



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

EXPEDIENT NUMBER: NEG 2026-006 CRO SERVICES (EAST-STROKE PROJECT, POC4TRIAGE PROJECT)

**DOCUMENT OF TECHNICAL SPECIFICATIONS
HARMONIZED TRADE – UNPUBLISHED NEGOTIATED PROCEDURE - URGENT
PROCEDURE**

CONTRACTING OF A CLINICAL RESEARCH ORGANIZATION (CRO) FOR THE PROVISION OF MANAGEMENT, COORDINATION, MONITORING, AND QUALITY CONTROL SERVICES FOR CLINICAL TRIALS WITHIN THE FRAMEWORK OF THE EAST-STROKE AND POC4TRIAGE PROJECTS FOR THE STROKE GROUP OF THE FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON - INSTITUT DE RECERCA (VHIR), DIVIDED INTO 2 LOTS



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la Unión Europea**

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Clause 1. Aim of the tender

The aim of this tender procedure is to contract a Clinical Research Organization (CRO) for the provision of management, coordination, monitoring, and quality control services for clinical trials as well as deployment of a Digital platform for treatment adherence and integrated systematic outcome data collection within the framework of two European Project, for the Stroke Unit of the Fundació Hospital Universitari Vall Hebron – Institut de Recerca (VHIR):

1. EASTSTROKE: Early treatment of Atrial fibrillation for Stroke prevention Trial in acute STROKE (101156541)
2. POC4TRIAGE: Point-of-Care Devices for Urgent Care Triage (101137358)

The Vall d'Hebron Research Institute (VHIR), through its Stroke Research Group, acts as a primary clinical lead. The CRO will be responsible for operationalizing the clinical validation protocols designed by the clinical coordinator of the consortium, ensuring that the transition from "prototype" to "clinically validated tool" meets all European regulatory standards.

Both for East-stroke than for POC4triage projects 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:

- Regulatory submissions and resubmissions (AEMPS-Agencia Española del Medicamento y Productos Sanitarios); CEICs- Ethical Committees and, if required CTIS- Clinical Trial Information System).
- Management of the Electronic Case Report Form (eCRF) and associated Completion Guidemines and Data Management
- All monitoring tasks till close out.
- Beside that for the East-Stroke project, the CRO must coordinate with the central German CRO contracted by the coordinator for document and files maintenance, final statistic analysis Report (SAR); final Clinical Study Report (CSR); and publication among others

To maintain strict adherence to the distinct regulatory requirements and operational workflows of the underlying European-funded initiatives, this contract is divided into two lots. This structure allows for precise alignment with the individual project plans and ensures the integrity of the separate financial reporting lines required by the grant authorities.

This tender is structured into **two Lots** also to ensure the specialized management and execution of services tailored to two independent projects. The tender is therefore divided into the following Lots:

1. Lot 1: EAST-Troke Project
2. Lot 2: POC4TRIAGE Project

This division is necessitated by the following factors:

- **Distinct Operational Frameworks:** Each project operates under a unique set of technical protocols, quality standards, and implementation plans that require dedicated oversight.
- **Funding Compliance:** The services are financed through **different European funding streams**. Splitting the tender into lots ensures transparent financial tracking, reporting, and auditing in strict accordance with the specific regulations of each respective funding body.
- **Project Independence:** While the services requested may share similarities, the objectives and deliverables of the two projects are independent, requiring a structure that allows for specialized service delivery.

Lot 1: EAST-Troke Project

Lot 1 focuses on the **East-Stroke project**, which presents a unique operational model compared to standard clinical trials. The selected CRO will be responsible for a dual-action strategy to ensure that CROs demonstrate not just monitoring expertise, but logistical capability in platform deployment and a deep understanding of Value-Based Healthcare (VBHC) metrics:

- **Deployment and Monitoring:** The CRO will lead both the technical and clinical deployment of the platform across participating centers, acting as the primary driver for site activation and ongoing follow-up
- **Digital platform for treatment adherence and integrated systematic outcome data collection:** A core objective is the collection of Health Outcomes (PROMs/PREMs) directly within these centers. These tasks are inherently linked to the digital platform for treatment adherence and integrated systematic outcome data the success of the platform deployment is measured by the quality and integrity of the health data gathered.
- **Scalability Framework:** The processes established in this lot must follow a methodology used for deployment and data collection is intended to be scalable and replicable in other European countries following the initial phase.

