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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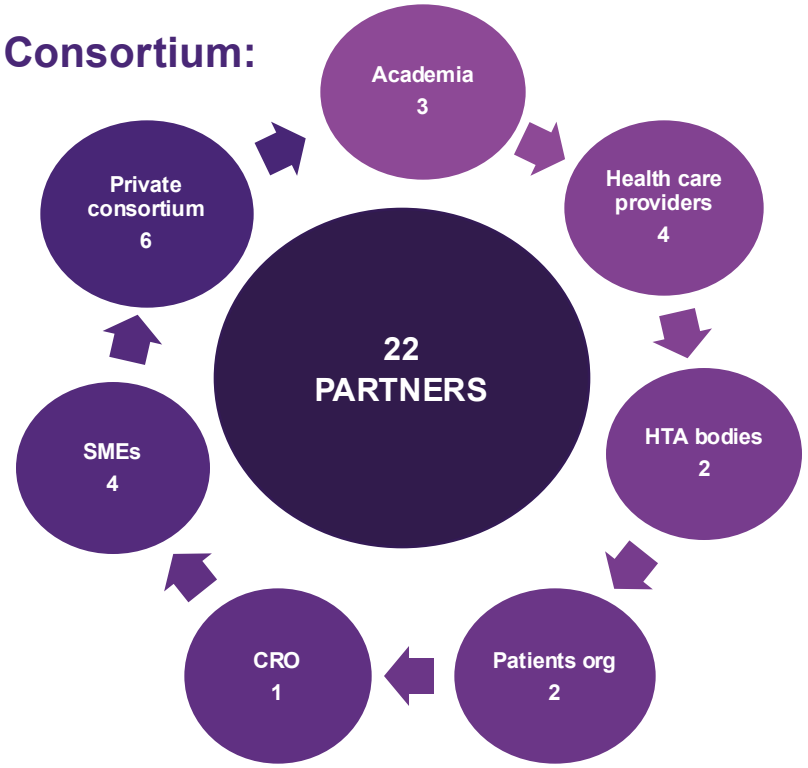
MDCG Clinical Investigation and Evaluation Working Group | 8 April 2025

The HEU-EFS project

Goal: Formulate recommendations for the establishment of an EFS Program within the EU, with a focus on ensuring patient safety and enhancing the EU single market competitiveness and attractiveness for R&D investments.

Consortium:



Timeline: 1 Oct 2023 – 30 Sept 2027.

Macro-areas of research implemented

- EU & US regulations and international standards.
- Approval pathways for pre-market clinical investigations (56 EU, EEA, non-EU countries).
- EFS database (552 studies).
- Case studies on technologies on the market after EFS.
- Challenges in pre-market clinical investigations (through survey, focus groups, interviews, workshops).

Informing the development of EU EFS Program

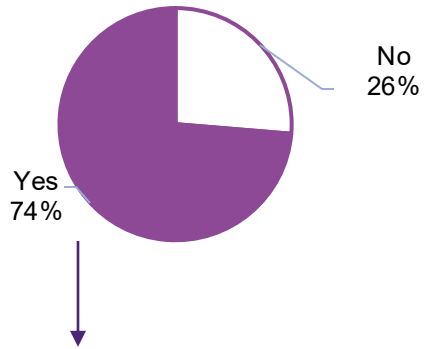
- **Eligibility criteria** for technologies, conditions, pre-clinical evidence, clinical sites and clinical competence.
- **Processes, procedures, actors, and timelines**.
- **Templates and checklists** for Clinical Investigation Plan (CIP), Informed Consent Form (ICF), Master Clinical Trial Agreement (MCTA), insurance agreement.
- **Performance Dashboard** to monitor the performance of the EU EFS Program.

Pilot EFS use-cases to test the proposed methodology

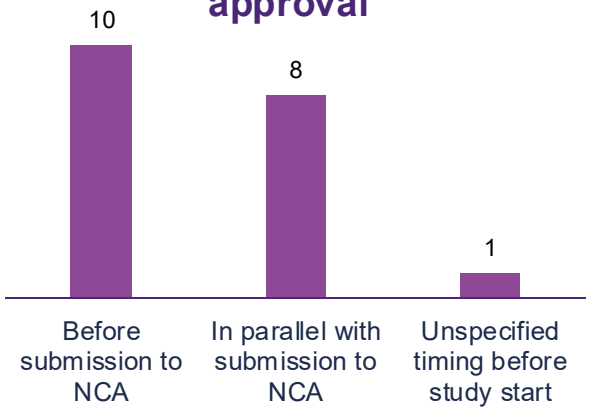
Recommendation areas for the EU EFS program informed by project results

