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

EXPEDIENT NUMBER: 2026-013 APP DEVELOPMENT (UICM24/00003)

DOCUMENT OF TECHNICAL SPECIFICATIONS
NOT HARMONIZED TRADE – OPEN PROCEDURE

DEVELOPMENT AND IMPLEMENTATION OF AN APPLICATION BY THE PROJECT UICM24/00003, FOR THE FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON (VHIR).

This study has been funded by Instituto de Salud Carlos III (ISCIII) through the project UICM24/00003 and by Next Generation EU funds under the Recovery and Resilience Mechanism (RRM).

Clause 1. Aim of the tender

The purpose of this tender procedure is to contract the development and implementation of a specialized software application designed to ensure the operational traceability of pediatric patients participating in decentralized clinical trials. The platform should integrate with hospital information systems, support hybrid (on site/remote) clinical operations, and comply with applicable regulatory requirements, as part of the Project UICM24/00003 entitled "*BRIDGE Project. (Breaking Barriers with Remote Integration for Global Pediatric Trials*", funded by Instituto de Salud Carlos III (ISCIII) through the project UICM24/00003 and by Next Generation EU funds under the Recovery and Resilience Mechanism (RRM) for the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR).

The Project UICM24/00003: BRIDGE aims to improve the accessibility, inclusivity, and connectivity of pediatric clinical trials through digital environments, interoperability, and remote monitoring services. The intrinsic complexity of decentralized pediatric clinical trials demands sophisticated digital infrastructures capable of coordinating remote operations, managing pseudonymised patient data, and ensuring continuous alignment with clinical-research regulatory requirements. Current institutional systems do not provide the necessary functionalities for real-time operational traceability, nor do they support the level of interoperability and structured workflow management required by the BRIDGE Project.

Moreover, it is essential that the digital solution be specifically adapted to the needs of the pediatric population, incorporating child-appropriate interfaces, communication mechanisms, remote-monitoring workflows, and safety controls aligned with pediatric care pathways. A bespoke digital platform is therefore indispensable to guarantee coherent data flows, standardized monitoring procedures, secure communication among investigators, study coordinators, data-entry personnel, and support teams, and to maintain an auditable record of all trial-related activities. Without such a solution, it would be impossible to ensure protocol fidelity, operational efficiency, and full compliance with the legislation and quality standards governing clinical research according to ICH E6(R3) and the Guideline on computerised systems and electronic data in clinical trials EMA/INS/GCP/112288/2023.

Furthermore, the characteristics of the digital platform to be developed, its integrated architecture, operational continuity needs, and data-protection implications, make it essential that the contract be executed by a single provider. The development, and implementation phases must be addressed within a unified technical framework to preserve the internal coherence of the system, avoid technological incompatibilities, and ensure that all components function correctly throughout the entire lifecycle of the platform. Fragmenting the procurement into multiple contracts or distributing the work among several companies would introduce substantial risks, including inconsistencies in design standards, divergent security protocols, and significant challenges in achieving system integration with hospital infrastructures. Such fragmentation would also compromise the integrity of the audit trail, the stability of the platform, and the capacity to guarantee regulatory compliance.

This document describes in detail the tasks included within the scope of this contract, as well as the scope of the proposed service.

Clause 2. Estimated value and maximum budget for tender

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 **"TWO HUNDRED THOUSAND EUROS" (200.000,00 €)** to which, if the amount corresponding to VAT is added, which is "FOUR HUNDRED AND TWENTY THOUSAND EUROS" (42.000,00 €), the total sum amounts to **"TWO HUNDRED AND FORTY-TWO THOUSAND EUROS" (242.000,00 €)**.

(*) Price that the tenderer, will be able to improve in the Envelope number 3 - ECONOMIC OFFER.

For this tender, the base amount has been estimated at 200.000,00 € based on internal historical data from comparable digital health projects, complemented by a benchmarking analysis of prevailing market prices and a functional cost breakdown reflecting the regulatory, technical, and operational requirements of this solution.

