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**NECESSITY REPORT TO ESTABLISH THE CONTRACTING OF THE 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 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).**

**2024-067 CRO SERVICES FOR (MuCCUA study / CRESCER Project)**

Dr. Israel Molina, IP of the communicable diseases' group of the Fundació Hospital Universitari Vall d'Hebron - Institut de Recerca, proposes that the corresponding file be included for 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).

Since given the technical characteristics, the specialized systems, and the international quality control standards that are essential for the adequate execution of the project activities, VHIR requires the contract of this service.

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 duration of the service object of this tender will coincide with the validity of the aforementioned project, which is until July 15<sup>th</sup>, 2026, the completion date of the project's “Operative Research Against Chronic Child Malnutrition in Angola” (CRESCER project).

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

The total maximum budget is FIFTY THOUSAND EUROS" (50.000,00 €), VAT exempted.

In view of all of the above,

**IT IS HEREBY DECIDED:**

1.- To order the opening of the tender file for 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



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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 maximum budget for this tender is set at 50.000,00€ VAT exempted.

2.- To order the certification of the existence of sufficient credit to certify that the VHIR has a sufficient budgetary endowment to face the expenses arising from this tender file.

3.- To draft the Specific Administrative Bidding Conditions and Technical Specifications in accordance with the provisions of the aforementioned Law.

Barcelona, on the digital signature date.

DocuSigned by:  
*Israel Molina*  
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7/11/2024 | 13:20 PST

**RESPONSIBLE**

**Dr. Israel Molina**

IP of the communicable diseases' group of the Fundació Hospital  
Universitari Vall Hebron - Institut de Recerca (VHIR)