Strategic vision for the future of European EFS

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What are Early Feasibility Studies

What	When	Why	Purpose
Limited clinical investigation of a medical device **early in development.**	Typically, **before the device design** has been finalized, for a specific indication. Additional **nonclinical** tests are either **not available** or **non informative**.	To evaluate the device design concept with respect to **initial clinical safety** and **performance or effectiveness** as per intended use in a **small number of subjects.**	Information obtained from an EFS can **guide device modifications.**

The FDA has an EFS Program since 2013

% MDs clinical studies in US

87%	45%
2004	2009

Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 1, 2013

The draft of this document was issued on November 10, 2011.

For questions regarding this document, contact CDRH's Andrew Farb, 301-796-6343, Andrew.Farb@fda.hhs.gov or Dorothy Abel, 301-796-6366, Dorothy.Abel@fda.hhs.gov, or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

EFS are 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

Regulatory Status	Pre-market			Post-market
Clinical development stage	Pilot stage (1.3.2)	Pivotal stage (1.3.3)		Post-market stage (1.3.4)
Type of design	Exploratory or confirmatory (1.4.2)	Confirmatory (1.4.3)		Observational (1.4.4)
Descriptors of clinical investigations	First in human clinical investigation (1.5.2) Early feasibility clinical investigation (1.5.3) Traditional feasibility clinical investigation (1.5.4)	Pivotal clinical investigation (1.5.5)	Post-market clinical investigation (1.2.3)	Registry[a] (1.5.6) Post-market clinical investigation[a] (1.2.3)
Burden to subject	Interventional (1.6.2)			Non-interventional (1.6.3)

EFS are beneficial

Patients

Patients with no or little treatment options access safe innovative technologies to improve prognosis and quality of life.

Health Systems

Payers and policymakers make evidence-based, informed investment decisions that meet patient needs and generate value for society.

Clinical & Innovation Excellence

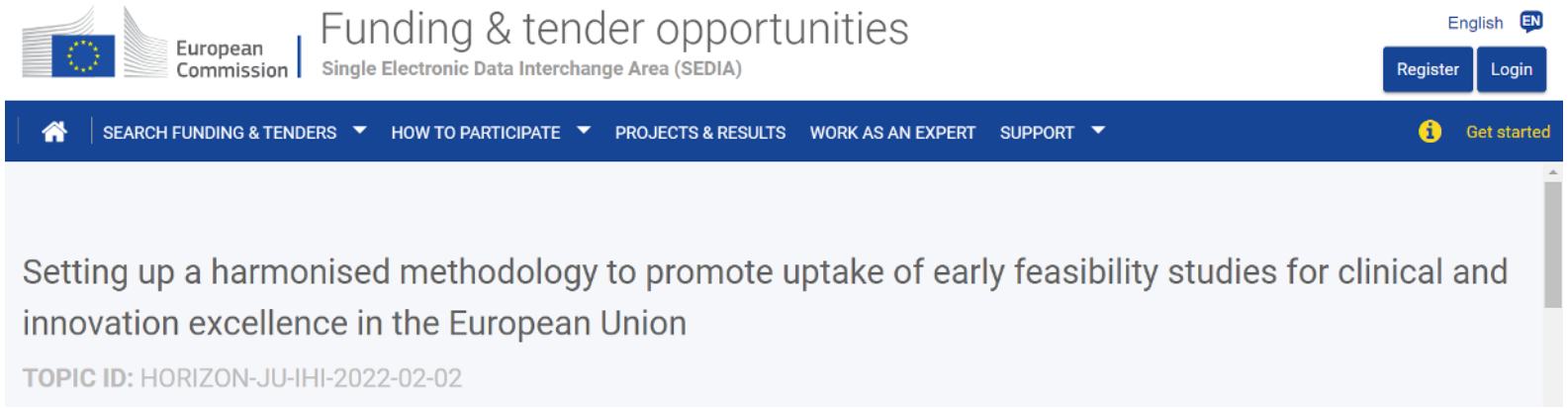
Companies develop innovations that meet patient and healthcare professional needs.

Healthcare professionals deepen their clinical development excellence.

But...