Within the EAST-Stroke Project, the Vall d'Hebron Research Institute (VHIR) leads a critical Work Package (WP) dedicated specifically to the collection and analysis of these health outcomes. The CRO will work in close coordination with VHIR to ensure that the data collection infrastructure aligns perfectly with the scientific requirements defined by the project leadership.

The East-Stroke project comprises an international multicenter trial and two international multicenter sub-studies. A Clinical Research Organization (CRO) is required to manage regulatory matters and monitoring across the eight (8) Spanish centers, in coordination with the central CRO contracted by the German coordinator. The selected CRO must have the

capacity, flexibility and expertise to carry out all assigned tasks in close contact and collaboration with the central CRO.

It is also mandatory that the platform can be able to capture PROMs and PREMs.

Lot 2: POC4TRIAGE Project

Lot 2 focuses on the **POC4TRIAGE Project** is centered on the rapid clinical validation of cutting-edge diagnostic hardware in high-pressure emergency environments.

The particularity of Lot 2 is the integration of medical devices with Edge AI and the critical need for data synchronization between ambulances and hospitals.

Lot 2 covers the clinical validation phase of the POC4triage project. This project aims to revolutionize emergency care through four innovative Point-of-Care (POC) devices (including EEG-caps and cardiorespiratory patches) equipped with Edge AI for instant triage.

- **Emergency Setting Validation:** Unlike Lot 1, this lot requires a CRO with experience in pre-hospital settings (ambulances) and Emergency Rooms (ER). The monitoring must account for the logistical challenges of data collection in acute care scenarios.
- **Device-Hospital Connectivity:** A core task is validating the Device-Hospital Connectivity Platform (DHCP). The CRO must ensure that the "Edge AI" results generated by the devices are accurately transmitted to Hospital Information Systems (HIS) in real-time.
- **Regulatory Focus (MDR/IVDR):** Since this involves new diagnostic hardware, the CRO must have deep expertise in the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) to ensure all clinical data supports future CE marking.

The POC4TRIAGE project comprises an international multicenter trial with medical devices and a connecting platform.

A Clinical Research Organization (CRO) is required to manage regulatory matters and monitoring in the hospital setting, Emergency and ambulances in the Hospital Vall d'Hebron, Stroke Unit.

The selected CRO must have the capacity, flexibility and expertise to carry out all assigned tasks within the framework of a European Funded Project.

Reasons for initiating urgent proceedings

An Urgent Procedure is required for the contracting of the Clinical Research Organization (CRO) services.

Stroke is a leading cause of death and morbidity. Non-valvular atrial fibrillation (AF) is considered a chronic condition linked to age and, therefore, to patient frailty. It is a risk factor for embolism, which accounts for up to 30% of ischemic strokes, so any improvement in its prevention will lead to a reduction in the social and economic costs of this disease. DOACs are the treatment of choice for the primary and secondary prevention of stroke due to AF. However, patients with AF can still suffer an ischemic stroke despite taking DOACs. Randomized clinical trials showed a risk of up to 2% of patients per year. However, real-world data have shown that this risk is much higher than expected due to the inclusion of patients who did not meet the strict criteria of clinical trials and who were not followed according to a standardized protocol. The main cause of recurrence is insufficient treatment with DOACs, which can account for up to 32% of cases. For this reason, strategies that enhance stroke prevention in this patient group are necessary, as they account for up to 48 stroke cases annually in our hospital. In 2020, the Early Treatment of Atrial Fibrillation for Stroke Prevention Trial (EAST AFNET 4) showed that a strategy of systematic early rhythm control using antiarrhythmic drugs or atrial fibrillation ablation significantly reduced the number of strokes and cardiovascular events compared with usual care in patients with recent atrial fibrillation. Therefore, it is imperative to initiate a clinical trial that includes patients who can be offered a strategy such as rhythm control after stroke to evaluate its efficacy in post-stroke patients and reduce the social and economic costs associated with stroke

Similarly, improvements in early stroke detection have direct effects on the clinical improvement of stroke patients. Effective treatments are currently available and have proven beneficial for a large number of patients. However, due to the difficulty in detecting stroke symptoms in the hands of non-expert personnel many patients cannot benefit from these treatments because stroke is not detected in time. The POC4trriage study will evaluate new techniques that allow for the detection of stroke selection of patients who could benefit from helicopter transfers or those for whom the treatment window can be extended. Therefore, it is crucial to initiate trials that assess the validity of these techniques urgently.

