innovative health initiative

HEU EFS
HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

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

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Clinical Investigations WG MD | 26 November 2025

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

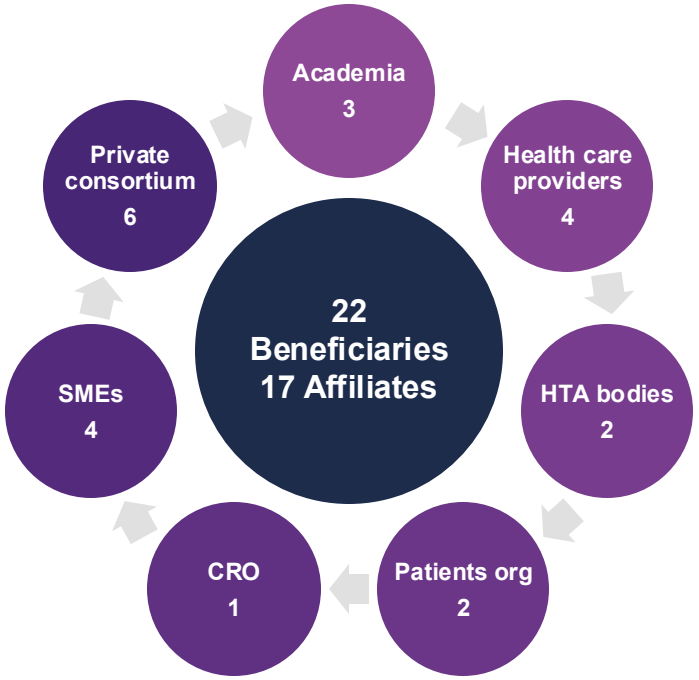
Project information

Start date: 1 October 2023
End date: 30 September 2027
DOI: 10.3030/101112185
Total cost: € 19 008 438,75

