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REQUEST FOR PROPOSALS

SPECIFIC AND TECHNICAL CONDITIONS FOR THE CONTRACTING OF A SUPPLIER TO DEVELOP AN APP THAT INTEGRATES THE INFORMATION OBTAINED THROUGH THE X-TREM DEVICE WITH CLINICAL DATA AND VITAL SIGNS AVAILABLE FROM THE PATIENT FOR THE ACROBAT PROJECT (FILE NUM. 56-2025)

I. Purpose

The purpose of this Request for Proposals is to invite suppliers to submit proposals for the development of an app (Clinical Risk Assessment App - CRA App) that integrates the information obtained through the X-Trem device with clinical data and vital signs available from the patient for the project "Appraising the Critical Role of prognostic Biomarkers in the Assessment and Triage of sick African newborns: Advancing a point-of-care device based on sTREM-1 towards CE marking and implementation - ACROBAT" with official number 101158797 founded by The European Commission.

All the technical specifications contained in this document are considered to be part of the minimum requirements and do not exclude any other needs for compliance with the purpose of the service contracted.

II. Scope

Background

The main concern of clinicians when addressing sick patients is to promptly identify - i.e., "not miss"- those at higher risk of severe disease, so as to prioritize their care and better target therapeutic interventions. Unfortunately, risk stratification practices for

infections remain suboptimal and prone to misclassification and misallocation of resources, particularly in children from Low- and Middle-Income Countries (LMICs). We aim to validate a point-of-care (POC) rapid test, named X-Trem, for risk-stratification of the sick newborn, the age-group concentrating ~50% of all mortality in children below 5 years-old, and particularly affected by severe infections and sepsis. X-Trem has been developed by our team through the Horizon-EU project EChiLiBRiST, which aims to enhance triage of febrile children in Sub-Saharan Africa (SSA). Our device is based on a biomarker of sepsis and prognosis, called sTREM-1 (soluble Triggering Receptor Expressed on Myeloid Cells 1), which stands out as a quantitative and independent predictor of severity and death in all-cause infections, being superior to other markers and clinical scores.

Interestingly, sTREM-1 has also been studied for risk-stratification of non-communicable diseases. Hence, we propose that measuring sTREM-1 in the sick newborn at first clinical presentation could determine, objectively and with high precision, those at risk of severe outcome, irrespective of the underlying aetiology, and with greater accuracy than any existing triaging approach.

X-Trem, based on a magneto-actuated immunoassay, is a rapid (20min), inexpensive and handheld POC device for quantitative assessment of sTREM-1, using only two drops of blood. Levels of sTREM-1 are displayed as concentration and automatically classified as low, moderate, or high-risk of death, similarly to a traffic-light system.

ACROBAT-newborns is the natural and ambitious next step to continue and accelerate the valorisation of our device, the industrialization of its prototype and its go-to market strategy, so that we ensure it reaches SSA markets, where it could have more impact. ACROBAT-newborns includes a clinical study in Mozambique, Ethiopia, Uganda and Gabon, as well as strong components of health economics, health impact assessment, socio-behavioural sciences (including usability, acceptability, and feasibility studies), with the overarching aim of generating the necessary data to support X-Trem introduction to the market. By introducing our device for enhanced risk-stratification of the sick newborn, we could improve outcomes and survival, as well as optimize use of healthcare resources, including antibiotics and high value therapeutics.

ISGlobal's (Barcelona Institute for Global Health) mission is to improve global health and promote health equity through excellence in research and the translation and

application of knowledge. To achieve this goal, we will require the support from a supplier to develop an App (Clinical Risk Assessment App - CRA App) that integrates the information obtained through the X-Trem device with clinical data and vital signs available from the patient.

In the framework of the ACROBAT-Newborns project (https://acrobatnewborns.eu/), ISGlobal is leading fieldwork amongst four Sub-Saharan countries to recruit neonates to appraise the critical role of prognostic biomarkers in the assessment and triage of sick African newborns.

Object of the procurement

ISGlobal is looking for a supplier laboratory to develop an App (Clinical Risk Assessment App - CRA App) that integrates the information obtained through the X-Trem device with clinical data and vital signs available from the patient.

The key deliverables are:

- To develop of an app (Clinical Risk Assessment App - CRA App) that integrates the information obtained through the X-Trem device with clinical data and vital signs available from the patient.
- To design and develop an Artificial Intelligence algorithm that provides a predictive value for the evolution at 48 hours, 28 and 90 days to guide patient management.
- To evaluate the performance of the Artificial Intelligence predictive model for risk-stratification of (all-cause) neonatal sick patients.
- To integrate the developed Artificial Intelligence model into the CRA App to provide real-time predictive capabilities.

III. Contract Responsible

ISGlobal will appoint a person responsible for relations with the supplier (the "Contract Responsible"), who will coordinate with the entity's staff and who will channel communications between the two parties.

