

**NECESSITY REPORT TO ESTABLISH THE CONTRACTING OF THE DEVELOPMENT AND IMPLEMENTATION OF AN APPLICATION BY THE PROJECT UICM24/00003, FOR THE FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON (VHIR).**



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**2026-013 APP DEVELOPMENT (UICM24/00003)**

Dr. Xavier Cañas Perea, Principal Investigator for Project UICM24/00003 of the Fundació Hospital Universitari Vall d'Hebron - Institut de Recerca, proposes that the corresponding file be included 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.

The duration of this service contract will coincide with the duration of the aforementioned project, which is until **31<sup>st</sup> 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.

The total maximum budget is "TWO HUNDRED THOUSAND EUROS" (200.000,00 €), without VAT.

In view of all of the above,

**IT IS HEREBY DECIDED:**

1.- To order the opening of the tender file for 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 maximum budget for this tender is set at 200.000,00 €, without VAT.

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

Barcelona, on the digital signature date.

**RESPONSIBLE**

Dr. Xavier Cañas Perea

Principal Investigator for Project UICM24/00003

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