Designing an EU support mechanism for pre-market early clinical investigation of medical devices

Francesco Malandrini[1,2], Niccolò Cusumano[1], Nicolas Martelli[2,3], Tess Martin[2,3], Alexandra Herborg Cornelius Poulsson[4], Giuditta Callea[1]

[1]SDA Bocconi School of Management, CERGAS, Milan, Italy | [2]Paris-Saclay University, GRADES, Faculty of Pharmacy, France | [3]Hôpital Européen Georges Pompidou, Assistance Publique – Hôpitaux de Paris, Paris, France | [4]Norwegian Institute of Public Health, Oslo, Norway

FACTS & FIGURES

Start date: 1st October 2023
End date: 30 September 2027
Total cost: €19.71 million
EU contribution: €10.53 million
Industry contribution: €9.17 million
Grant agreement: 101112185
Website: heuefs.eu

TASK 3.1.6 OBJECTIVE: Develop recommendations for a potential EU public support mechanism tailored to **pre-market first-in-human and early clinical investigation** of medical devices (around TRL 5–7).

CHALLENGE

Pre-market early clinical investigation is the point at which initial human evidence can still inform medical device (MD) or procedure refinement.

The problem is fragmented support: separate programmes cover specific stages, activities or applicants, without forming a coordinated pathway.

Task focus: mapping of support systems and building consensus for future recommendations.

APPROACH & METHODOLOGY

Evidence-to-recommendation pathway

Sequential mixed-methods design

1. **DEFINE ELIGIBILITY** Four GO/NO-GO criteria: EFS/FIH-stage overlap; design not finalised; no prior clinical evidence required; no CE mark or FDA clearance/approval required.
2. **MAP & COMPARE** 60 candidates screened → 40 mechanisms in 9 jurisdictions; 30-item extraction, central quality control and cross-country / cross-mechanism analysis.
3. **TRANSLATE EVIDENCE INTO DELPHI DIMENSIONS** iindings were synthesised into six policy-design dimensions.



4. **BUILD CONSENSUS** The HEU-EFS network will complete a two-round modified Delphi: 9-point ratings, controlled feedback and reassessment by the same panel.
5. **CO-DEVELOP RECOMMENDATIONS** Co-develop and validate recommendations with national and EU policy-makers to strengthen European MedTech competitiveness.

RESULTS

A fragmented support landscape for pre-market early clinical investigation

40 mechanisms | 9 jurisdictions | 60 candidates screened

SCOPE: technology-agnostic 26, MD-specific 14



TRL EVIDENCE: official 13, inferred 18, unspecified 9



LEAD ACCESS: SME-only 16, consortium 11, hospital/academia 9, large enterprise 4



SUPPORT FORM: grants 28, in-kind 6, loans 3 • other 2, coverage 1



0/40 formal HTA / reimbursement links

NO SEQUENCED PATHWAY support remains split across programmes, applicants and instruments.

REPORT-DERIVED PRIORITY GAPS limited early-clinical support · R&D–HTA disconnect · restricted industry access · no sequenced innovation pathway

VALUE OF IHI COLLABORATION

Mapping described the gaps; the IHI partnership converted them into testable design choices.

CROSS-COUNTRY VALIDATION | public partners and local experts checked programme eligibility, access and implementation.

MULTI-STAKEHOLDER DESIGN | industry, hospitals, regulatory, HTA and patient perspectives reshaped the questions and response options.

CONSENSUS ROUTE | a two-round anonymous Delphi will test potentially complementary components before policy-maker co-development.

IHI ADDED VALUE | funding provides access to public and private experts who jointly develop recommendations for a European support mechanism.

CAREER IMPACT

PUBLIC–PRIVATE PERSPECTIVE | I learned to integrate industry, clinical, regulatory, HTA and policy perspectives.

SKILLS DEVELOPED | Cross-country evidence mapping, stakeholder engagement, Delphi methods and policy translation.

CAREER PATH | HEU-EFS linked my PhD to medical device development and European innovation policy.

This project is supported by the Innovative Health Initiative Joint Undertaking and its members.