No harmonised procedural framework, guidelines or common reference standards to conduct EFS in the EU

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



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

innovative health initiative

HEU EFS

Project information

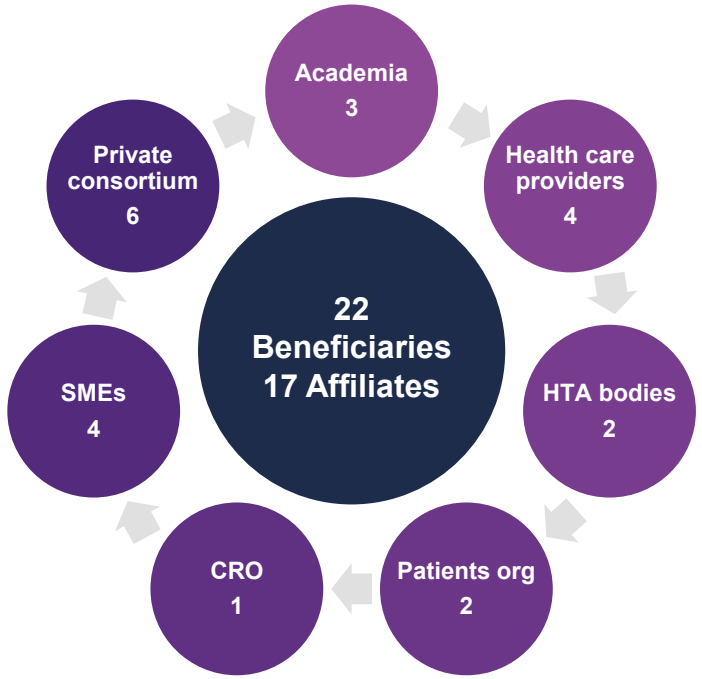
Start date: 1 October 2023
End date: 30 September 2027

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

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**.

Consortium

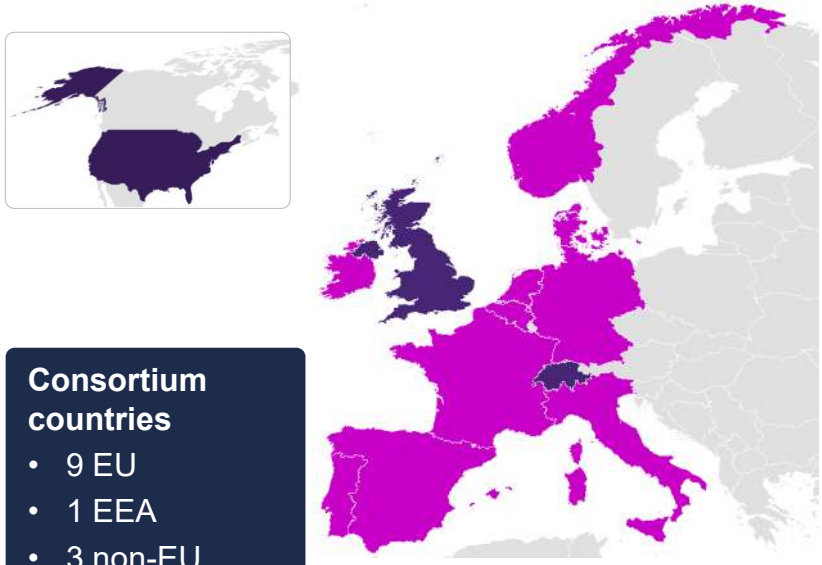


Advisory Board

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

Patient Advisory Group

10 members



Consortium countries

- 9 EU
- 1 EEA
- 3 non-EU

HEU-EFS Consortium

Bocconi

Edwards

Ollscoil na Gaillimhe University of Galway

Philipps Universität Marburg

NIPH Norwegian Institute of Public Health

Clínic Barcelona | Universitat de Barcelona
Fundació Clínic Barcelona

EPF European Patients Forum

Global Heart Hub

age.na.s. Agenzia Nazionale per i Servizi Sanitari Regionali

Abbott

Meditrial Digital Research Organization

Idris Oncology

Medtronic

Gemelli

Assistance Publique Hôpitaux de Paris

Johnson&Johnson MedTech

Region of Southern Denmark

GORE

CARMAT

Newronika®

Qurasoft

PHILIPS

Phases of the HEU-EFS Project

1 Research & analysis	2 Framework development	3 Framework test
Consultation with HEU-EFS Consortium		
Literature review	Mapping of EU regulatory pathways	Pilot use cases
Review of US FDA EFS program		
Data collection on EFS		
Analysis of international standards, EU regulation, MDCG Guidance		
Mapping of pre-market approval pathways and ethical approval process		
Surveys, interviews & focus groups		
Consultation with AB, PAG, DGSANTE, CIE WG		

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innovative health initiative

COCIR

efpia

EuropaBio

MedTech Europe

Vaccines Europe

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