



Tender for Contracting

Fundació Sant Joan De Déu, has launched a tender for clinical data analysis and medical writing services for the results obtained in the ReLink Advanced and AirVault clinical investigations. Both medical devices pretend to make IV therapy safer for healthcare personnel and patients by: (i) preventing mechanical complications, such us accidental dislodgement, and (ii) removing harmful air bubbles in a closed system. The project location is Barcelona, and the tender is closing on 5th July 2024. SAFE-Infusion is financed by HORIZON 2020 EU Fast Track to Innovation (GA: 971225).



TECHNICAL DOSSIER OF THE SERVICE

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1. INTRODUCTION TO THE PROJECT

The requested services are part of the *"Stop Adverse Fluid Events in Infusion: weak-link tube connection and air removal devices monitored in the cloud for safer, more accurate and cost-effective IV therapy in hospital and at home"* (SAFE-Infusion) project, funded by the European Union's Horizon 2020 EU Fast Track to Innovation program under Grant Agreement no. 971225.

Overall objective: SAFE-Infusion project aims to disrupt the intravenous (IV) tube market by maturing and launching the next-generation tube connection and air removal device, thereby making IV therapy safer for healthcare personnel and patients. The technology partnership will advance healthcare by (1) preventing mechanical complications, such as accidental dislodgement of the IV tube which causes patient harm, wastes valuable fluid resources including blood and IV drugs, and (2) removing harmful air bubbles and toxic vapours mixed with IV fluids. Overall, this project intends to increase patient safety leading to faster recovery. Our technology can help to reduce hospital costs by as much as 90%, enabling IV therapy to be delivered safely in every environment. By reducing adverse events this project will support EU efforts to reduce healthcare costs, occupational harm and address the environmental burden of plastic waste and carbon footprint.

Problem to address and business opportunity: Over 80% of in-hospital patients receive IV therapy, making it the most performed invasive treatment with 3.8 billion disposable IV tubes used annually in Europe and USA. This procedure is not safe neither for healthcare personnel nor patients, with serious consequences generating additional health care costs of €43 billion every year. According to the European Federation of Nurses Associations (EFN) more than 7.3 million nurses are exposed to toxic vapour every year during infusion of hazardous drugs. There is also a huge environmental impact, with over 26,000 tonnes of extra plastic waste in Europe and USA per year due to disposable IV tubes discarded after dislodgement and syringes used to evacuate air.

SAFE-Infusion is an international and multidisciplinary consortium focused on pretend to make IV therapy safer for healthcare personnel and patients.

Fundació Sant Joan de Déu is SAFE Infusion's project partner responsible for clinical investigations.

2. CONTRACTING SERVICE AND DELIVERABLES

2.1. CONTRACTING SERVICE

The SAFE-Infusion project includes specific evaluation & validation of clinical studies and Health economics and outcomes research (HEOR).

To conduct those specific activities, it is necessary to involve an external organization with the right expertise in medical scientific writing and the capacity to carry out statistical data analysis.

Study details regarding data analysis are briefly summarized in the following table:



Study	N	Groups of study	Main variables	Statistics
ReLink Advanced	938 PIVC	Control and intervention	<ul style="list-style-type: none"> • Number of mechanical complications: Phlebitis, Infiltration, Occlusion and Dislodgement • Frequency and severity of Adverse Events • Questionnaire for healthcare workers • Costs 	Descriptive statistics and statistical inference
AirVault	120 devices	Intervention	<ul style="list-style-type: none"> • IV setup • IV fluids • Flow rates • Set-up • Duration of infusion 	Descriptive statistics and statistical inference

3. REQUIREMENTS

3.1 REQUIREMENTS ABOUT THE SUPPLIER

- Be an organisation focused on generating scientific content (writing of scientific publications and statistical data analysis)
- Have previous experience with medical writing services in medical devices.
- Previous experience in projects related to patient safety will be desirable.

3.2. REQUIREMENTS REGARDING THE PROPOSAL OF SERVICE

Design the technical proposal to perform every task detailed in this tender. Including:

- Detailed planning of activities and objectives
- Team
- Budget

4. WORKING METHODOLOGY

The contractor selected will work under the coordination and together with the team of FSJD, leading the clinical data analysis and medical writing services for the results obtained in the ReLink Advanced and AirVault clinical investigations.

5. BUDGET

The quality of the technical proposals submitted, and the corresponding budget will be considered in the assessment phase to choose the contractor.

6. SUBMISSION OF PROPOSALS AND EVALUATION

6.1. DEADLINE FOR THE SUBMISSION OF THE PROPOSALS:

The deadline to submit proposals is the 5th July 2024, at 12 pm CEST.



6.2. DOCUMENTATION TO BE SUBMITTED:

6.2.1. Documentation about the supplier

- Institutional expertise for proposed service.
- Composition of the team: An outline of the staff who will be involved in the activities.
- Technical proposal
- Budget

6.3. CRITERIA OF EVALUATION:

An interdisciplinary team of FSJD will assess the different proposals submitted. This will be formed by:

- Principal Investigator of SAFE-Infusion Project, and Head of the Patient Safety Committee.
- Unit Innovation Coordinator and Project Managers of the Safe-Infusion project.
- International Project Manager.

The expertise and the proposal of activities will be evaluated together. The maximum score for every aspect will be:

- Curriculum of expertise of the institution: 5 points
- Composition and expertise of the team: 5 points
- Geographic proximity: 5 points
- Technical proposal: 5 points
- Adequacy to the needs of the investigator team: 5 points
- Budget: 5 points

Only the proposals which achieve at least 15 points will be considered as candidates to perform the activities of this contract. The best technical quality proposal with the fairest budget will be selected.

7. CONTRACT DURATION

Between 1st September 2024 and until scientific publications are published.

8. ADDITIONAL INFORMATION

For any additional information related to this tender, the contact email will be: parcsanitari.innovacio@sjd.es, Subject: Safe-Infusion - Tender for contracting medical writing