HEU-EFS Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union

Giuditta Callea, PhD | Bocconi University, Principal Investigator

EU Health Technology Assessment: Advent of a new era of collaboration

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Background

EFS

WHAT?

A **limited clinical investigation** of a device **early in development**

WHEN?

typically **before the device design** has been finalized, for a specific indication […].

WHY?

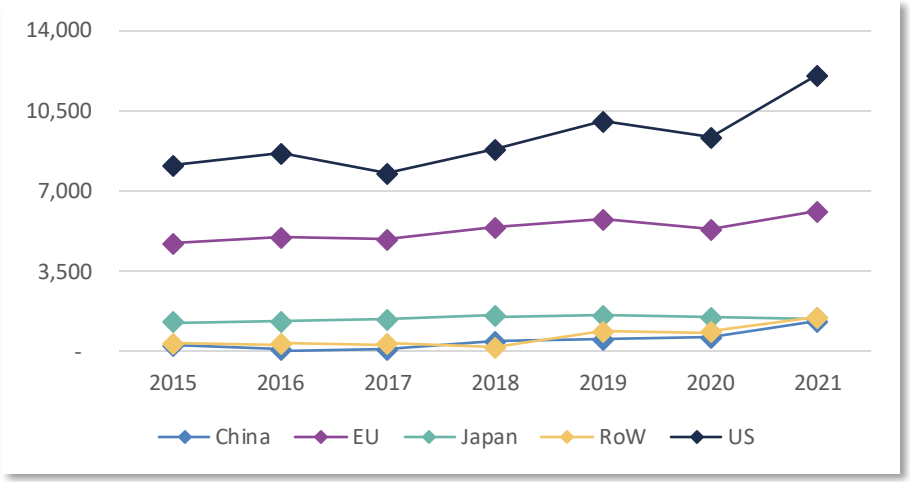
It can be used to **evaluate the device design concept** with respect to **initial clinical safety** and device **clinical performance or effectiveness** (if appropriate) as per intended use in a **small number of subjects** when this information cannot practically be provided through additional nonclinical assessments or appropriate nonclinical tests are unavailable. Information obtained from an early feasibility clinical investigation can **guide device modifications**. […]

- **Feasible** in the EU:
  - **ISO 14155:2020** Clinical investigation of medical devices for human subjects — good clinical practice.
  - **MDR 2017/745** and **HTAR 2021/2282** early dialogue and life cycle approach for clinical evidence generation.
  - **MDCG 2021-6** – Rev 1. December 2023 Q&A regarding clinical investigation.
- **Beneficial** to patients, clinical sites & trialists, technological innovation developers.
- But **no standardized procedural framework**, guidelines or common reference standards to conduct EFS in the EU.

Why an EU EFS Program

- The EU is at **risk of losing competitiveness and attractiveness** for innovation and investments.

R&D investments (million €) in healthcare equipment and service industry (Grassano et al 2022)



Expected CAGR of the global medical technology market 2017-2022 (Statista)

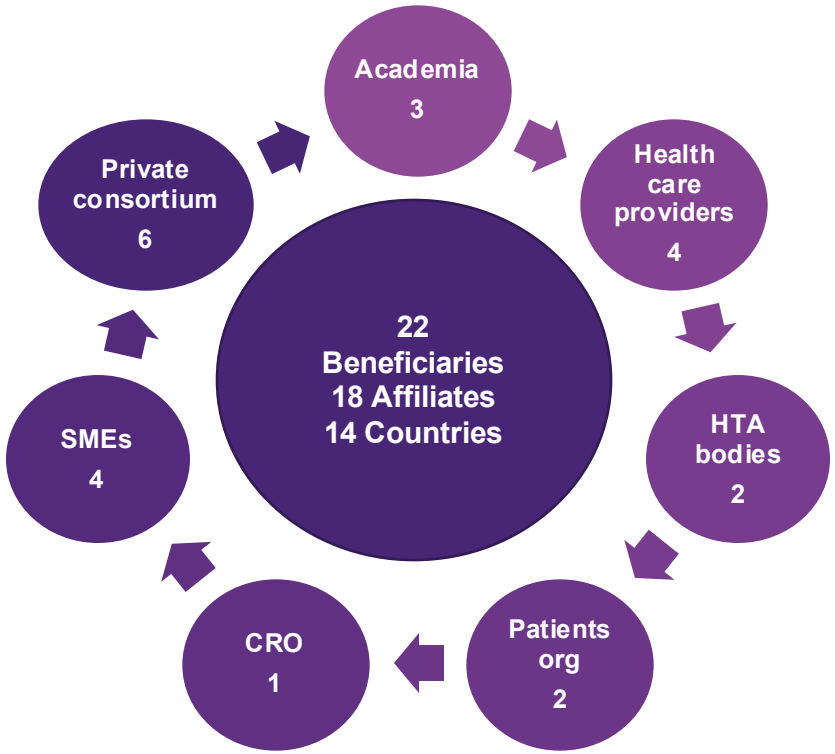
Harmonized Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS)