The estimated value for this tender will be **"TWO HUNDRED AND FIFTEEN THOUSAND EUROS" (215.000,00 €)** to which, if the amount corresponding to VAT is added, which is "FORTY-FIVE THOUSAND AND ONE HUNDRED AND FIFTY EUROS" (45.150,00 €), the total sum amounts to **"TWO HUNDRED AND SIXTY THOUSAND AND ONE HUNDRED AND FIFTY EUROS" (260.150,00 €)**.

Concept	Amount
Total tender base budget	200.000,00 euros
Possible modifications	15.000,00 euros
Possible extensions	0,00 euros
Total	**215.000,00 euros**

In accordance with Article 204 of Law 9/2017, the contract may be modified upwards, up to a maximum of 7,5% of the total tender budget. This amount will be paid to the company in the same manner and under the same conditions as those regulated in these specifications, upon presentation of the invoice by the successful bidder.

The causes that may lead to possible modifications are as follows:

- Regulatory or cybersecurity changes
- Project scope expansion
- Unforeseen technical requirements
- Critical system issues
- Justified need to add hospital-system integrations necessary for safe operation
- Additional validation and training needs

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.

The duration of this service contract will coincide with the duration of the aforementioned project, which is until **31st December of 2026**, the end date of Project UICM24/00003.

The service will start on the day after the contract is formalized, and its duration will coincide with the duration of the aforementioned project. It will be understood to be 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 specifications for platform provisioning, remote care, and delivery of result reports included in the budget:

0. Source data preparation, quality, transfer and traceability

a) **Open-Source Code Requirements**
The source code developed under this contract shall be delivered in full and made available to the Contracting Authority under an open-source licensing model. The Bidder shall provide the complete source code, including all components, modules, libraries (unless restricted by third-party licensing), configuration files, documentation, build scripts, and deployment instructions.
The software shall be released under a recognized open-source licence (e.g., MIT, Apache 2.0, or equivalent) that permits unrestricted access, use,

modification, and redistribution by the Contracting Authority and other authorized third parties. No part of the solution developed specifically for the project may be subject to proprietary restrictions, usage limitations, or technological lock-ins.
The Bidder shall guarantee that the Contracting Authority receives perpetual rights to access, audit, modify, extend, and reuse the source code for internal purposes and for future developments related to research, clinical operations, or institutional digital infrastructures.

b) Environment setup
The awarded bidder shall carry out the installation, secure configuration and technical validation of the system including provision secure environments (DEV/TEST/PROD), configure organization/tenant metadata, and enable secure connectivity with the contracting entity's systems (e.g., ASSCLI, identity provider, CTMS, file transfer zones). The examples are provided by way of illustration only and are not intended to be limiting.

The bidder must also provide documental technical evidences of the security configuration applied as well as the existence of secure remote access mechanisms.

Initial onboarding will include role catalogues, study master data structures, and messaging channels required for remote workflows.

c) Source data preparation
Ingestion of structured and semi-structured sources for trial operations (e.g., study calendars, investigator rosters, subject registries, cost schedules), patient-reported measures, and remote biometrics, applying validation rules and standard dictionaries where provided by the contracting entity.
The examples are provided by way of illustration only and are not intended to be limiting.

d) Data quality control
System should guarantee that any data is collected, accessed, edited and maintained according to ALCOA++ principles (Attributable, Legible, Contemporary, Original, Accurate, Complete, Consistent, Durable, Available) hence, it can support robust results and good decision making throughout all data lifecycle.
The platform will implement automated validations (schema, value ranges, referential integrity) and provide dashboards for conformance/completeness, with exportable quality reports. All validations should ensure accuracy, reliability, and consistent intended performance and any necessary documentation should be developed and maintained to demonstrate that the system is kept in the validated state. Any relevant validations of the platform that provide relevant changes within the functionality of the system and/or data, should be notified to VHIR and the system must be validated for its intended use in any specific tests.

