

The VHIR's fiscal data that must be included in the invoice are the following:

FUNDACIÓ HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA
VAT: G-60594009
Passeig Vall d'Hebron, 119-129
08035 Barcelona

In the event that the invoice is not issued in accordance with the criteria established and referenced at the beginning of this clause, payment will not be made and the invoice will be withheld until the requested data is correctly indicated.

In case of electronic invoicing, this will be rejected until the requested data is not correctly indicated.

Once the contract ends, including any extensions that may be executed, VHIR will only accept invoices issued after the end of the contract as long as the period of execution of the same is within the term of the tender.

In the event that the invoice is issued after the end of the contract and in accordance with the above paragraph, VHIR will only pay invoices issued within two (2) months after the end of the contract.

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 is Israel Molina the Head of the Infectious Diseases Group of the Fundació Hospital Universitari Vall d'Hebron - Institut de Recerca, who will be basically responsible, among others, for the functions of management and supervision of the contracted supply, conforming the invoicing issued by the service; monitoring, control and dictation of the instructions necessary for the proper execution of the contract; determine whether the service provided complies with the requirements established for its

execution and compliance and receipt of the contract at the end, and comply with the obligations assumed by the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR) in this contract.

Clause 8. Confidentiality, Protection of personal data, and Intellectual Property

Notwithstanding the provisions of current legislation on intellectual property, protection of personal data and confidentiality, the successful bidder will expressly commit itself not to provide the information and / or Data provided by the VHIR, or any use not provided for in this document, and / or expressly authorized by the Head of the assigned Unit.

The successful bidder will have to extend to the employees that adhere to the service, the obligations contained and assumed by the successful bidder, with reference to confidentiality, intellectual property and protection of Data, in particular those relating to the secret, the reservation and confidentiality of all the information that, under the service, may be aware of.

These will be understood as being exclusively granted in favor of the VHIR worldwide, for the maximum time established in applicable laws and / or international treaties that are applicable and for their exploitation through any format and / or modality of exploitation, all rights, 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 company awarded the contract that is derived from this tender procedure (hereinafter, "Intellectual and / or Industrial Property"), and which derive directly or indirectly from the relationship between VHIR and I The company awarded by the contract that is derived from this tender procedure.

The company that awards the contract that is derived from this tender procedure undertakes to inform the VHIR of any discovery, creation, invention, idea or any other element that constitutes or is likely to constitute a right of Industrial Property and / or Intel Legal and that develops partially or totally during the term of the contract that is derived from this tender procedure. In the event that the contracting company that derives from this tender procedure discovers or develops any creation of intellectual or industrial property, it will be understood that the discovery or development constitutes confidential information of the VHIR.

The company that awards the contract that is derived from this tender procedure undertakes to sign all those public and / or private documents that are necessary, at the discretion of the VHIR, to allow the accreditation of the ownership of the VHIR or the proper protection of the aforementioned rights of Intellectual Property and / or Industrial in favor of the same or of any third party designated by it.

The company that awards the contract that is derived from this tender procedure authorizes the VHIR for the transformation, modification, publication, public communication and exploitation by any means of the works that it develops as a result of the execution of the contract that is derived from it This tender procedure.

Clause 9. Allocation criteria

1. Criterios evaluables mediante fórmulas automáticas	Maximum 51 points
- Economic Offer	Maximum 31 points
- Automatic Evaluation Criteria	Maximum 25 points
2. Criteria evaluated by means of value judgment	Maximum 49 points

9.1 Criteria that can be assessed through automatic formula.....(maximum 51 points)

9.1.1 ECONOMIC OFFER.....up to 31 points

$$P_v = \left[1 - \left(\frac{O_v - O_m}{IL} \right) \times \left(\frac{1}{VP} \right) \right] \times P$$

- P_v = Bid Score to Rate
- P = Economic criteria points
- O_m = Best Offer
- O_v = Offer to be Valued
- IL = Bid Amount
- VP = Weighting Value = 1

**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. $P_v = 0$.*

9.1.2 AUTOMATIC EVALUATION CRITERIA.....up to 20 points.

- Experience in clinical trial management (minimum 10 years) certified by scientific articles, institutional presentations and/or other documents of public access10 points
- Data Management system as per international quality standards certified by proper documentation.....10 points

9.2 Criteria evaluated by means of value judgment.....(up to 49 points)

The criteria indicated below will be evaluated by means of value judgments and will be applied to the contents of Envelope No. 2. will be applied to the contents of envelope nº 2:

The technical proposal will be evaluated in relation to the criteria subject to value judgments, according to the numerical values established for each criterion and sub-criteria in the Tender Document. the numerical values established for each criterion and sub-criterion in the Specific Administrative Clauses of Particular Administrative Clauses and in the Technical Specifications, and the different proposals will be the different proposals evaluated shall then be ordered in decreasing order, and the following formula shall be applied to obtain the following formula to obtain the following formula to obtain the following formula to obtain the following formula the following formula shall be applied to obtain the score,

$$P_{op} = P \times \frac{VT_{op}}{VT_{mv}}$$

P_{op} = Score of the offer to be scored.

P= Score of the criterion

VT_{op} = Technical Evaluation of the Bid to be Scored.

VT_{mv} = Technical Evaluation of the Highest Scored Bid.

9.2.1 Qualitative and technical features of the service.....(up to 49 points)

Work proposal..... (up to 40 points)

It must include:

- Activities plan and detailed description of the services (15 points)
- Quality and control plans, 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.) (11 points)
- Timelines and events schedule (07 points)
- Detailed description of the eCRF system(07 points)

Memory of experience.....(up to 09 points)

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

- Presentation of the organization ("About" information) (02 points)
- Memory of experience (05 points)
- Data Manger and Statistician CVs and a brief presentation of the team... (02 points).

In order to apply the formula established in Directive 1/2020 on the Application of Formulas for the Evaluation and Scoring of Economic and Technical Proposals, the threshold for each criterion and sub-criterion proposed to be evaluated and subsequently scored is as follows:

- Work proposal: 20 points
- Memory of experience: 4,5 points

Therefore, there are two possible options with respect to the function of this threshold depending on whether none of the bids exceeds it (option 1) or at least one of the technical bids exceeds it (option 2).

Option 1 - If no evaluation of the bids exceeds the minimum threshold value, all bids score the value obtained in the evaluation phase and none are excluded from the bidding process.

Option 2- If any evaluation of the bids exceeds the threshold, all bids are evaluated and no company is excluded from the scoring phase, nor from the bidding process.

In the event that only one bidding company is submitted to the tendering procedure, the formula presented in the technical aspects will not be applicable for this one, the results obtained after the subjective evaluation by the person in charge will be sufficient.

IMPORTANT NOTE: A minimum total score of **27 points** in the technical evaluation, after application of the formula if applicable, is required for the bidder to continue in the selective process. Failure to obtain at least 30 points in the technical bid will result in exclusion from the bidding process.

Barcelona, December 12th of 2024

CONTRACTING ORGANISM

Mrs. Montserrat Gimenez Prous

Manager

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