HARMONISATION

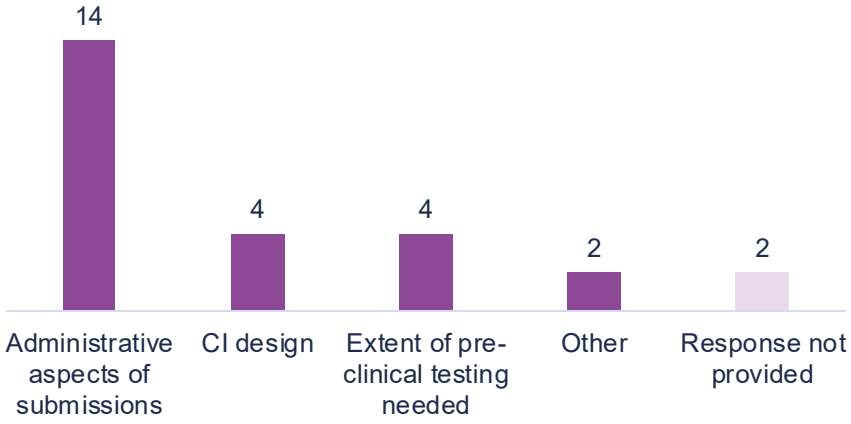
Provision of guidance for pre-market CIs



Timing of ethical approval

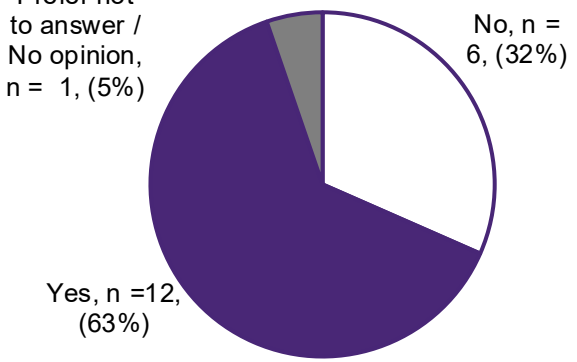


Key focus in pre-market CI guidance

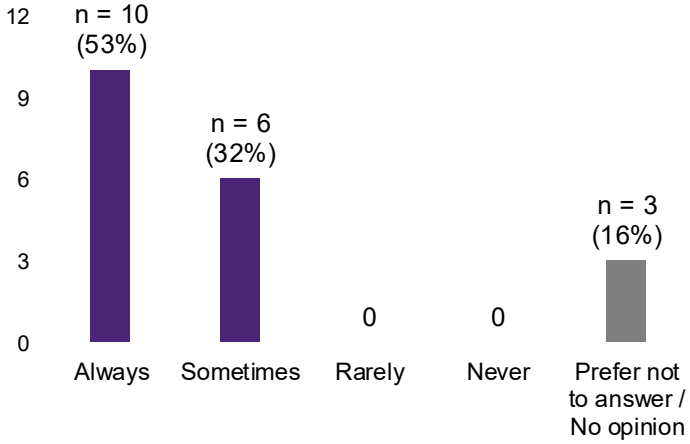


DIALOGUE

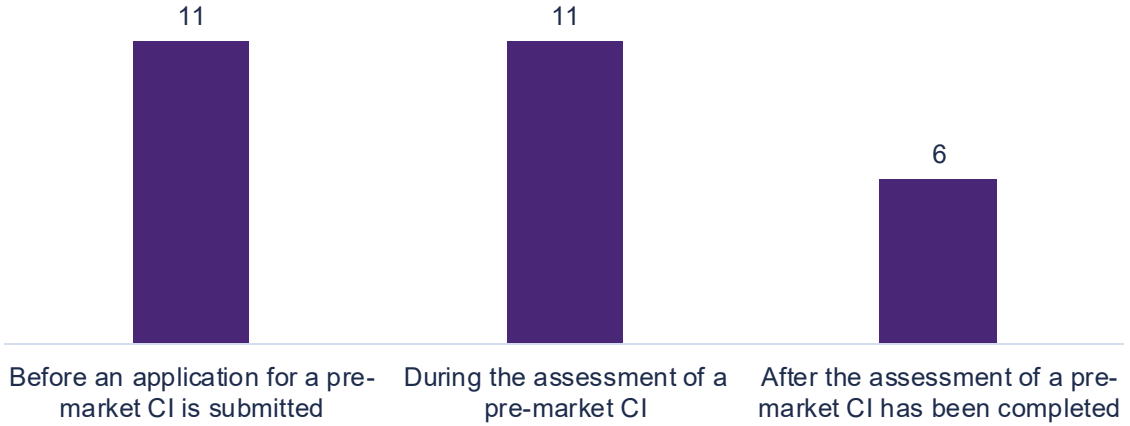
Dialogue between NCA and sponsors for pre-market CIs



Does dialogue improve CI application quality?