The hiring of a CRO, following the correct recommendations for the implementation of randomized clinical trials, is essential. The CRO's role in ensuring the proper inclusion of patients, while adhering to the ethical guidelines for clinical trials, is crucial for the study's commencement. Therefore, hiring a CRO for both projects is considered urgent and essential for their implementation.

In summary, without a CRO to guarantee proper patient enrolment, compliance with ethical guidelines, and rigorous protocol implementation, both trials would be stalled, delaying essential clinical progress and perpetuating the significant impact that stroke continues to have on public health and associated social and healthcare costs.

Furthermore, the delay in incorporating the CRO poses a direct and significant threat to the viability of both the East Stroke and POC4trriage projects, due to their respective financial and operational structures.

1. Financial Risk Associated with the Lump Sum Model

The East Stroke project uses a European Commission lump sum funding model. Under this scheme:

- Payments are only released when deliverables are 100% complete.
- Partial payments are not possible: if a milestone is not met by the scheduled date, the corresponding funding is withheld in full.

Therefore, any delay in the CRO's implementation implies a failure to meet clinical milestones, resulting in the withholding of all funding for that period and generating a deficit that threatens the institution's financial stability.

2. Dependence on an external and non-extendable timeline

The project timeline is set externally by the European Commission. Any delay in starting activities implies an irrecoverable loss of revenue, as deadlines cannot be adjusted to accommodate administrative processes such as public procurement. This lack of flexibility significantly increases the risk of financial and operational impact. This process must be handled with urgency, as it should already have begun.

3. Specific impact on POC4triage

Although POC4triage is not governed by a lump sum funding model, the immediate implementation of a CRO is equally essential and critical. Any delay in the schedule not only negatively impacts budget execution but also causes a disruption that compromises the continuity of scientific and operational activities, slowing data generation and postponing the entire technological development cycle.

4. Disruption of the consortium's critical path

The VHIR is responsible for generating the primary clinical data necessary for European partners—engineers and data scientists—to develop and refine their triage algorithms.

A delay in clinical activity generates:

- A domino effect: the other partners cannot move forward without the Spanish data.
- Penalties for under-execution and the risk of the EU requesting reimbursement of funds for failing to execute the agreed work plan.

Given that Spain acts as one of the consortium's leading centers, any local delay has visible consequences for the productivity and continuity of the other countries.

5. Global threat to the international consortium

The VHIR is a fundamental pillar within the international consortium. Its progress sets the pace for the project. A delay in the contracting of the CRO by the VHIR not only affects the local area, but also paralyzes the international work chain, jeopardizing the scientific and technical advancement of the entire consortium.

Reasons for inviting the company NORAHEALTH, S.L.:

NORAHEALTH S.L. is then invited to submit to this procedure for its Technical Uniqueness and Infrastructure Advantage

A platform is required that:

- Allows for the automatic collection of patient data from hospital computer systems during and after the patient's hospital stay, using a patient communication tool that enables the inclusion of structured data.
- Has a secure storage system for sensitive patient data.
- Provides a web panel for clinical and hemodynamic monitoring of patients.
- Provides a web panel for monitoring patients in the subacute and chronic phases of stroke, allowing for clinical follow-up, evaluation of risk factor control, and assessment of therapeutic adherence.
- Enables, through an alarm system, the activation of an urgent reassessment pathway in case of alterations in the clinical and/or hemodynamic characteristics of the selected follow-up profile.
- Enables communication with the patient via telematics to obtain relevant scales for the study, such as the PROMS and PREMS scores, which are required as study objectives.

In addition to the functional requirements already described, it is necessary to demonstrate that only NORAHEALTH S.L. can meet the project's technical needs, and that no equivalent alternative exists on the market capable of providing an integrated, secure, and clinically validated solution within the established deadlines. This exclusivity is based on the following elements:

1. Lack of equivalent technical alternatives on the market

The preliminary analysis of available solutions demonstrates that no platform exists capable of integrating, in a single environment and immediately:

- Automatic data collection from hospital information systems.
- Continuous clinical and hemodynamic monitoring.
- Specific subacute and chronic monitoring for stroke patients.
- A clinical alert system connected to actual care pathways.
- The generation of PROMS and PREMS scales valid for research.
- Complex interoperability with hospital information systems.

Most solutions on the market offer only partial functionalities, failing to cover the entire set of requirements. Therefore, there are no equivalent substitute products, an essential requirement to justify an exclusive contract.