e) Transfer of data and deliverables

The platform shall support secure transfer of raw operational data (events, audit logs, message metadata) and analytic datasets (KPIs, PROM/PREM summaries, adherence metrics) in standard formats (CSV/Excel/PDF) through secure channels designated by the contracting entity. The platform also shall deliver a Results Report covering the period, techniques/features used (e.g., modules enabled), data quality summary, KPIs and incidents resolved.
The examples are provided by way of illustration only and are not intended to be limiting.
Reports, indicators, dashboards and other analytical outputs may be delivered in English, at least. The data transfer process should be validated according to the criticality of the data and the validation process should guarantee assurance within data and file integrity during any kind of transfer.

f) Traceability and sample/process identification

Must ensure end-to-end traceability for all patient, study, task and device interactions, including immutable audit trails and unique identifiers across ingestion, workflow execution, communication events and exports.

g) Incident Management

The bidder shall provide an incident-management service that ensures timely response, classification and resolution of all platform-related issues, including technical errors, operational disruptions and user inquiries. Incidents must be logged and monitored until closure, applying corrective and preventive actions when required. For every resolved incident, the contractor shall issue a brief report summarizing the issue, actions taken and measures to avoid recurrence.

The bidder must comply with the following mandatory minimum **service-desk coverage** requirement:

Service Desk Coverage (SDC): 8/5 coverage (standard business hours)
The bidder shall provide, at minimum, support availability during standard business hours (8 hours per day, 5 days per week). This level of coverage is mandatory and constitutes a minimum compliance requirement for this contract.

Requests and incidents shall be addressed within the following maximum response times:

- **Requests**: Requests related to user support, configuration changes, clarifications, or general operational queries shall be responded to within 48 hours.
- **Incident-management**: Incidents affecting system performance, access, or functionality shall be responded to within a maximum of 4 hours, unless a shorter response time is offered by the bidder.

Critical incidents shall be understood as any system malfunction, failure, or disruption that prevents users from continuing to work with the platform or from accessing, entering, processing, or retrieving data in a safe and functional manner. These incidents have an immediate and severe impact on the operational continuity of the service and require urgent intervention.

The response time for **critical incidents** shall be a maximum of **2 hours**.

Likewise, During the guarantee period, and without any additional cost for VHIR, the supplier shall ensure the continuous proper functioning of the platform and perform the technical actions strictly necessary to preserve its correct operation, security and reliability. These actions shall be carried out by qualified personnel and in coordination with the VHIR IT team, with the sole purpose of ensuring the stability, safety, and conformity of the delivered system.
The actions included within this guarantee technical support may comprise, but are not limited to:

- Corrective updates and security patches required to resolve defects or vulnerabilities identified after delivery.
- Adjustments essential to maintain the correct configuration of the system, only where necessary to ensure its proper operation.
- Proactive application of critical security measures, when required to preserve the integrity and availability of the platform.
- Verification of system operability when strictly needed to confirm that the delivered solution continues functioning according to its intended use.
- These actions shall not entail any modification of the contracted functionalities, nor the provision of evolution, expansion or development beyond the scope of the present contract.

h) Inactivity logout
The System must include an automatic inactivity logout, which logs out a user after a defined period of inactivity and regular users should not be able to set the inactivity logout time

i) Remote connection
If remote connection to the System is required, a secure and encrypted protocol (virtual private network (VPN) and/or hypertext transfer protocol secure (HTTPS)) should be in place

j) Data back-up and contingency plans
System must have a robust infrastructure to prevent the risk of data loss hence periodic backups of the original data must be performed to avoid any kind of destruction or alternation. Frequency and location storage of backups should be documented and provided to VHIR. A disaster recovery and/or mitigation plan

should exist and should be shared with VHIR. This plan must contemplate the following:

- Procedures for responding to serious failures
- Recovery time objectives
- Redundancy mechanisms
- Restoration procedures

k) Revision and service termination

Service should have an established procedure in the eventuality of returning and transitioning the service and therefore, the following minimums are requested:

- Custody, preservation and delivery of the logs.
- Secure and certified disposal of all information owned by the VHIR.
- Full return (if applicable) of any asset owned by VHIR.
- Knowledge and technical documentation transfer in an orderly manner.