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

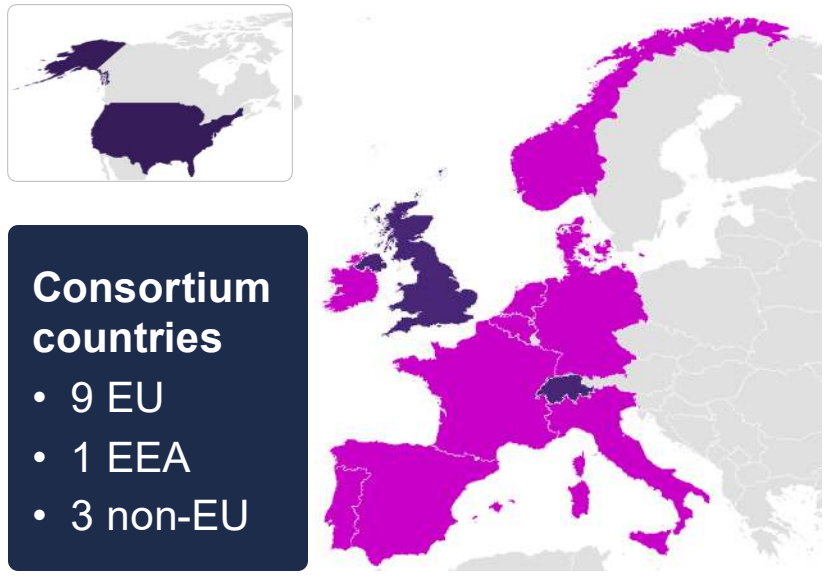


Advisory Board

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

Patient Advisory Group

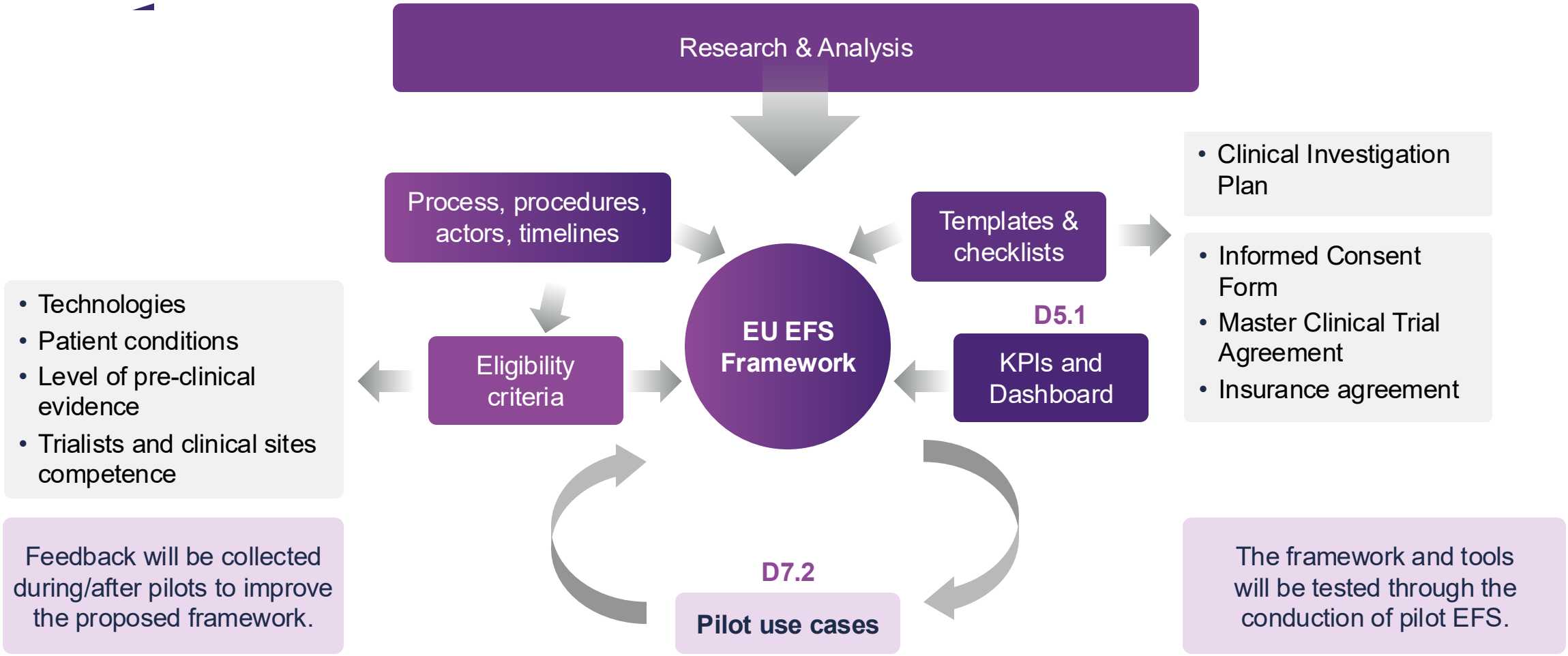
10 members



Consortium countries

- 9 EU
- 1 EEA
- 3 non-EU

EU EFS Framework



HEU-EFS approved deliverables can be downloaded from https://cordis.europa.eu/project/id/101112185/results

HEU-EFS open call for pilots

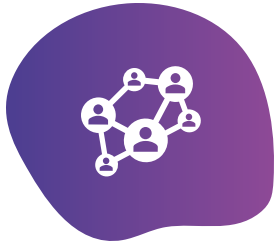
Main objectives of pilots

1. To test the HEU-EFS project methodological framework with selected pilot use-cases.

2. To recommend adjustments needed to improve the methodology.

Increase the number of pilots (max 10)

Expand the patient conditions



Obtain valuable feedback from entities not involved in HEU-EFS preparation

Increase awareness on EFS

What is in for pilot proposers?

Proposers have a distinctive chance to evaluate the methodological framework of the upcoming EU EFS Programme by advancing their innovation through a pilot regulatory process.

Specifically, participants will:

Get the opportunity to test streamlined process and templates for EFS submissions.

Benefit from a unique learning opportunity and engage with our consortium experts.

Contribute feedback that will shape the development of the future EU EFS programme.

Eligibility Criteria for the Pilots Technology

General criteria:

High-risk devices (Class III and Class IIb), where a clinical investigation will be required as part of the conformity assessment.

Breakthrough Device / Unmet Patients Needs

Anatomical Understanding

New / Expanded Intended Uses or Indications for Use for Patients

EFS Proposed Process

Pre-Submission | **Submission & Review**

Contact Point → **Early Dialogue** → **Submission** → **Validation** → **Review**

Pre-submission phase

- Contact point early in the process to allow for planning and resource allocation
- Multi stakeholder early dialogue for sponsor, NCA and where appropriate and relevant Ethics Committee, experts on the NCA, Principal investigator of clinical site. Option to invite other Member States if EFS is conducted in multiple countries

National Competent Authority (NCA)

Initial "Validation" Phase → completeness of submission file

- NCA Assessment time
- Proceed to Review Phase or Request for Information (RFI)
- RFI Cycle time for Sponsor and NCA

Review Phase → Scientific Review of submission file

- NCA review time, including utilizing a “stop-clock“ approach, and encouraging “rolling review process“ to facilitate timely review
- Approval or request for Information (RFI)
- RFI Cycle time for sponsor and NCA

Target 30% Reduction in Overall Process Timelines Compared to Current MDR

Submission process

Key process steps

1. **Online form: Expression of Interest**
2. **Information Call: Proposers with HEU-EFS point of contact**
3. **Online self-evaluation**
4. **Prioritized pilots informed by the point of contact**
5. **HEU-EFS Training for pilot proposers**
6. **Pilot Implementation can kick off**

About Pilot Application and Implementation

- HEU-EFS Point of Contact manages sponsor interaction & execution of pilots
- Training on HEU-EFS process and documentation will be provided

About the Point of Contact and Screening

- Bocconi University (point of contact) and HEU-EFS Screening Committee responsible for review of pilot application, answer questions and training
- Contact point: pilot@heuefs.eu
- Information: www.heuefs.eu

Key Timelines and Information

Timelines

- Submission of Interest open from today **until 31st March 2026.**
- Further to pilot selection, sponsors are expected to submit their application to authorities **no later than November 2026.**

Feedback mechanism

- **Feedback mechanism** on experiences with pilot implementation will be provided throughout the pilot.

Pilots

- A maximum of **10 public pilots** may be selected.
- Application and review process will be handled on a **first-come-first-serve basis.**
- **Note:** proposers should finance their own studies. No public funding will be available from IHI or from HEU-EFS consortium.

All information here: https://heuefs.eu/open-call-for-pilots/.
Expression of Interest here.

Interested in finding out more?

SCAN ME

Dedicated Webinar on Pilots on
5 December 2025, 15.00 – 16.00 CET
Register : https://lnkd.in/d_Q-yTaS

All information on pilots and expression of interest on www.heuefs.eu

All questions on pilots: pilots@heuefs.eu

www.heuefs.eu

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Thank you!

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innovative health initiative

COCIR

efpia

EuropaBio

MedTech Europe

Vaccines Europe

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