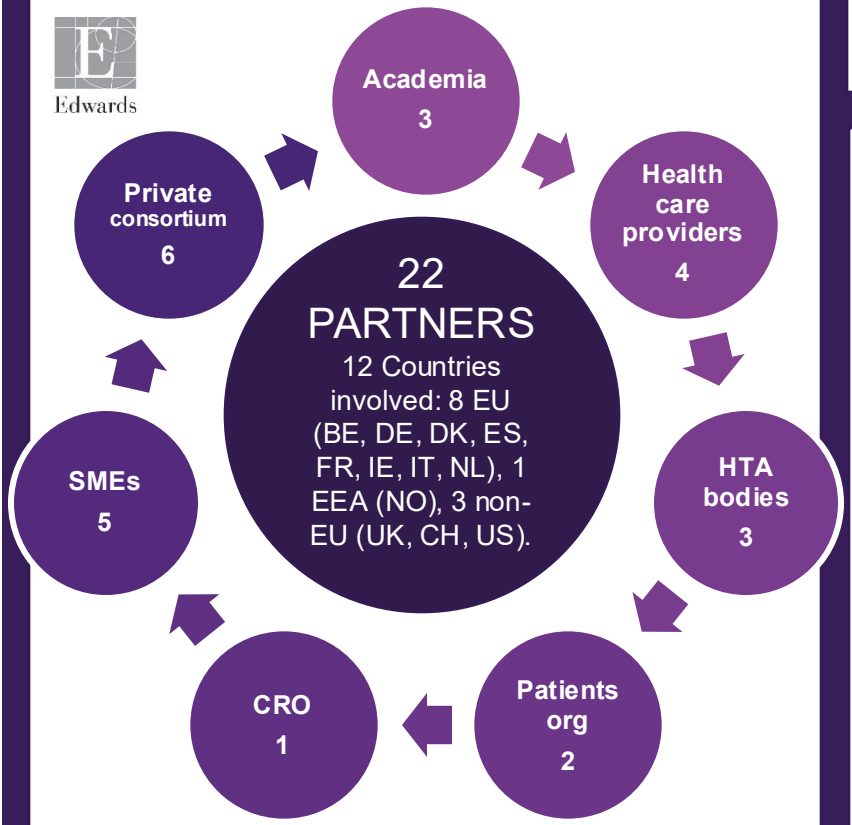
Harmonized Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS)

Consortium

Bocconi

Edwards



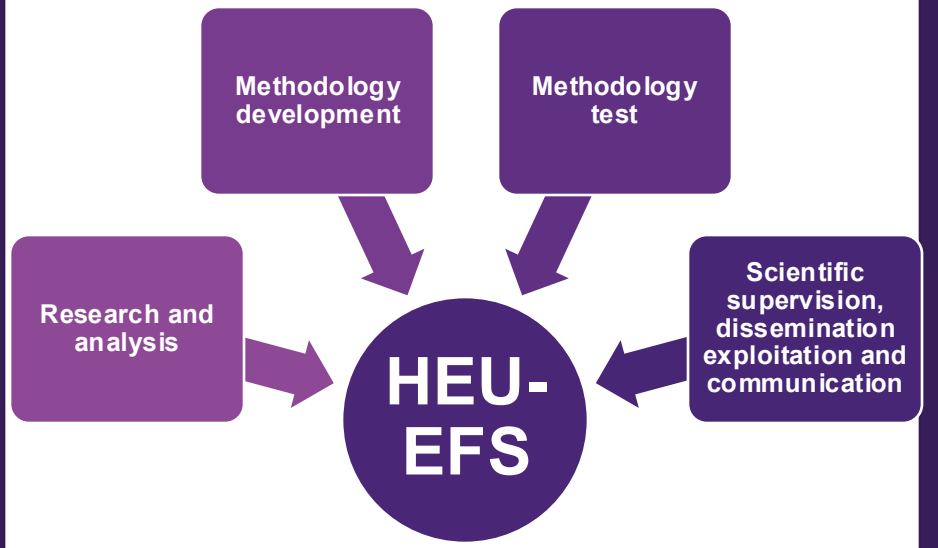
Goal

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



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