Timing of dialogue

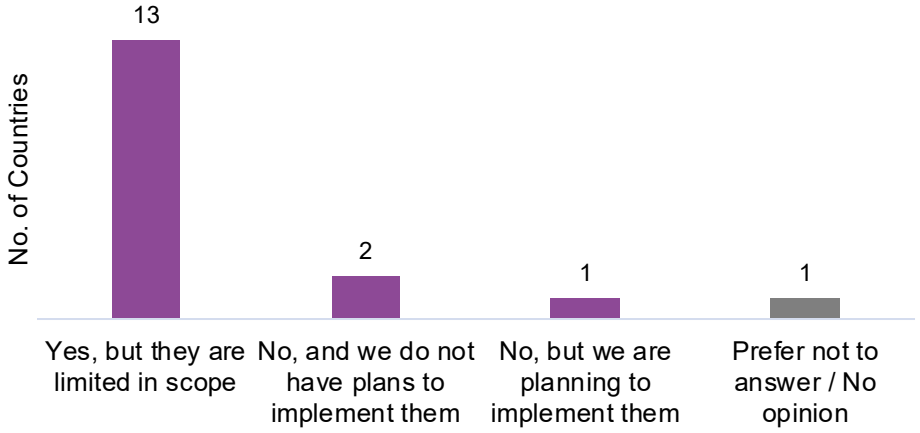


Source HEU-EFS Survey for NCAs (Dec 2024 - Jan 2025), n=19/30 (61%)

Recommendation areas for the EU EFS program informed by project results

EXPERTISE & AWARENESS

Training programs for staff on medical devices and digital health advancements



Source HEU-EFS Survey for NCAs (Dec 2024 - Jan 2025), n=19/30 (61%)

21 EU countries + Norway conducted **124 EFS-like studies**

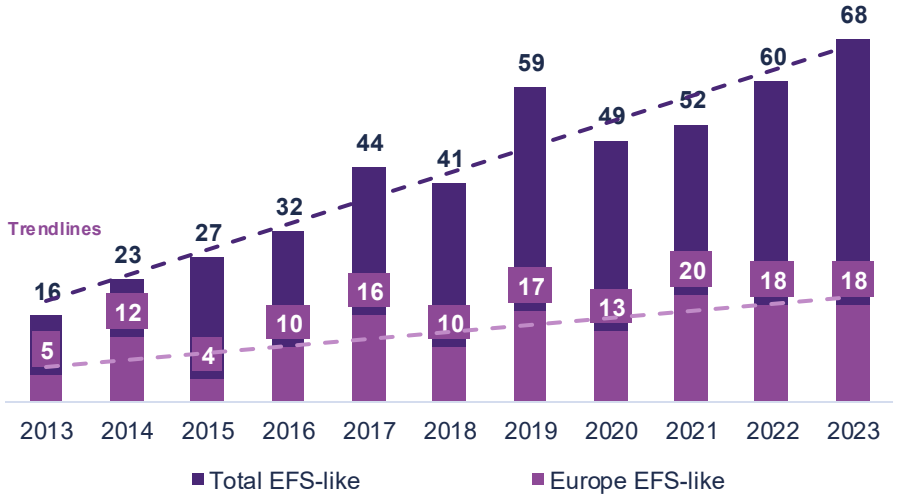
TRANSPARENCY

No public databases or repositories currently classify studies as EFS.

