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

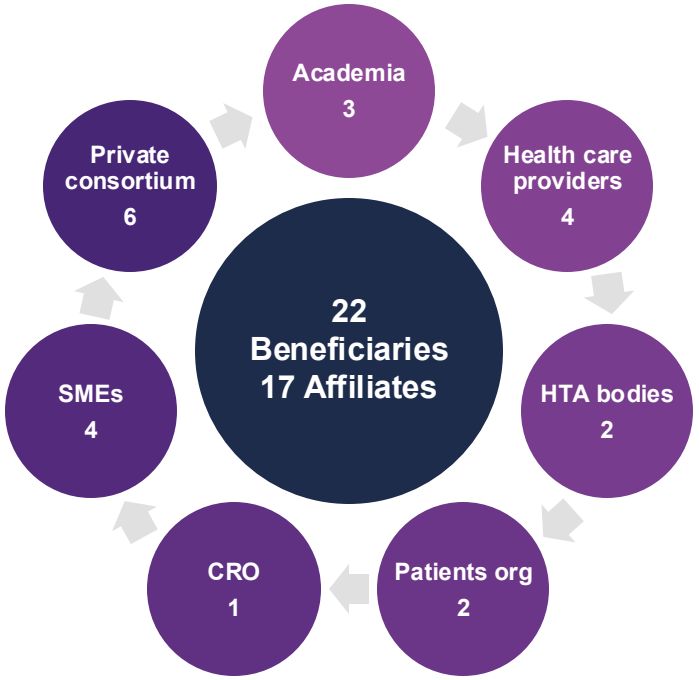
Project information

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

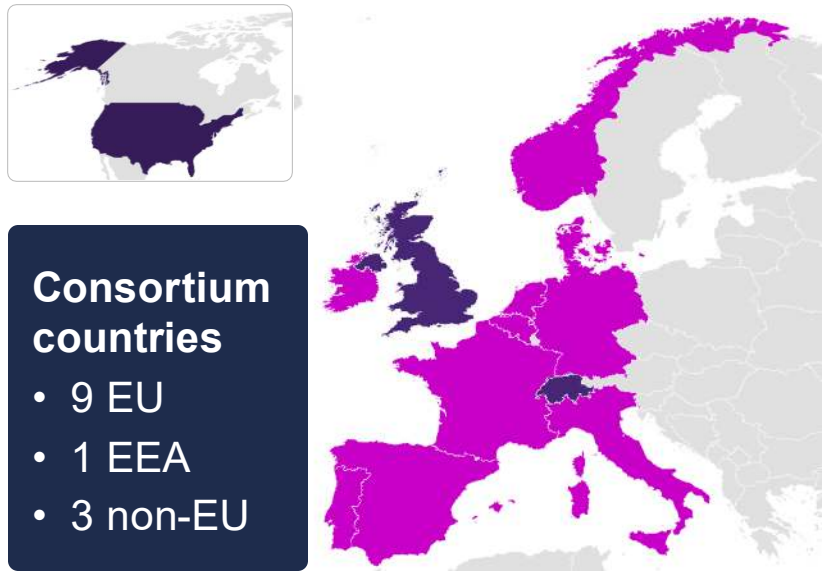


Advisory Board

- 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

HEU-EFS Progress (update M25)

Completed	Completed	Completed	Ongoing - pilots begin January 2026
Research & analysis	Recommenda-tions	Framework development	Framework test
• Pre-market CI approval pathways • Barriers & challenges of pre-market CI • Characteristics of EFS • EU regulatory framework and international standards • Organisational characteristics of NCA • Ethics approval in the EU	• Harmonisation • Dialogue • Expertise and awareness • Transparency • Stakeholder involvement • Incentives for R&D • Reflect DHT-specific needs	• Eligibility criteria • Process, procedures and timelines • Templates & checklists • KPIs and Dashboard	• Preparation for pilot use cases • Launch of open call for pilots

EU EFS Framework

CIRCABC space to share materials

D1.1, D1.2, D1.3, D2.1, D2.2, D2.3, D2.4

Research & Analysis

D3.2

Process, procedures, actors, timelines

D3.1

- Technologies
- Patient conditions
- Level of pre-clinical evidence
- Trialists and clinical sites competence

Eligibility criteria

EU EFS Framework

Templates & checklists

D5.1

KPIs and Dashboard

- Clinical Investigation Plan

D4.1

- Informed Consent Form
- Master Clinical Trial Agreement
- Insurance agreement

D6.2

D7.2

Pilot use cases

Feedback will be collected during/after pilots to improve the proposed framework.

The framework and tools will be tested through the conduction of pilot EFS.

