Challenges of pre-market clinical investigations of medical devices: a multi-stakeholder perspective

Giuditta Callea, PhD | PI of the HEU-EFS Project

Issue Panel Bridging the Gap in Early-Stage Clinical Research: Lessons for EU Stakeholders from the US FDA Early Feasibility Studies Program

ISPOR 2025 | Montréal, 15 May 2025

Disclaimer

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The HEU-EFS project

Objectives

To 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.

innovative health initiative

HEU EFS

Harmonised approach to Early Feasibility Studies for medical devices In the EU

Grant agreement ID: 101112185

DOI: 10.3030/101112185

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

1

Research & Analysis:
State of Play, Barriers, Best practice

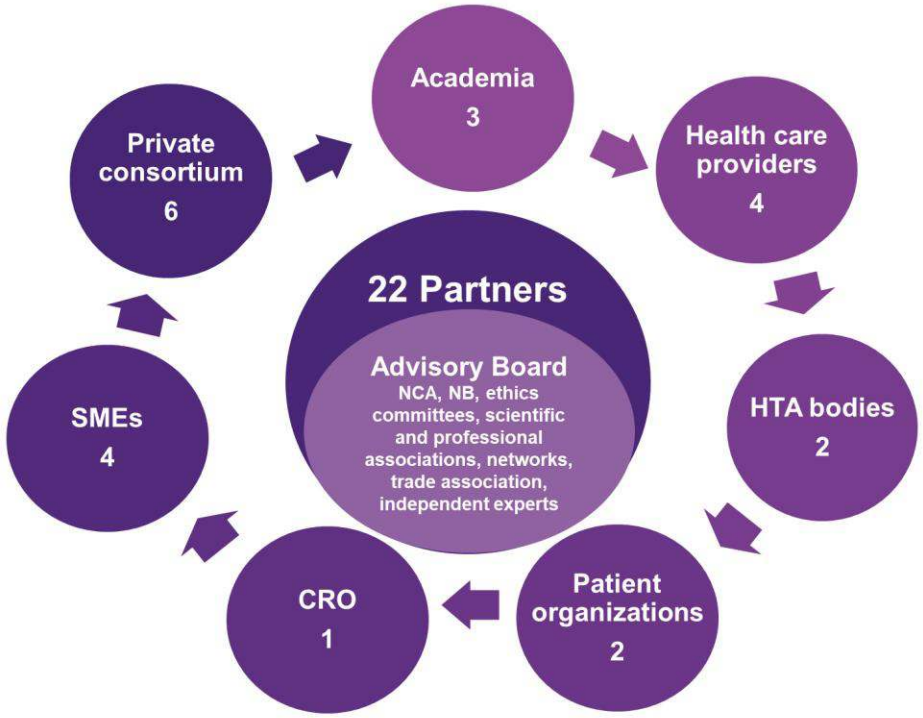
2

HEU EFS Methodology:
Process, Templates, KPIs

3

Pilot Use-Cases:
Pilots to test & validate the methodology

The HEU-EFS Consortium



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Background, objectives and methods

- EFS play a crucial role in the development of novel medical devices (MDs) before full-scale clinical trials.
- The complex EU regulatory landscape makes early-stage clinical research challenging, with different stakeholders facing several obstacles.

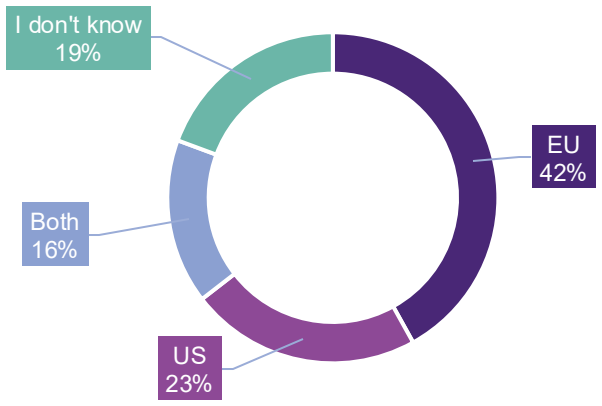
- We aimed to explore barriers and solutions to fostering EFS in the EU by gathering stakeholder perspectives to improve trial efficiency and medical innovation in pre-market CIs) of MDs.

- Methods
  - Online survey for sponsors of CIs to gather insights on challenges in pre-market CIs of MDs.
  - Open-ended interviews with HTA bodies, NBs, NCAs, clinical sites, scientific and professional associations, IEC, CRO, patient representatives, sponsors of CIs to explore key success factors for EFS, challenges and opportunities
  - Running a focus group with the projects' Patient Advisory Board to identify patient-reported challenges and solutions in CIs.