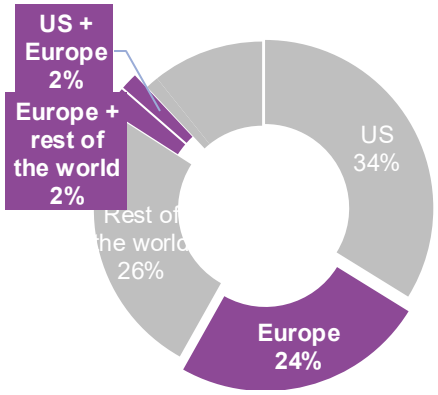
11 (**58%**) of the surveyed NCAs **record the clinical development stage for CIs**, **6** document if the study is an **EFS.**

Lack of routine monitoring about the extent to which EFS are currently conducted, **where and how they fit into manufacturers' overall evidence generation plans.**

Global trend



Overall 559 studies in the EFS-DB

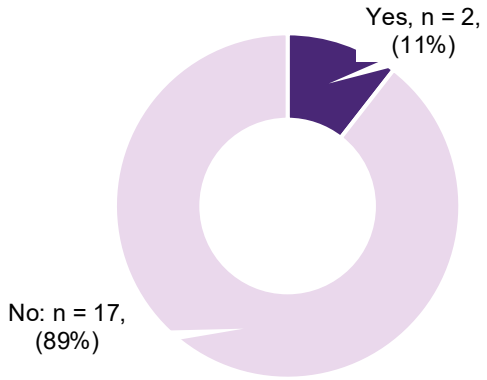


Source Analyses based on HEU-EFS EFS-DB (Dec 2024)

Recommendation areas for the EU EFS program informed by project results

STAKEHOLDER INVOLVEMENT

Dialogue with patients or their organisations



Source HEU-EFS Survey for NCAs (Dec 2024 - Jan 2025), n=19/30 (61%)

REFLECT DHT-SPECIFIC NEEDS

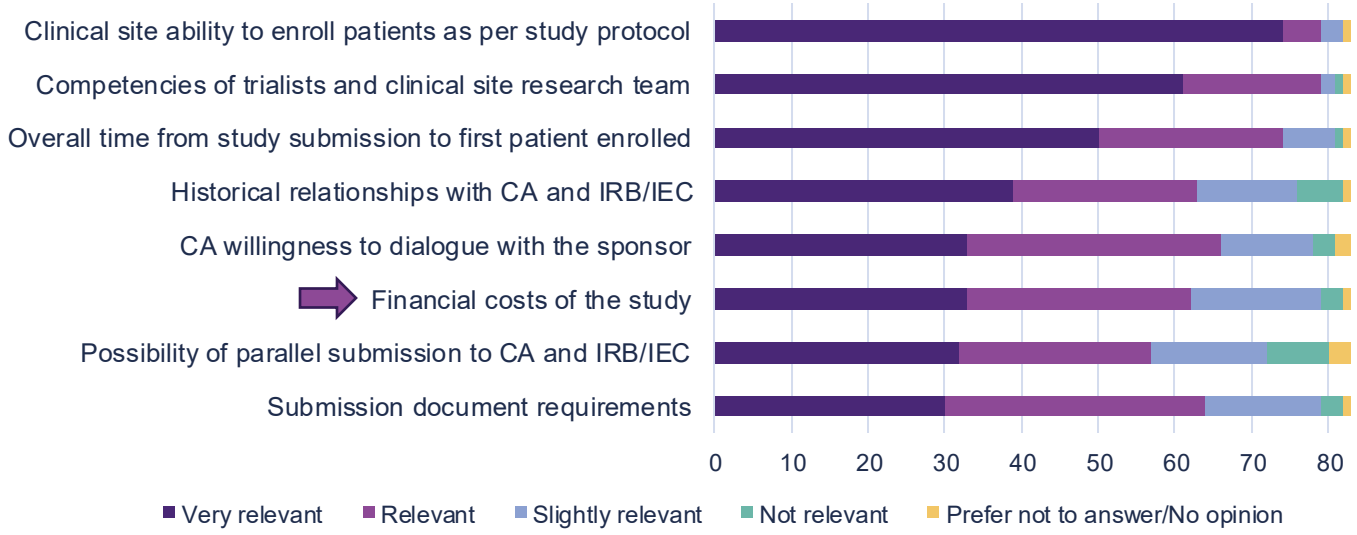
- Lack of pre-market DHT-specific guidance.
- AI-enabled medical devices (AIeMDs) often qualify as both MDs under MDR and "high-risk AI systems" under the EU AI Act.
- Creating potential overlaps in risk management, clinical evidence needs, and post-market obligations.

FACILITATORS FOR R&D IN THE EU

48% of the surveyed sponsors favour the EU as a hub for R&D, **18%** are indifferent between Europe and the US.

High costs disproportionately impacting SMEs when conducting EFS.