Synergies with EU pathways (e.g., HTAR JSC, Expert Panel Scientific Advice), coordinated assessment , and draft MDCG breakthrough guidance.

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

Approved
Under evaluation

Eligibility Criteria for EFS Pilots

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

Pre-Submission Details

Contact Point → Early Dialogue

Contact Point

- Alerts NCA (and other recipients) to incoming file
- Identifies key principles of device technology
- Outlines qualifications for accelerated review
- Cycle timing: 1-2 weeks

Early Dialogue (optional)

- Opportunity to have targeted discussions related to the device, patient population, etc.
- Pre-submission to include appropriate background information
- Cycle timing: 30-60 days

Submission: Validation and Review Details

Submission → Validation → Review

Validation

Validation under MDR (Article 70) Timing (10 - 55 days)

- NCA Assessment: 10 – **15** days
- Sponsor response to identified gaps: 10 – **30** days
- Final NCA decision: 5 – **10** days

Proposed Accelerated (HEU-EFS) Timing (7 - 39 days)

- NCA Assessment: 7 – **12** days
- Sponsor response to identified gaps: 7 – **17** days
- Final NCA decision: 5 – **10** days

Review

Review under MDR (45 - 65 days)

- NCA Assessment: 45 – **65** days
- Sponsor response to identified gaps: Timing not specified
- Final NCA decision: Utilization of remaining clock

Proposed Accelerated NCA Assessment (30 - 45 days)

- Deficiency Communication:
  - Rolling Review/Interactive Questions approach
  - “Stop Clock” approach
  - “Approval with Conditions” approach
- Sponsor response to identified gaps: rapidly, be prepared
- Final NCA decision: Utilisation of remaining clock

HEU-EFS develop standardized checklists and template

Clinical Investigation Plan

- **Template -** based heavily on MDCG 2024-3 but tailored to EFS.
- **Checklist -** aids sponsors **internally** verify that **CIP is completed appropriately** specifically for EFS.

Informed Consent Form

- **Template - based on MDR** provides a standardised format for sponsors — particularly SMEs — that may lack internal documentation resources.
- **Checklist -** aids sponsors **internally** to verify that patient requirements are met, for the application process for the NCA and EC approval to be **compliant** with **relevant regulation**.

Master Clinical Trial Agreement

- **Checklist -** ensures all relevant and EFS-specific contractual elements are included.

Insurance Agreement

- **Guidance -** is a practical solution given that the insurance agreement is typically non-negotiable.
- It serves as a reference document to ensure inclusion of the **minimum essential elements required.**

Interviews with NCAs

8 one-to-one interviews (90 minutes, online)

- ITALY (pilot) — AB
- NORWAY (pilot)
- IRELAND * — AB
- PORTUGAL — AB
- CZECH REPUBLIC
- BELGIUM*
- FRANCE*
- AUSTRIA

AB = Member of HEU-EFS Advisory Board
* Coordinating Member States for pilot coordinated assessments

Experience with EFS-like studies
- Lack of formal EFS definition & homogeneous assessments across NCAs
- Poor documentation quality and limited evidence on novel devices challenge EFS validation and evaluation

Dialogue between NCAs and sponsors for EFS
- Dialogue - formal or informal - improves assessment efficiency and speed through NCA adaptability and sponsor cooperation

Challenges to and opportunities for harmonization
- Coordinated assessment helps NCAs learning from each other, paving the way for unified EFS assessment in EU and MDCG-endorsed guidance

Efficiency of EFS applications evaluation
- Additional data from sponsors and standardised templates address and prevent missing information from applications

Ethical approval
- Diverse ethics approval models across Member States generate struggles for NCAs and underscore the need for a harmonized model

Initial findings regarding best practices implemented by EU NCA

Innovation Desk for scientific advice to sponsors in the form of written exchanges and/or discussions.

Pre-submission dialogue adapted to each sponsor's needs.

Scientific Technical Advice service handled by a separate department; tiered structure in the form of written responses and/or meeting based on complexity of sponsors' request. Sponsors may also submit informal inquiries.

Dialogue available via a separate department focused on scientific and regulatory advice; sponsors can consult voluntarily.

New wave of interviews is starting.

Help us mapping additional best practices!

Please fill the doodle you have received.

HEU-EFS open call for pilots

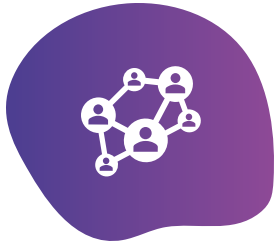
Main objectives of pilots

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

www.heuefs.eu @HEU-EFS @HEUEFS

Thank you!

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