

AGREEMENT ON THE NEED, SUITABILITY AND SHORTFALL IN RESOURCES OF THE TENDER FILE TO SET THE HIRING OF A CRO SPECIALIZED IN THE MANAGEMENT OF PHASE IN 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).







2022-028 CRO SERVICES FOR (MuCCUA study / CRESCER Project)

Mr. Israel Molina Head of the Infectious Diseases Group of the Fundació Hospital Universitari Vall d'Hebron- Institut de Recerca, has proposed a tender file for "THE CONTRACTING OF 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)."

The mandate of the Board of Trustees and the Board of Directors of the VHIR is to ensure the continuity and correct development of projects entrusted to this entity, seeking to find formulas to optimize internal functioning and management. In this regard, and in order to avoid affecting the aforementioned project throughout its duration and ensuring its continuity and optimization based on the specific and ever-changing requirements of the pursuit of excellence sector, it has been decided to make this procedure regarding 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), to ensure that the services provided are economically viable and with the best value for money over a long period of time.

The duration of the service object of this tender will coincide with the validity of the aforementioned project, which is until <u>February 14 of 2025</u>, 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.





The maximum approved budget for the tender for the provision of the services for to the total duration of the procedure, is **NINETY THOUSAND EUROS** (€90.000,00) without VAT.

The contracting entity will not be obliged to exhaust the entire base budget for the tender, but will only be billed for the services actually executed based on the prices offered by the contractors.

In view of the need to carry out an open procedure with ordinary processing and non-harmonized regulations as per the criteria of Law 9/2017, of 8 November, on Public Sector Contracting, whereby Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014, are transposed into Spanish law.

In view of all of the above,

IT IS HEREBY DECIDED:

- 1.- To order the opening of the tender file for the HIRING OF 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). The maximum budget for this tender is set at € 90.000,00 without VAT.
- 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, April 28th of 2022.

THE CONTRACTING ORGANISM

Dr. Joan X. Comella CarnicéDirector
Fundació Hospital Universitari Vall Hebron
- Institut de Recerca (VHIR)

RESPONSABLE

Mr. Israel Molina Romero Head of the Infectious Diseases Group Fundació Hospital Universitari Vall d'Hebron- Institut de Recerca (VHIR)