1. Core Clinical Trial Management

l) Study setup and scheduling

Configuration of study metadata (sponsor/investigator records), study arms, visit calendars per cohort/arm, and eligibility criteria, including lifecycle tracking of study phases and milestones upon agreement with the research team.

m) Investigator and site management

Registry and maintenance of professionals, assignment to study teams with role and participation windows, qualification/training tracking, and issuance of participation certificates where applicable.

n) Participant management

Subject master records with longitudinal updates, visit tracking, expense recording, adverse events and deviation logging; configurable workflows to support decentralized or hybrid visit patterns.

o) Operational tasking

Creation and follow-up of tasks by owner and due date, private/public scope, coordinator and data entry overviews, and one-click access to external platforms (e.g., eCRF).

The examples are provided by way of illustration only and are not intended to be limiting.

p) Financial management

Unit costs per visit/procedure, study budgets and invoicing support, fund distribution by teams, and export of financial statements.

q) Operational and performance reporting

Key performance indicators for recruitment, timelines, efficiency, and cost control with filters and export to standard formats (CSV/Excel/PDF).

r) Document management

Versioned repository (e.g. protocols, forms, reports, manuals) with access control (e.g. view, edit, download) and full audit trail for uploads, downloads and approvals. The examples are provided by way of illustration only and are not intended to be limiting.

s) Access control and notifications

Role-based access control with configurable permissions; system notifications and alerts for deadlines, credentials, tasks and training expiries. Access to the system should only be granted to trained site users after having the training documentation in place and the access should grant unique access to the operational users. The authorized users and access permissions should be documented and permissions should be removed when no longer are needed.

The system must support different user roles (at a minimum: Administrator, Operational Manager, Research team, and Patient).

i. *Administrator*: full permissions regarding system configuration, user management, operational parameters, and overall process validation.
ii. *Research teamr*: able to access the information and functionalities required for conducting research activities: view, manage, approve, or respond to operational requests within the study workflow (e.g., documentation handling, scheduling, internal validations, task follow-up).
iii. *Patient*: able to view information relevant to their own case and update personal or logistical data when permitted, as well as submit requests or communications to the team, without access to other users' information or management functions.

The examples are provided by way of illustration only and are not intended to be limiting.

t) Audit trail

End-to-end audit trail recording user, timestamp and action for all relevant configuration/data changes with its related relevant metadata associated, exportable for audit / inspection. The audit trail should not allow "normal" users to deactivate them and should be stored within the system itself and the system must ensure that the automatic capture of date and time entries are unambiguous.

1. Virtual care and remote monitoring for hybrid/decentralized clinical trials

a) Patient and professional workspaces

Dedicated workspaces for clinicians and patients, supporting plan-driven tasks, appointment handling (on-site and virtual), secure messaging, and longitudinal follow-up. Such workspaces will allow, where applicable, the secure access by clinicians from external organizations. Patient workspaces will feature a child-friendly interface with gamification elements to encourage engagement and adherence throughout the trial.

b) Telehealth channels
Synchronous (video) and asynchronous (chat/secure mail) communications with configurable templates and reminders; multilingual support where provided by the organization. The supported languages will be Catalan, Spanish and English.

c) PROM/PREM and questionnaires
Configurable questionnaires for outcomes and experience, with scheduling, and analytics dashboards. If PROM/PREM and questionnaires are designed to allow data correction, any corrections should be documented and drawn within the audit trail.

d) Biometrics
Capture of patient biometrics either manually or via connected devices; near real-time ingestion pipelines and alerting thresholds. A documented procedure must exist to transfer and/or transcribe the information when needed and such data should be accompanied by relevant metadata concerning the used device. Any data loss, failure or interruption of data transmission should be avoided and procedures should exist to prevent them.

e) Personalized care plans and adherence
Definition of standardized and individualized remote-care plans, task adherence tracking, escalations and progress monitoring.

f) Alerts and safety
Configurable, tiered alerting for clinical parameters and plan deviations with traceable acknowledgment and resolution. A log of the events related to alerts and safety must be in place.

g) Interoperability
Integration with clinical systems to support single sign-on and context launch, leveraging healthcare interoperability standards to facilitate information exchange where required by the contracting entity. The solution shall provide APIs and adapters aligned with healthcare standards, and support integration with VHIR/HUVH systems. Where applicable, the platform shall also be able to interface with telemedicine tools and imaging systems (PACS).

h) Security and privacy

Controls to ensure confidentiality, integrity and availability, aligned to GDPR and institutional policies; export of data in standard formats when authorized.