2. Prior, specific, and non-replicable integration with the center's clinical systems

NORAHEALTH has a digital infrastructure already integrated with hospital information systems (HIS) and existing clinical communication tools. This integration:

- Is based on proprietary developments and specific connectors not available to third parties.
- Requires complex technical adaptations that have been previously validated in this environment.
- Cannot be reproduced by another provider within the project timeframe without compromising security or regulatory compliance.

Replicating this integration with another operator would require months of development, testing, certification, and validation, which is incompatible with the established timelines for EAST Stroke and POC4triage.

3. Specialized and exclusive knowledge in stroke and advanced telemonitoring

NORAHEALTH brings a unique combination of:

- Specific clinical expertise in stroke.
- Advanced technological capabilities for automated data collection.
- Proprietary infrastructure for continuous remote monitoring.
- Demonstrable prior experience in complex hospital environments.

This combination of clinical and technological expertise is unique and not available from other CROs, making NORAHEALTH a technically irreplaceable provider for the scope of the project.

4. Scientific, technical, and operational risks if an alternative provider is used

Selecting a different provider would result in:

- Complete redesign of the care protocol and monitoring workflow.
- Revalidation of alarm systems, scales, and tools, with the consequent delays.
- Delays that would compromise the availability of essential clinical data.
- Potential failure to meet scientific and technical milestones.

In the EAST Stroke and POC4triage projects, any delays could lead to loss of funding, penalties for underperformance, and the risk of breaching commitments made to European funding bodies.

5. The Need for the CRO to Act as a Digital Extension

Given the very nature of the projects—driven by real-time data, direct patient engagement, and constant oversight—the CRO acts as a seamless digital extension of the clinical part. By integrating remote monitoring and real-time screening of codified patients, we alleviate the administrative load on clinical staff while significantly accelerating patient identification.

This true integration is only possible with a fully operational platform within the hospital ecosystem, a condition met only by NORAHEALTH S.L.

In conclusion, the engagement of NORAHEALTH S.L. is fully justified by the technical uniqueness of its solution, the lack of equivalent alternatives on the market, its prior and non-replicable integration with hospital systems, and its specialized knowledge in stroke and advanced telemonitoring. Selecting a different provider would cause delays incompatible with the projects' objectives and deadlines, as well as scientific, technical, and operational risks that could jeopardize their viability and even the continuation of funding. Taken together, all these elements constitute an unavoidable technical necessity that justifies exclusive contracting in accordance with current regulations.

Clause 2. Maximum tender budget and estimated value of the contract.

In the present tender procedure, the maximum tender budget and the estimated value of the contract matches.

The maximum tender budget, corresponding to the duration of the service, amounts to the sum of **"THREE HUNDRED SIXTY-NINE THOUSAND SIX HUNDRED EUROS" (369.600,00 €)** to which, if the amount corresponding to VAT is added, which is **"SEVENTY-SEVEN THOUSAND SIX HUNDRED SIXTEEN EUROS" (77.616,00 €)**, the total sum amounts to **"FOUR HUNDRED FORTY-SIX THOUSAND SIX HUNDRED SIXTEEN EUROS" (446.616,00 €)**.

Therefore, the maximum total budget for this tender for the two lots is:

- Lot 1: EAST-Troke Project

The maximum tender budget, corresponding to the duration of the service, amounts to the sum of **"THREE HUNDRED SIXTY THOUSAND" (360.000,00 €)** to which, if the amount corresponding to VAT is added, which is **"SEVENTY-FIVE THOUSAND AND SIX HUNDRED EUROS" (75.600,00 €)**, the total sum amounts to **"FOUR HUNDRED THIRTY-FIVE THOUSAND SIX HUNDRED " (435.600,00 €)**

Therefore, the maximum total budget (excluding VAT) for each unit of service to be carried out shall therefore be:

Description	Price
Year 1) Regulatory;study start up; all monitoring tasks, platform deployment and integrated outcome collection	72.000,00 € (*)
Year 2) All monitoring tasks,study follow up ,platform deployment and integrated outcomes collection	72.000,00 € (*)
Year 3) All monitoring tasks,study follow up ,platform deployment and integrated outcomes collection	72.000,00 € (*)
Year 4) All monitoring tasks,study follow up ,platform deployment and integrated outcomes collection	72.000,00 € (*)
Year 5) All monitoring tasks,study follow up ,platform deployment and integrated outcomes collection	72.000,00 € (*)
TOTAL	360.000,00 €

() Price that the tenderer, will be able to improve in the ECONOMIC OFFER – [Envelope Unique](#)*

The maximum 360.000,00 euros budget of the tender is integrally charged to the subcontracting dedicated budget (VHIR's internal account: EAST.STROKE 2024.1224)
 The estimated base amount for the services outlined in the Grant Agreement. This amount has been determined to be 360.000.00 €, based on an assessment of the costs associated with similar services.

