Harmonized Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS)

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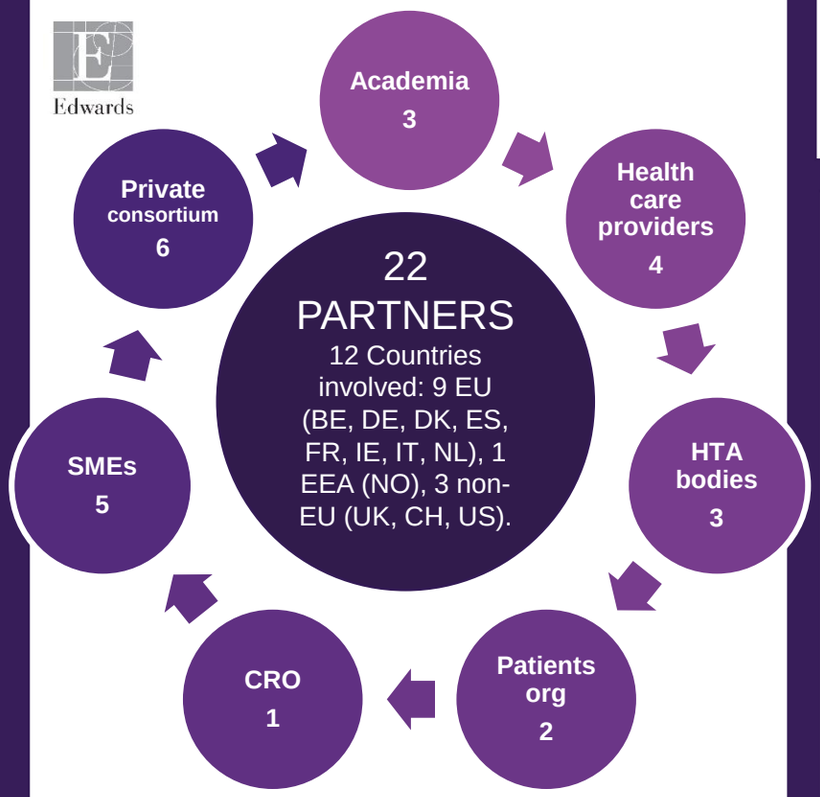


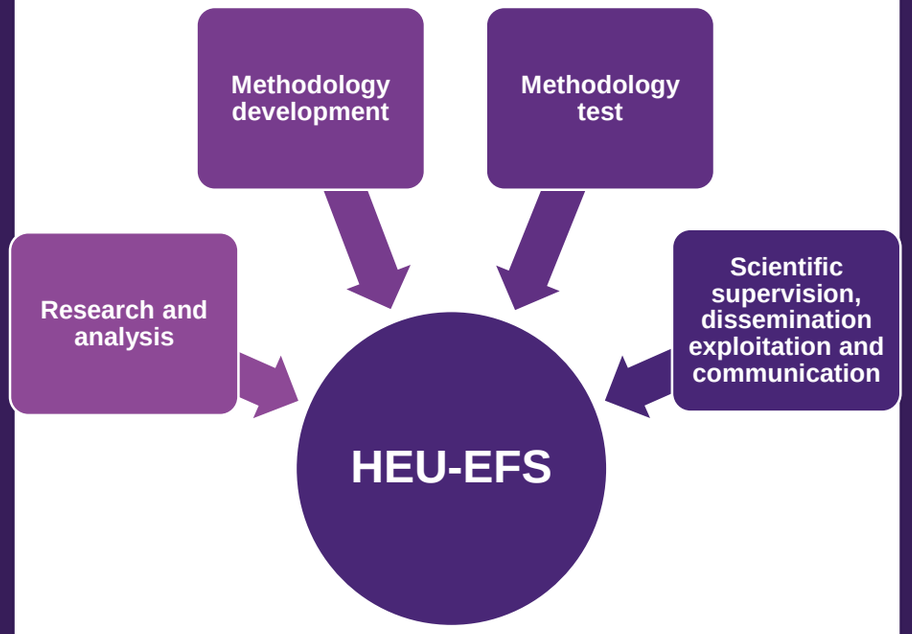
Goal

Formulate recommendations for the establishment of an Early Feasibility Studies Program within the European Union, with a focus on ensuring patient safety and enhancing the EU single market competitiveness.

Objectives

1. Conduct **research and analysis** on regulatory framework and characteristics and impacts of pre-market programs
2. Build a **sustainable network** of stakeholders to promote the implementation of EFS in the EU
3. Develop a **harmonised EU methodology** and recommendations to uptake EFS
4. Undertake **pilot use cases** to test the proposed methodology
5. Develop **performance measurement instruments** for the EU EFS Program
6. Implement an open access **online portal** dedicated to EFS and **disseminate** results and recommendations

Structure



Public consortium

Università Bocconi MILANO · Trinity College Dublin · Philipps Universität Marburg · Meditrial · Gemelli · Clínic Barcelona · EPF European Patients Forum · CARMAT · Newronika · Idris Oncology · Global Heart Hub · NIPH Norwegian Institute of Public Health · Qurasoft · Assistance Publique Hôpitaux de Paris · agenas · Region of Southern Denmark

Private consortium

Edwards · Abbott · Philips · GORE · Medtronic · DePuy Synthes

Project Information

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€ 19 008 438,75

EU Contribution:
€ 10 532 197,5

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WP
WP1 Research and analysis on state of play of pre-market programs and implementation barriers to EFS
WP2 Research and analysis on regulatory framework and organization of clinical evidence generation programs in the EU
WP3 Methodology development: rationale, processes, and procedure
WP4 Methodology development: evidence requirements, data, and statistical tools
WP5 Methodology development: EU EFS program monitoring system
WP6 Methodology development: ethical and legal aspects
WP7 Testing the methodology: pilot use cases
WP8 Web portal, dissemination, exploitation, and communication
WP9 Scientific supervision and project management

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