2. AI-assistance procedures

a) Patient-facing assistance
Virtual agent to collect PROM/PREM in natural language (voice/chat) and generate clinician-ready summaries; conversational assistant for protocol and logistics queries; generation of lay-language materials.

b) Professional-facing assistance
Conversational search over protocol and patient records; intelligent summarization of clinical documentation; trial-matching recommendations; patient clustering; dropout risk scoring and suggested mitigations; operational load forecasting and staff allocation proposals; financial forecasting with deviation alerts.

Clause 5. Project Support and Regulatory Compliance Obligations

1. Training, operations and user assistance

a) The bidder shall provide, at no additional cost to the Contracting Authority, all preparatory activities and training sessions required for the correct and safe use of the platform. These activities form part of the delivery and implementation obligations of the awarded bidder and shall not generate any additional cost for the project or be invoiced separately. These trainings might be provided in either Catalan, Spanish or English as accorded between both parties. Updated versions of these materials will be delivered after each release that introduces functional changes. Additional refreshers may be provided following major releases—defined as updates introducing new functionalities or modifying existing workflows—and shall also be included within the warranty obligations. For the purpose of this contract, a "major release" shall mean any software update that incorporates new functionalities, modifies existing workflows or affects the interpretation of system outputs. The training should guarantee, at least, these topics:
   i. General and safe use of the system including routine operations.
   ii. Security measures and their correct use.
   iii. Management and configuration access to the system including but not limited to: user registration, modifications and any log consultation and interpretation (if applicable).
   iv. Response procedures in front of any security incidents.
   v. Most common incident resolution.
   vi. Preventive and routine actions required to ensure proper system use within the scope of the warranty phase.

b) When AI modules are in scope, the bidder will provide model outputs with explanatory context (e.g., eligibility reasoning, dropout risk factors) and be available for Q&A sessions with the research team.
The examples are provided by way of illustration only and are not intended to be limiting.

2. Technical expertise of the bidder project responsible

The person designated as project manager shall demonstrate proven experience in the design, development, implementation and commissioning of the systems of similar scope and complexity.

In addition, the project manager shall have appropriate background and specialized training related to the scope of the project. Knowledge of the applicable regulatory framework shall be evidenced through both prior professional experience and formal training in legal and compliance matters.

Prompt communication to VHIR should be made in writing in the event of any third party subcontracting of the services provided to VHIR. The bidder will ensure that any subcontracted third parties comply with the same technological, organizational and security requirements set out in the specifications of this tender.

3. Requirements for Compliance with ENS

The Bidder must provide a certificate ensuring compliance with the requirements of the National Security Scheme (ENS), High Category, in accordance with Royal Decree 311/2022, in order to ensure the quality, security and continuity of IT processes, as well as the adequate protection of any sensitive data processed.

The certificate must:

- Be issued by an accredited conformity assessment body.
- Be valid on the deadline for submission of tenders and valid throughout the entire duration of the contract.
- Explicitly include within its certified scope the services subject to this procurement procedure and the information systems supporting those services.

Failure to provide a valid ENS High Category certification covering the scope of the contracted services shall result in the exclusion of the Bidder from the procurement procedure.

4. Audits

The successful bidder shall allow and facilitate technical, if necessary, documentary and operational audits, preferably through features integrated into the software itself by granting access to VHIR to any auditable reports and records related to:

- System updates and applied security patches.

- Detected incidents and their resolution.
- Relevant accesses and activities
- Operational actions relevant to platform performance and continuity.
- Follow-up reports relating to cybersecurity regulation and compliance.

The Contractor shall grant access to the relevant European and national control and audit bodies, upon request, for the purpose of inspections, audits, or verifications related to the contract.