This figure is reflected in the Grant Agreement to ensure clarity and agreement on the financial basis of our collaboration. (GRANT AGREEMENT Project 101156541 — EAST-STROKE)

- Lot 2: POC4TRIAGE Project

The maximum tender budget, corresponding to the duration of the service, amounts to the sum of **"NINE THOUSAND SIX HUNDRED EUROS" (9.600,00 €)** to which, if the amount corresponding to VAT is added, which is "TWO THOUSAND SIXTEEN EUROS" (2.016,00 €), the total sum amounts to **"ELEVEN THOUSAND SIX HUNDRED SIXTEEN EUROS" (11.616,00 €)**

This maximum total budget will be broken down as follows for two year:

- Years 1: 4.800,00 € (excluding VAT)
- Years 2: 4.800,00 € (excluding VAT)

Therefore, the maximum total budget (excluding VAT) for each unit of service to be carried out shall therefore be:

Description	Price
Year 1) All monitoring and regulatory tasks	4.800,00 € (*)
Year 2) All monitoring and regulatory tasks	4.800,00 € (*)

() Price that the tenderer, will be able to improve in the ECONOMIC OFFER – [Envelope Unique](#)*

The maximum 9.600,00 euros budget of the tender is integrally charged to the subcontracting dedicated budget within the internal VHIR count 2024-0658 POC4Triage 2024.

The estimated base amount for the services outlined in the Grant Agreement. This amount has been determined to be 9.600.00 €, based on an assessment of the costs associated with similar services.

This figure is reflected in the Grant Agreement to ensure clarity and agreement on the financial basis of our collaboration. (Project: 101137358 — POC4TRIAGE — HORIZON-HLTH-2023-TOOL-05)

The estimated value for this tender will be **"THREE HUNDRED SIXTY-NINE THOUSAND SIX HUNDRED EUROS " (369.600,00 €)** to which, if the amount corresponding to VAT is added, which is **"SEVENTY-SEVEN THOUSAND SIX HUNDRED SIXTEEN EUROS"** (77.616,00 €), the total sum amounts to **"FOUR HUNDRED FORTY-SEVEN THOUSAND TWO HUNDRED SIXTEEN EUROS" (447.216,00 €)**.

Concept	Amount
Total tender base budget Lot 1	360.000,00 euros
Total tender base budget Lot 2	9.600,00 euros
Possible modifications Lot 1	0,00 euros
Possible modifications Lot 2	0,00 euros
Possible extensions Lot 1	0,00 euros
Possible extensions Lot 2	0,00 euros
Total	369.600,00 euros

In no case shall the estimate of the volume of service provision be binding; the VHIR shall pay the invoices for the service actually provided.

*** The service must comply with all legal requirements at the time of contracting and throughout the contract period.

Clause 3. Duration of the contract.

- Lot 1: EAST-Troke Project

The provision of this service will have an initial duration of **five (5) years**, with no possibility of extension.

The service will begin on the day following the formalisation of the contract. The contract shall be deemed formalized on the date of the last digital signature.

However, if this project were to be found, for any unforeseen reasons, 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. Provided that the maximum term of 5 years for the tender is not exceeded.

- Lot 2: POC4TRIAGE Project

The provision of this service will have a duration of **two (2) years**, with no possibility of extension

The service will begin on the day following the formalisation of the contract. The contract shall be deemed formalized on the date of the last digital signature.

However, if this project were to be found, for any unforeseen reasons, 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. Technical characteristics of the service.