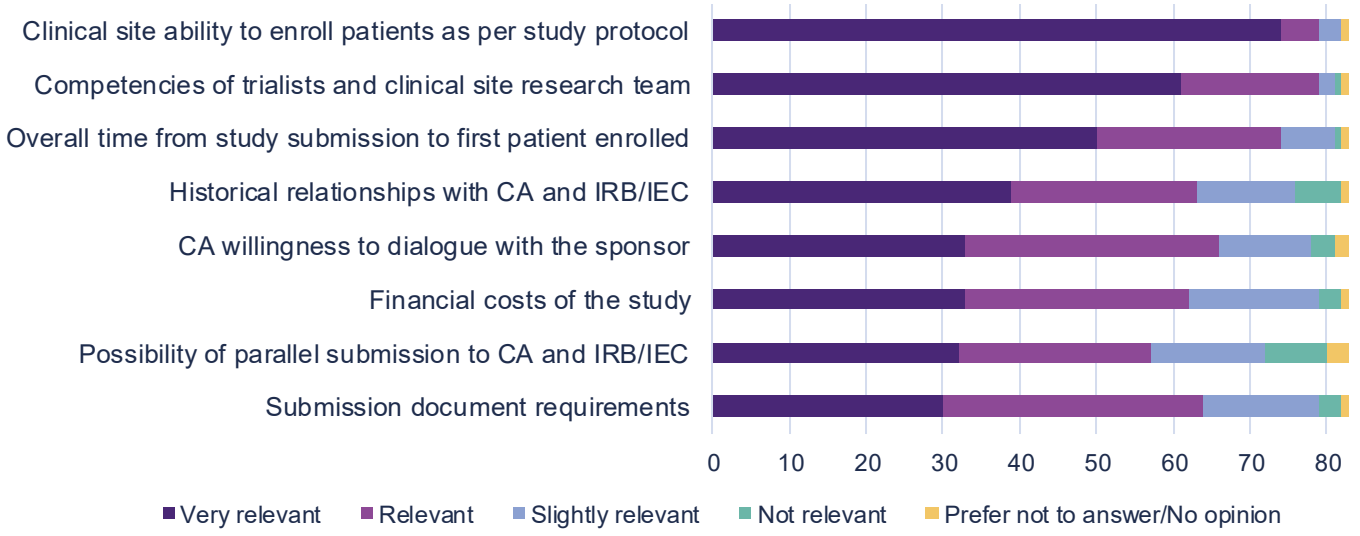
Challenges perceived by sponsors of CIs

- Survey respondents (n=83) favour the EU for pre-market CIs mainly due to site enrollment capacity, trialists' expertise, and quicker study timelines, but face barriers such as lack of stakeholder dialogue and documents approval.

Favourite location for conducting pilot CIs (n=83)