Clause 6. Subcontracting Conditions

In accordance with the applicable public-procurement regulations, subcontracting shall be permitted only under the terms expressly established in this clause.

1. **Non-subcontractable Core Components**

   The **core functionalities** of the platform—those directly related to the **design, development, implementation, configuration, validation, and operational continuity of the core Clinical Trial Management and remote-care system—shall not, under any circumstances, be subcontracted**.
   These core services comprise all elements that are essential to ensuring system integrity, interoperability, regulatory compliance, traceability, auditability, security, and overall platform coherence throughout its lifecycle.

   Subcontracting of these core components is strictly prohibited due to the criticality of maintaining a unified technical architecture, a consistent security framework, and a single point of accountability for system performance and regulatory obligations.

2. **Subcontractable Components**

   The successful bidder may subcontract **non-core components**, provided these do not affect the integrity, security, functionality, or regulatory alignment of the core system.
   Subcontractable activities may include, but are not limited to:

   - Artificial Intelligence (AI) assistance modules.
   - Advanced analytics, data-science processing or modelling components.
   - Complementary development tasks not affecting the core architecture.
   - Specialized UX/UI or accessibility features.
   - Auxiliary integrations or adapters not considered critical for core system operation.

Any subcontracted activity must remain fully aligned with the specifications, regulatory requirements (including GDPR and ENS), security controls, and interoperability standards defined in this document.

3. **Prohibited Subcontracting**

Any subcontracting that affects the core functionalities defined in section 1, or that may compromise system security, coherence, interoperability, traceability, or regulatory compliance, shall be expressly prohibited and shall constitute grounds for contractual non-compliance.

Clause 7. Location and timetable for the provision of the service.

Location where the service is to be provided: The service will primarily be carried out remotely from the company's own facilities. Where applicable, key meetings will be held at the central building of the Vall d'Hebron Research Institute (VHIR), located at Passeig Vall d'Hebron 119-129, 08035 Barcelona, Spain. The cost of attending these key meetings is included within the total tender amount and will not entail any additional charges.

Hours of service: The bidder will have to provide the service covered by this tender within its established hours. However, the hours for providing support for resolving technical incidents and orders, as well as questions and queries about the service/results, will be Monday to Friday from 9 a.m. to 5 p.m. (Spanish peninsular time), except on non-business days (Barcelona calendar).

Clause 8. 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	**A09006467**	Fundació Hospital Universitari Vall d'Hebron-Institut

			de Recerca (HUVH IR)		de Recerca (HUVH IR)

Invoicing will be issued on a monthly basis. The amount of each monthly invoice will correspond to the proportional distribution of the total awarded contract value divided by the full duration of the contract, with no additional costs beyond the awarded amount. A single invoice will be issued at the end of the service completed monthly.

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 2026-013**".

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 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

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

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

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 the case of electronic invoicing, this will be rejected until the requested data is 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 9. Responsible of the contract

The responsible for the contract is Dr. Xavier Cañas Perea, Principal Investigator for Project UICM24/00003, who 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 10. 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 11. Allocation criteria

The following criteria and percentages of evaluation of the tender proposals and the determination of the most economically advantageous will be considered for the evaluation of the tender proposals:

1. Criteria evaluable through automatic formulas	**Maximum 60 points**
• Economic Offer	Maximum 40 points
• Automatic Evaluation Criteria	Maximum 20 points
2. Criteria that can be assessed through value judgments	**Maximum 40 points**

11.1 Criteria that can be assessed through automatic formula…….... up to 60 points

FINANCIAL OFFER.....up to 40 points

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

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

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.***

AUTOMÁTIC EVALUATION CRITERIA…….…. up to 20 points.