Technical characteristics of the service for both lot:

The selected CRO must operate with the understanding that they are legally and operationally bound by the Description of Action (DoA) and the Grant Agreement governing these European projects. Specifically:

- Synchronization with VHIR Deliverables: The Vall d'Hebron Research Institute (VHIR) is responsible for key scientific and technical milestones. The CRO must manage its activities to ensure VHIR meets every deliverable on schedule, as any delay at the site level directly prevents VHIR from fulfilling its obligations to the European Commission.
- Compliance with the Master GANTT: All CRO activities—including site feasibility, ethics committee submissions, patient recruitment, and data cleaning—must strictly align with the global GANTT chart of the consortium. Bidders must demonstrate the agility to adjust resources to maintain the "Critical Path" of the project.

- The CRO is responsible for all site-specific costs arising from contract negotiations, regulatory authorities, or local site requirements, and must allocate a dedicated budget line item specifically for these expenses.

Throughout this specification, the tasks included in the scope of this contract are specifically described below for both lots, as well as the scope of the proposed service.

- Regulatory submission AEMPS-CTIS and CEIC
- 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.
- Follow-up visits
- Close-out visits
- Analysis and final report (CSR) of the study
- Publication
- DM protocol regular reviews
- eCRF maintenance
- Update/Review of the following study documents/systems
- Edit check programming
- Provision
- Maintenance of Master File
- Data cleaning and validation (including query management)
- 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
- Project-Specific Collection of PROMs and PREMs

I. Project Initiation and Management including Regulatory (Aemps/CEIC/CTIS)

This phase encompasses from contract signing to final trial closure.

- **Project Leadership:** Oversee and manage the entire project from documentation handover post-contract signing through to clinical trial closure.
- **Meeting Coordination:**
 - Organize and attend investigator meetings, including presentation delivery and minute-taking.
 - Schedule and lead regular coordination meetings and teleconferences.
- **Documentation & Protocol:** In coordination with the central CRO, provide translations (where necessary) for the study protocol and all related monitoring and regulatory documentation.
- **Contract Management:** Collaborate with the Sponsor, Sponsor's CRO, and the study coordinator to manage site contracts until final signature (if applicable).
- **Trial Master File (TMF) Management:**

- Manage, safeguard, and maintain the central electronic Trial Master File (eTMF) until its final handover to the Sponsor upon study completion.
- Update the electronic Investigator Site File (eISF, provided by the Coordinator, for each participating center.
- Ensure both the eTMF and eISF comply with ICH-GCP & 3R standards.
- **Monitoring Planning:** Develop and finalize the monitoring plan and guide.

II. Reporting and Regulatory Interaction

The CRO is responsible for timely and accurate communication regarding project status and safety.

- **Quarterly Project Reporting:** Provide a quarterly report to the Sponsor (or designated persons) detailing project development, including:
 - Status of study recruitment.
 - Summary of Serious Adverse Events (SAEs) and Serious and Unexpected Adverse Reactions (SUSARs).
 - Documentation of protocol violations.
 - Any relevant actions or communications with regulatory bodies or other involved organizations, to be performed following ongoing specific rules.
- **Extraordinary Reporting:** Immediately notify the Sponsor with an extraordinary report in the event of:
 - A serious protocol violation.
 - A serious violation of current Clinical Trial legislation or Good Clinical Practice by the research team.
 - Extraordinary communication of Adverse Events (AEs) to the Regulatory Agency (AEMPS) as required by law.
- **Regulatory Liaison:** Manage all necessary interaction and communication with the Ethics Committee (CEIC) and the Regulatory Agency (AEMPS), ensuring full compliance with current legislation.
- **CRO Service Flexibility:** Coordinate between all involved parties and adapt services to meet the Sponsor's evolving needs, functioning as a comprehensive CRO partner.

III. Clinical Monitoring

The core function of ensuring data integrity and site compliance.

- **Site Visit Execution:** Conduct initial visits, routine monitoring visits, and final closure visits.
 - Includes 1 in-person initial visit per center.
 - Perform approximately 10-12 routine monitoring visits per center (estimated 80-90 visits across 8 centers).
 - Perform 1 closing visit per center, emphasizing the Principal Investigator's (PI) responsibilities for essential document custody.
- **Site Training:** Provide comprehensive and updated training to Investigators, nurses, and site study coordinators.

- **Data Quality Control (QC):**
 - Perform 100% Source Data Verification (SDV) for data and information recorded in the CRDe by the investigator.
 - Conduct remote or on-site data review for all included patients.
 - Provide support for query resolution throughout the study and during database closure.
- **Reporting:** Generate detailed reports following each visit to participating centers for review by the Sponsor or designee.
- **Ancillary Management:** Manage contracts and liaison with the clinical trial insurance provider (if applicable).