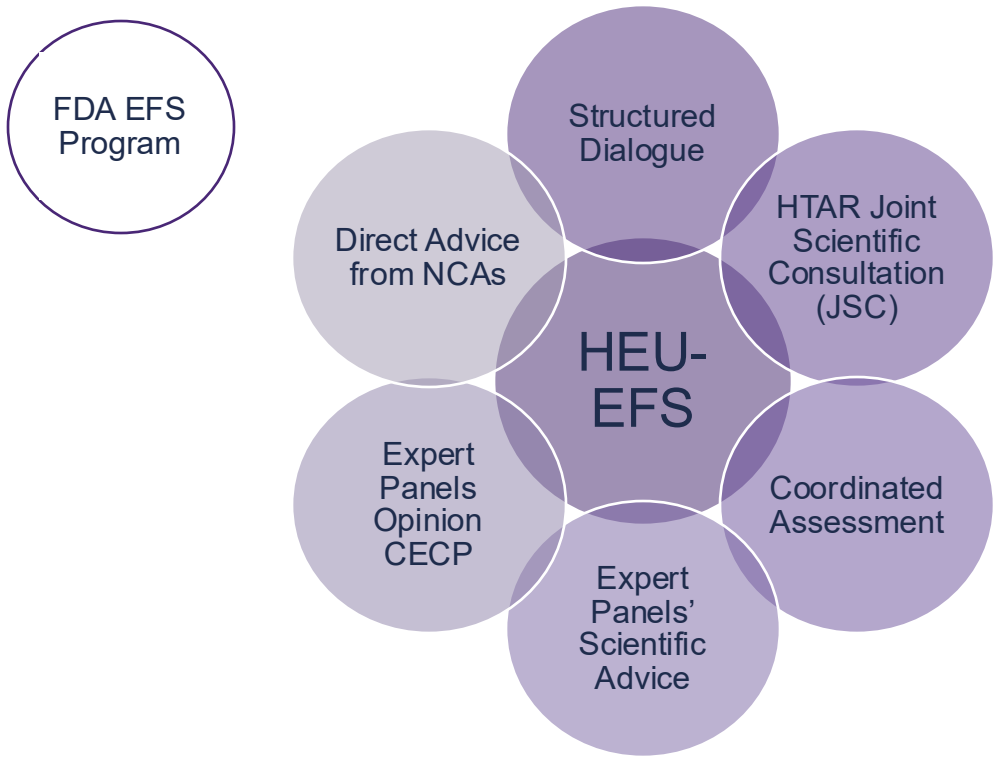
Key criteria influencing the selection of the country



Source HEU-EFS Survey for CI sponsors (Oct-Nov 2024), n=83

Current areas of work

ANALYSIS OF EXISTING EU OR NATIONAL PATHWAYS TO INFORM PROCESSES, PROCEDURES, ACTORS, TIMELINES



FURTHER ANALYSIS OF NCA EXPERIENCE WITH EFS-LIKE STUDIES

DEVELOPMENT OF TEMPLATES AND CHECKLISTS

IDENTIFICATION OF ETHICAL APPROVAL PROCESS FACILITATING EFS

DEVELOPMENT OF PERFORMANCE DASHBOARD

IDENTIFICATION OF TECHNOLOGIES AND COUNTRIES FOR RUNNING PILOT USE CASES

*EU Breakthough Technologies Pilot Expected in 2025

Opportunities to collaborate

1:1 meetings with NCAs

- Each NCA will receive a list of EFS-like studies conducted in the country and an invitation to an individual meeting.
- Timing: April-May 2025.
  - Doodle will be sent soon. Options:
    - 28-29-30 April or 5-6-7 May morning.
- Items for discussion:
  - Experience with EFS-like studies.
    - How does the NCA consider the studies (EFS?). Which considerations led to approve the study. Challenges encountered during the evaluation. Management of protocol and/or product modifications.
  - Considerations on the proposed framework.
  - Interest in being involved in the EFS pilots.

Workshop with NCAs

- Dedicated workshop aimed to discuss the methodological framework for EU EFS:
  - Timing: June 2025.
  - Format: online, 3-hours meeting.
  - 2 sessions to facilitate participation.
  - Doodle will be sent soon. Options:
    - 4 June afternoon;
    - 10 June morning or afternoon;
    - 11 June afternoon;
    - 12 June morning.

Ethical approval by Bocconi University Ethics Committee.

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Thank you!
Questions?

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