Tenderers must mark the automatic evaluation criteria in Appendix No. 1 of the PCAP, which they must provide in Envelope No. 3, as well as the documentation that accredits this, if applicable:

- Reduction of Response Time (SLA) ..... up to 10 points
  Scoring will be applied as follows:
  - Requests responded to within 48 hours ..... up to 5 points
    - Response time between 1 and less than 12 hours ..... 5 points
    - Response time between 12 and less than 24 hours ..... 3 points
    - Response time between 24 and less than 48 hours ..... 2 points

  - Incidents-management responded to within 4 hours ..... up to 2 points
    - Response time for incidents under 1 hour ..... 2 points
    - Response time for incidents between 1 and less than 4 hours ..... 1 point

  - Critical incidents responded to within 2 hours ..... up to 3 points
    - Response time for critical incidents under 1 hour ..... 3 points
    - Response time for critical incidents under 1 hour and 30 minutes ... 2 points

- Service Desk Coverage…… up to 5 points
  This criterion evaluates the level of availability of the Bidder's technical assistance service for users, including hours of operation and accessibility channels.
  Scoring will be applied as follows:
    - 24/7 coverage (bank holidays included) ..... 5 points
    - 24/7 coverage (bank holidays not included) ..... 3 points
    - 12/5 coverage (12 hours/day, 5 days/week) ..... 1 point

- Compliance with ISO/IEC 27001:2022……..... up to 2 points
  This criterion evaluates whether the Bidder holds an ISO/IEC 27001:2022 certification covering the scope relevant to the services subject to this procurement procedure. Scoring will be applied as follows:
    - Certification covers the services offered under this contract ……2 points
    - Certification does not cover the relevant service scope……1 point

  The certificate must be submitted in Envelope No. 3, and it must be issued in the name of the bidding company.

- Compliance with ISO 22301:2019……..... up to 3 points
  This criterion evaluates whether the Bidder holds an ISO 22301:2019 certification covering the scope relevant to the services subject to this procurement procedure, ensuring that the Business Continuity Management System effectively applies to the services provided under the contract. Scoring will be applied as follows:
    - Certification covers the services offered under this contract ……3 points

- Certification does not cover the relevant service scope……..…2 points

The certificate must be submitted in Envelope No. 3, and it must be issued in the name of the bidding company.

11.2 Criteria that can be assessed through value judgments..... up to 40 points.

The following criteria can be assessed through value judgments. The value will be done in compared with the tenders submitted. The highest score will be given to the offer that best fits the technical requirements set out in this document. All other bids will be scored proportionally by comparison. Subsequently, the various proposals evaluated in descending order will be sorted out, and the following formula will be applied to obtain the score,

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

P_{op}= Score the offer to value
P = Criteria score
VT_{op}= Technical evaluation of the scored offer
VT_{mv}= Technical evaluation of the best scored offer

It will be necessary to present a technical offer of a **maximum of 20 single-sided pages in Arial 11 font.** In the case of submitting a technical offer of more than 20 pages, it will not be evaluated after page 21.

The following criteria will be evaluated by value judgments. The award criteria for assessing the contents of Envelope No. 2 are as follows:

Training and Capacity-Building Quality…….…….. up to 5 points
This criteria evaluates the quality, suitability, and completeness of the training programme proposed by the Bidder for professional users, system administrators, coordinators, and support teams. The assessment will consider not only the total number of training hours included, but also the methodological approach, the clarity and relevance of the content, and the program's ability to ensure effective adoption and autonomous use of the platform.

The evaluation will take into account, the following aspects:

- Structure and coherence of the training plan, including modules, sequencing, and defined learning objectives.
- Relevance, depth, and accuracy of the content for each user profile (clinical, coordination, administrative, technical).
- Quality and usability of training materials provided (guides, manuals, quick-reference sheets, videos, tutorials).
- Training methodology, including practical exercises, simulations, hands-on sessions, and real-use clinical scenarios.

- Adaptation to the decentralized and pediatric clinical-research context, including remote operations, digital workflows, and safety considerations.
- Availability of refresher sessions, follow-up support, and additional reinforcement mechanisms after deployment.
- Capacity of the training plan to ensure user autonomy, minimize operational errors, and support efficient platform adoption.

Scoring is up to 5 points, based on the overall quality, clarity, completeness, methodology, and alignment of the proposed training program with the operational needs of the project.