IV. Pharmacovigilance (PV)

Ensuring participant safety and proper reporting of adverse events.

- **PV Training:** Train the project team on all aspects of Adverse Event (AE) communication and monitoring.
- **AE Management:** Collect and manage both serious and non-serious AEs.
- **Regulatory Notification:** Ensure timely notification of SUSARs following the requirements of each involved CEIC and the AEMPS according to applicable legislation.
- **Safety Adjudication:** Control and track AEs of special interest for the study, including requesting documentation necessary for adjudication by study committees.

V. CRDe Data Management

Guaranteeing the security, integrity, and analysis readiness of all study data.

- **System Compliance:** Utilize a secure computer system for data storage and confidentiality, complying with ICH-GCP guidelines (3R).
- **Data Planning:** Develop the Data Management Plan and final Data Management Report.
- **Data Processing:**
 - Manage and interact with other areas or CROs involved in the clinical study.
 - Perform data tabulation and data cleaning.
 - Implement the Discordance Plan for managing and sending data discrepancies.
- **Database Closure & Archival:**
 - Prepare for pre-closure data review to assess the quality of key variables.
 - Execute the database closure.
 - Provide a final data file (or external memory) to each research center for safekeeping (delivered during the closing visit).
 - Complete the final Data Management Report after database closure.
 - Archive the CRDes.
- **User and Security Management:** Manage user accounts, permissions, and roles, including providing researcher training on the CRDe.

- **Safety Monitoring:** Manage the database specifically for partial safety analyses required by the Data and Safety Monitoring Board (DSMB).

Technical characteristics of the service for Lot 1: EAST-Stroke Project

The study will include 290 patients, randomized, distributed in 8 centers in Spain, which is why it is necessary to hire a CRO to provide the initial preparation, regulatory approval, all monitoring tasks, coordination and management services of the project, as well as the other below detailed services, such as resolve all queries/complaints and the closure of the database after the patient's follow-up is completed as well as the regulatory and pharmacovigilance activity when required.

The international coordinator of the study has contracted a central CRO in Germany

The spanish local CRO will have to work in close contact and coordination with the central CRO and must adopt the Central Monitoring Plan. The initially estimated number of visits is 8 (eight), but it will be at VHIR's discretion to extend that number.

The selected CRO is expected to performe face-to-face and online visits: 1 initial visit per centre, 8-9 monitoring visits per centre and 1 closing visit per centre (total 8 initial, 80 aprox monitoring visits and 8 closing).

The management of the study archives will be done in coordination with the central german CRO.

The contracted CRO will have to coordinate all the spanish participating centres and other entities involved in the study.

In detail with the completion of the contractual object referred to, the contracting body intends to cover the following needs and/or functionalities:

The contracting company will assume comprehensive functions essential for the execution, monitoring, and successful closure of the clinical trial, adhering strictly to global regulatory standards (e.g., ICH-GCP).

Moreover the execution of **Lot 1 (East-Stroke)** requires a CRO capable of managing a highly integrated operational cycle that blends technical deployment with clinical data excellence. Rather than acting as a traditional passive monitor, the selected CRO will serve as the **primary driver for site activation**, leading both the **technical and clinical deployment** of the platform across all participating centers. This "hands-on" approach ensures that site follow-up is directly informed by the real-time installation and adoption needs of each center.

Central to this mission is the **integrated collection of Health Outcomes (PROMs/PREMs)**. In the East-Stroke framework, platform deployment and data collection are not separate workstreams but are **intrinsically linked**: the ultimate validation of a

successful deployment is the seamless generation of high-quality, high-integrity health data. The CRO will be responsible for ensuring that the digital infrastructure effectively captures these metrics at the point of care, providing the clinical evidence necessary to evaluate the project's success.

Finally, this lot is designed with a **Scalability Framework** at its core. Every process, from initial center onboarding to final data extraction, must be documented to serve as the foundational model for the project's future expansion, ensuring that the deployment strategies and data collection protocols are fully **replicable and scalable across other European member states** following the successful conclusion of this initial phase.

The Lump sum model is Deliverable-Based Performance: In accordance with the Lump Sum funding model, the CRO's performance will be measured by the timely submission of the technical evidence required for each milestone. Failure to respect these timings carries significant financial risk for the entire consortium.