IV. Management of work and quality control

ISGlobal and the supplier representative will establish by common agreement a calendar of communications that will consist of monthly progress calls.
Regardless of these scheduled calls, the Contract Responsible and the project management team may meet at any time if any of the two parties considers it appropriate, depending on the progress of the work hired. At any meeting the responsible person may choose to bring additional participants from ISGlobal if considered convenient. Frequent reports will be provided by the awarded supplier.

V. Required qualifications

The supplier should meet these requirements;

- Demonstrated experience in the development of App in the context of health care.
- Extensive experience in Artificial Intelligence models to guide clinical decisions.
- Adequate capacity to develop tools for biomedical data analysis.
- Previous experience in projects related with technological development in the context of LMIC is preferred.

Notice: The proposals received will be evaluated according to the level of compliance with the requirements, which can be found in Annex I.

VI. Period of execution and delivery of reports

The execution of the work will be carried out over a period of 48 months. The current agreement would cover the 48 months, provided ISGlobal is successful in delivering the data and input required for the development of the App and related Algorithm.

VII. Essential contractual obligations

The following will be considered as essential obligations of the awarded supplier:

- Ensuring real-time processing capabilities while maintaining data privacy and security standards.
- Report any problems encountered during analyses.
- Frequent report on progress of the work.

- Delivery of final results

VIII. Duration and start date

The duration of the contract will be of 48 months.
The estimated start date of the contract is October 1, 2025.

IX. Estimated value

The contract budget is set to a maximum amount of 125.000,00 Euros, excluding taxes. The amount will not exceed this budget in any case. Consequently, for non-exempt suppliers, the final price of the contract will be the budget amount plus the corresponding Value Added Tax (VAT).

X. Method of payment

The supplier will periodically provide reports on the development of the App and the related algorithm. Payment will always be made upon invoice, within 30 days of invoice date, by bank transfer, proposed calendar of payments:

- First payment (signing of contract): 30%
- Second payment (CRA App delivered): 30%
- Third payment (Final Artificial Intelligence Model Deployed): 20%
- Final payment upon completion of work and end of maintenance period: 20%

XI. Advertising

The present Request for Proposals document will be published in the Suppliers section of the contracting entity's website: https://www.isglobal.org/en/contrataciones

XII. Procurement procedure:

The selection procedure will be made complying with the internal procurement regulations of the contracting entity, as provided in sections VIII and IX of the Procurement Manual.

XIII. Nature of the contract

This contract is considered a private contract and is subject to private law, governed by the contract and attached documentation, and by the applicable civil and commercial legislation.

XIV. Submission of proposals

Interested applicants are invited to submit a comprehensive proposal, addressing the needs described in the Request for Proposals document, to the following e-mail address: contrataciones@isglobal.org

Proposals must be sent in one single consolidated document in PDF format.

The deadline for the submission of proposals is set on October 9, 2025, at 15:00 h (CET).

Barcelona, September 23th , 2025

ANNEX 1 - AWARD CRITERIA
(FILE N.º 56-2025)

The proposals received will be evaluated according to the level of compliance with the requirements requested by ISGlobal:

1. AWARD CRITERIA TO BE EVALUATED BY VALUE JUDGMENT AND CONTENT OF BIDS ……..... Up to 20 points

The supplier must submit a proposal describing the following topics:

(i) The detailed workplan on delivered results
(ii) how the data collected from the clinical studies will be incorporated in the App
(iii) how will the supplier ensure real-time processing capabilities while maintaining data privacy and security standards
(iv) how troubleshooting and/or technical support will be provided, and
(v) how are identified the potential risks and how the mitigation plan is proposed.

The proposal must be written in a maximum of 8 pages in Arial 12 font, single spaced

The proposal will be evaluated according to the following criteria:

- **from 14 to 20 points**: The proposal is consistent. It is adapted to the needs of the project. It is a proposal that considers and concretizes the appropriate information for the development of the project.
- **7 to 13 points**: The proposal is correct. It adapts to the needs of the project, but the proposal leaves doubts and shows aspects that are underdeveloped or ambiguous. It deals in a generic way with the development of the project.
- **1 to 6 points**: The proposal is deficient. Relevant technical aspects are poorly developed or ambiguous and are not adapted to the development of the project.
- **0 points**: The proposal does not refer to the requested tasks. Critical technical aspects are not adapted to the needs of the project. The supplier's vision is vague and inconsistent.

2. AWARD CRITERIA EVALUABLE BY AUTOMATIC FORMULAS ..... Up to 80 points

a. THE BID PRICE WILL BE SCORED AUTOMATICALLY BY THE FOLLOWING FORMULA ……. Up to 75 points

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

Where:

Pv= Score of the offer to be valued

P = Economic criterion points

Om = Best Offer

O = Offer to Value

IL = Bid Amount

VP = Weighting Value, set at 2.

b. OBJECTIVE CRITERIA BASED IN EXPERIENCE ……. Up to 5 points

Demonstrated experience in developing App to integrate results with clinical data to guide patient's management currently on the market.

5 points: 5 or more Apps
4 points: 4 apps
3 points: 3 apps
2 points: 2 apps
1 point: 1 apps
0 points: 0 apps

The determination of experience will be completed with the list of applications developed by the provider.