Project Execution Methodology and Governance..... up to 35 points

This criterion evaluates the soundness, completeness, and maturity of the Bidder's proposed project-execution methodology and governance framework. The purpose is to assess the Bidder's capacity to deliver the project reliably, transparently, and in alignment with the operational and regulatory requirements of VHIR and the BRIDGE Project.

The evaluation will consider, in a detailed manner, the following aspects:

1. **Work Plan Structure and Feasibility…….. up to 5 points**
   - Clarity and coherence of the overall work plan.
   - Logical sequencing of activities, tasks, and work packages.
   - Realistic timelines aligned with project constraints and dependencies.
   - Clear identification of phases, including design, development, integration, validation, deployment, and training.

2. **Definition of Milestones, Deliverables and Acceptance Criteria… up to 5 points**
   - Quality and specificity of the proposed milestones.
   - Adequacy, relevance and clarity of deliverables (technical, functional, regulatory, operational).
   - Appropriateness of acceptance criteria for each deliverable and milestone.
   - Mechanisms for documenting and demonstrating completion and quality.

3. **Governance Model and Roles……. up to 10 points**
   - Definition of governance bodies (e.g., Steering Committee, Project Management Office).
   - Clear assignment of roles, responsibilities and decision-making authority.
   - Identification and qualification of key personnel.
   - Mechanisms for escalation and conflict resolution.
   - Experience and qualifications of the assigned project team will be assessed, specifically their prior involvement in digital health platforms development, interoperability projects, decentralized/hybrid clinical trial tools, telemedicine workflows, or healthcare data management environments.

4. **Risk-Management Strategy…… up to 5 points**
   - Identification of potential technical, operational, regulatory, and interoperability risks.
   - Robustness of mitigation measures.
   - Monitoring and periodic review of risks throughout the project lifecycle.
   - Inclusion of contingency planning for high-impact risks.

5. **Change-Management Procedures…… up to 4 points**
   - Processes for evaluating, approving and documenting changes.
   - Impact analysis for schedule, scope, cost and quality.
   - Criteria for accepting or rejecting change requests.
   - Traceability and transparent communication of approved changes.

6. **Communication Plan with VHIR…… up to 3 points**
   - Structure and periodicity of coordination meetings.
   - Communication channels and reporting mechanisms.
   - Procedures for sharing technical updates, support plan for resolving technical incidents, version notes and documentation.
   - Capacity to ensure transparency, traceability and smooth collaboration with VHIR stakeholders.

7. **Quality-Assurance and Monitoring Mechanisms…… up to 3 points**
   - Methodology for controlling the quality of development, integration and testing activities.
   - Definition of KPIs, indicators or control points.
   - Procedures for reviewing and validating deliverables.
   - Commitment to corrective and preventive actions.

In accordance with Directive 1/2020 on the Application of Evaluation Formulas and Scoring of Economic and Technical Proposals, a threshold is established for each criterion to be evaluated and subsequently scored, which in no case may be less than 50% of the evaluation of each criterion.

Therefore, the minimum scores for each sub-criteria in order to apply the formula will be:

1. Work Plan Structure and Feasibility (2,5 points)
2. Definition of Milestones, Deliverables and Acceptance Criteria (2,5 points)
3. Governance Model and Roles (5 points)
4. Risk-Management Strategy (2,5 points)
5. Change-Management Procedures (2 points)
6. Communication Plan with VHIR (1,5 points)
7. Quality-Assurance and Monitoring Mechanisms (1,5 points)

There are two possible options regarding 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 the evaluation of the bids exceeds the minimum evaluation threshold, all of them obtain as a score the value obtained in the evaluation phase and no bid is excluded from the tender.

- Option 2- If any of the bids exceed the threshold, all the bids are scored and no bid is excluded from the scoring phase, nor from the tender.

In the event that only one bidder submits a tender, the formula presented in the technical criteria will not be applicable by the bidder, the results obtained after the subjective evaluation by the person in charge will be enough.

IMPORTANT NOTE: In order to be awarded the contract, the tenderer must obtain at least **twenty-five (25) points** in the proposal relating to the criteria quantifiable according to value judgements. Otherwise, the bidder will be excluded.

Barcelona, 11th March of 2026

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