Technical characteristics of the service for Lot 2: POC4TRIAGE Project

The study, with medical devices, will include 200/300 (depending on the statistical needs) patients, randomized, in a unic center in Spain, which is why it is necessary to hire a CRO to provide the initial preparation, regulatory approval, all monitoring tasks, coordination and management services of the project, as well as the other below detailed services, such as resolve all queries/complaints and the closure of the database after the patient's follow-up is completed as well as the regulatory and pharmacovigilance activity when required.

The selected CRO is expected to perform face-to-face and online visits: 1 initial visit per Centre, 10-12 monitoring follow up visits and 1 closing visit (total 12-14 visits).

In detail with the completion of the contractual object referred to, the contracting body intends to cover the following needs and/or functionalities:

The contracting company will assume comprehensive functions essential for the execution, monitoring, and successful closure of the clinical trial, adhering strictly to global regulatory standards (e.g., ICH-GCP-3R).

Lot 2 is dedicated to the clinical validation phase of the **POC4triage** project, an ambitious initiative designed to revolutionize emergency care through the deployment of four innovative Point-of-Care (POC) devices. These tools, which include advanced **EEG-caps and cardiorespiratory patches**, are equipped with **Edge AI** to provide instantaneous triage capabilities.

The execution of this lot demands a CRO with specialized expertise in the high-pressure environment of **pre-hospital settings and Emergency Rooms (ER)**. Validation in these contexts requires a sophisticated monitoring approach capable of overcoming the unique

logistical hurdles of data collection within moving ambulances and during acute care scenarios, where precision and speed are paramount.

A central component of this scope is the validation of the **Device-Hospital Connectivity Platform (DHCP)**. The CRO must ensure a seamless digital thread where "Edge AI" insights generated in the field are accurately and securely transmitted to **Hospital Information Systems (HIS)** in real-time. Given that this involves cutting-edge diagnostic hardware, the selected partner must possess deep regulatory mastery of the **Medical Device Regulation (MDR)** and **In Vitro Diagnostic Regulation (IVDR)**. This expertise is critical to ensuring that all clinical evidence gathered is robust enough to support future **CE marking** and successful market entry

Clause 5. Location and Schedule for both Lots

Location:

The service will be carried out telematically and in person and communication with the company will be maintained via email and telephone and video calls and in- person meetings whenever required and in periodic meetings to be determined once the service begins

The selected company must designate a person to attend international meetings related to the study.

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	A09006467	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (HUVH IR)

			Recerca (HUVH IR)		
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The invoice will be issued on a fixed bi-annual (twice a year) schedule but are strictly contingent upon the successful completion and approval of all technical deliverables required for those specific milestones. 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 “N 2026-006– Lot X” The corresponding lot number must be specified in “X”.

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 of the contract.

The responsible for the contract by Lot 1 East-Stroke is Dr. Jorge Pagola, Investigator of East-stroke trial in charge with the coordination of the spanish centers.

The responsible for the contract by Lot 2 POC4Triage is Dr. Marian Muchada, investigator for VHIR.

The responsables will basically be responsible for, among others, the functions of management and supervision of the contracted service, conforming the invoicing issued by the service, monitoring, control and issuing the necessary instructions for the proper execution of the contract; determine whether the service provided complies with the prescriptions established for its execution and compliance and reception of the contract on its completion, 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 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 of VHIR or of any designated third party.

The awarded company authorizes VHIR to transform, modify, publish, communicate and exploit the work resulting from the execution of the contract derived from this tender procedure.

Clause 9. Allocation criteria for both Lots

The following criteria and percentage points will be used to evaluate the tender proposals and determine the most economically advantageous one:

1. Criteria evaluable through automatic formulas	Maximum 100 points
• Economic Offer	Maximum 100 points

9.1 Criteria that can be assessed through automatic formula..... up to 100 points

ECONOMIC OFFER.....up to 100 points

It will be valued automatically for each unitary service, in accordance with the following formula:

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

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

The automatic formula will be applied to each unit price, and the average score will be established.

** If after applying the automatic formula to a submitted bid, the resulting value is negative, you will be directly assigned zero (0) points of the economic part.
 $P(N) = 0$.*

Clause 10. Negotiate items for both Lots

The negotiate items will be the following ones:

- Potential reduction of price
- Publish and disseminate a periodic Clinical up date letter for spanish sites
- Team Stability/Continuity: to promote a continuous learning curve.

Barcelona, March 30, 2026

CONTRACTING ORGANISM

Dr. Begoña Benito Villabriga

Director

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