Project information

Start date: 1 October 2023
End date: 30 September 2027

DOI: 10.3030/101112185
Total cost: € 19 008 438,75

Consortium



Advisory Board

- Competent Authorities
- Notified Bodies
- National Ethics Committees
- Medical societies
- Networks
- Independent Experts
- Trade Association

Patient Advisory Group

- 11 members

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.

The HEU-EFS Project

WP9 Scientific supervision and project management

Research and analysis

- WP1 State of play of pre-market clinical evidence generation programs and implementation barriers to EFS
- WP2 Regulatory framework and organization of clinical evidence generation programs in the EU

Framework development

- WP3 Rationale, processes, and procedure
- WP4 Evidence requirements, data, and statistical tools
- WP5 Program monitoring system
- WP6 Ethical and legal aspects

Framework test

- WP7 Pilot use cases

WP8 Web portal, dissemination, exploitation, and communication

Progress of the activities

Research & analysis

- Characteristics of pre-market CI approval pathways
- Barriers and challenges of pre-market CI
- Characteristics of EFS
- EU regulatory framework and international standards
- Organisational characteristics of NCA

Recommenda-tions

- Harmonisation
- Dialogue
- Expertise and awareness
- Transparency
- Stakeholder involvement
- Incentives for R&D
- Reflect DHT-specific needs

Framework development

- Eligibility criteria
  - ❖Technologies
  - ❖Patient conditions
  - ❖Level of pre-clinical evidence
  - ❖Trialists and clinical sites competence
- Process, procedures, actors, timelines
- Templates & checklists
  - ❖CIP
  - ❖ICF
  - ❖MCTA
  - ❖Insurance agreement
- KPIs and Dashboard

Framework test

- Preparation for pilot use cases

Completed | Completed | Ongoing – Deliverables due September 2025 | Ongoing - pilots begin January 2026

Call for papers

28 April 2025

Early Feasibility Studies for Medical Devices: goldmine or fool's gold?

Submission deadline: **30 September 2025**

Special issue information:

This specialty update will present the experience and lessons learnt in the first 10 years of the FDA EFS Program and discuss the desirability and potential of these studies. It aims to gather empirical evidence and discuss, among others, whether their introduction has been successful in attracting early clinical investigations and facilitating early access to technological innovation in the US, where they stand in the evidence generation plan for MDs, whether products that come to the market after an EFS have a higher risk of safety issues for patients, what are the benefits perceived by the patients, and which feedback mechanisms can be put in place to include their preferences in the development of new MD. Case studies relating to individual technologies that arrived on the market after an EFS was conducted are welcome. We encourage submissions of contributions presenting strengths and weaknesses of EFS with a multi-stakeholder perspective including regulators, clinical sites and trialists, technologies developers, experts of ethical issues, patients and their associations.

https://www.sciencedirect.com/special-issue/321847/early-feasibility-studies-for-medical-devices-goldmine-or-fool-s-gold

www.heuefs.eu @HEU-EFS @HEUEFS info@heuefs.eu

Thank you!

giuditta.callea@unibocconi.it

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