Key criteria influencing the selection of the country



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

Challenges perceived by sponsors of CIs

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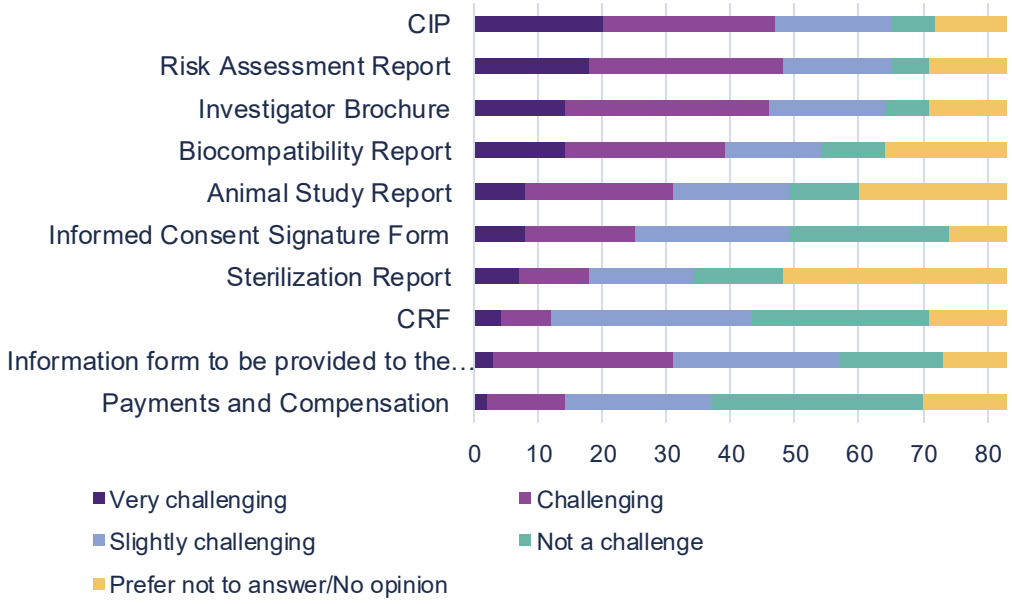
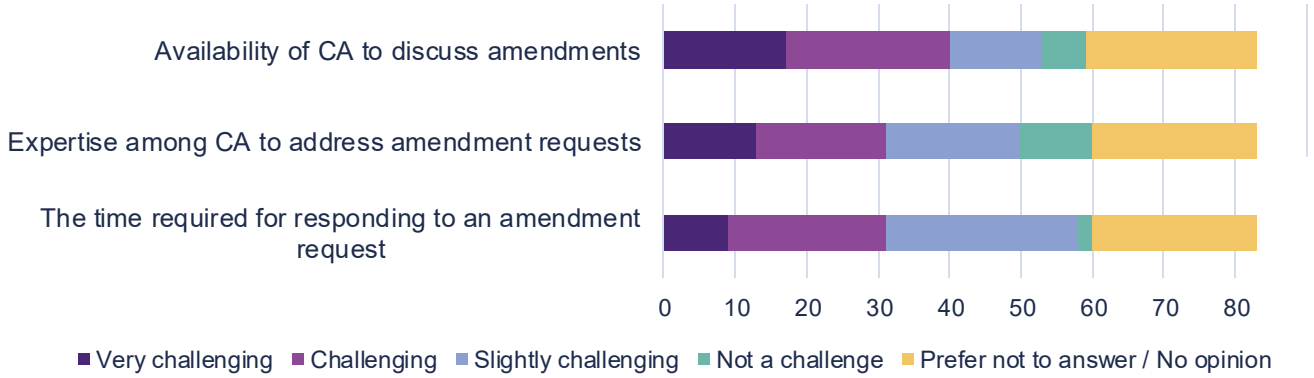
Most challenging documents to get approved by NCAs



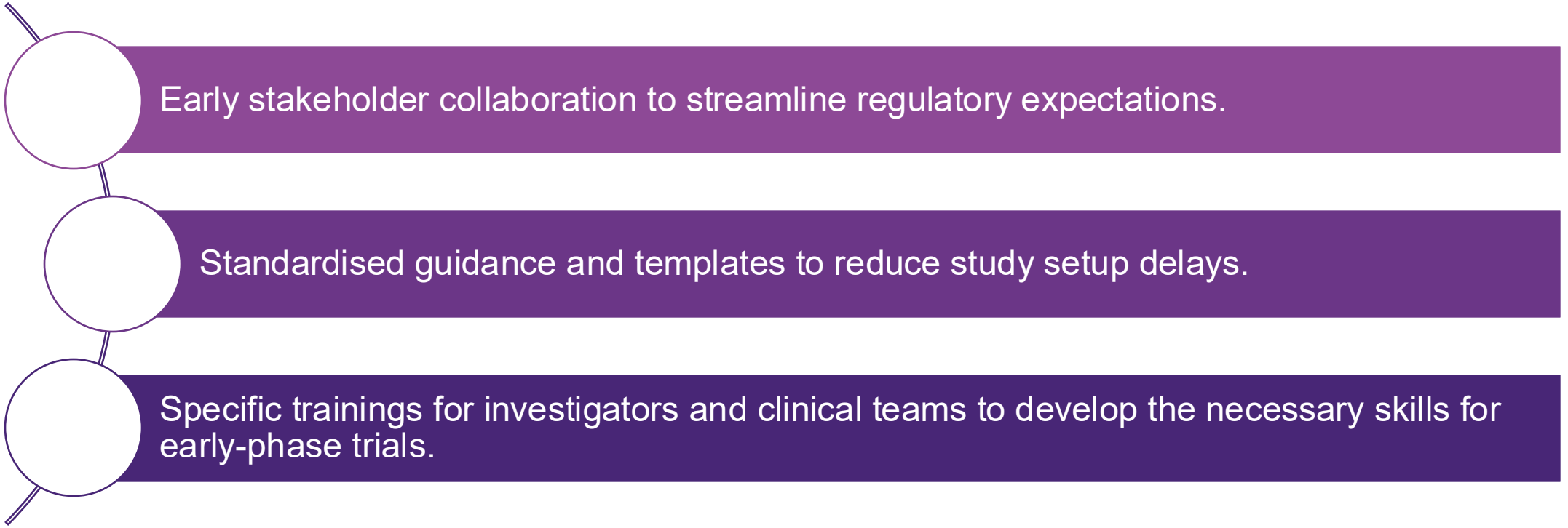
Challenges of the dialogue with NCAs when managing amendments to the CI



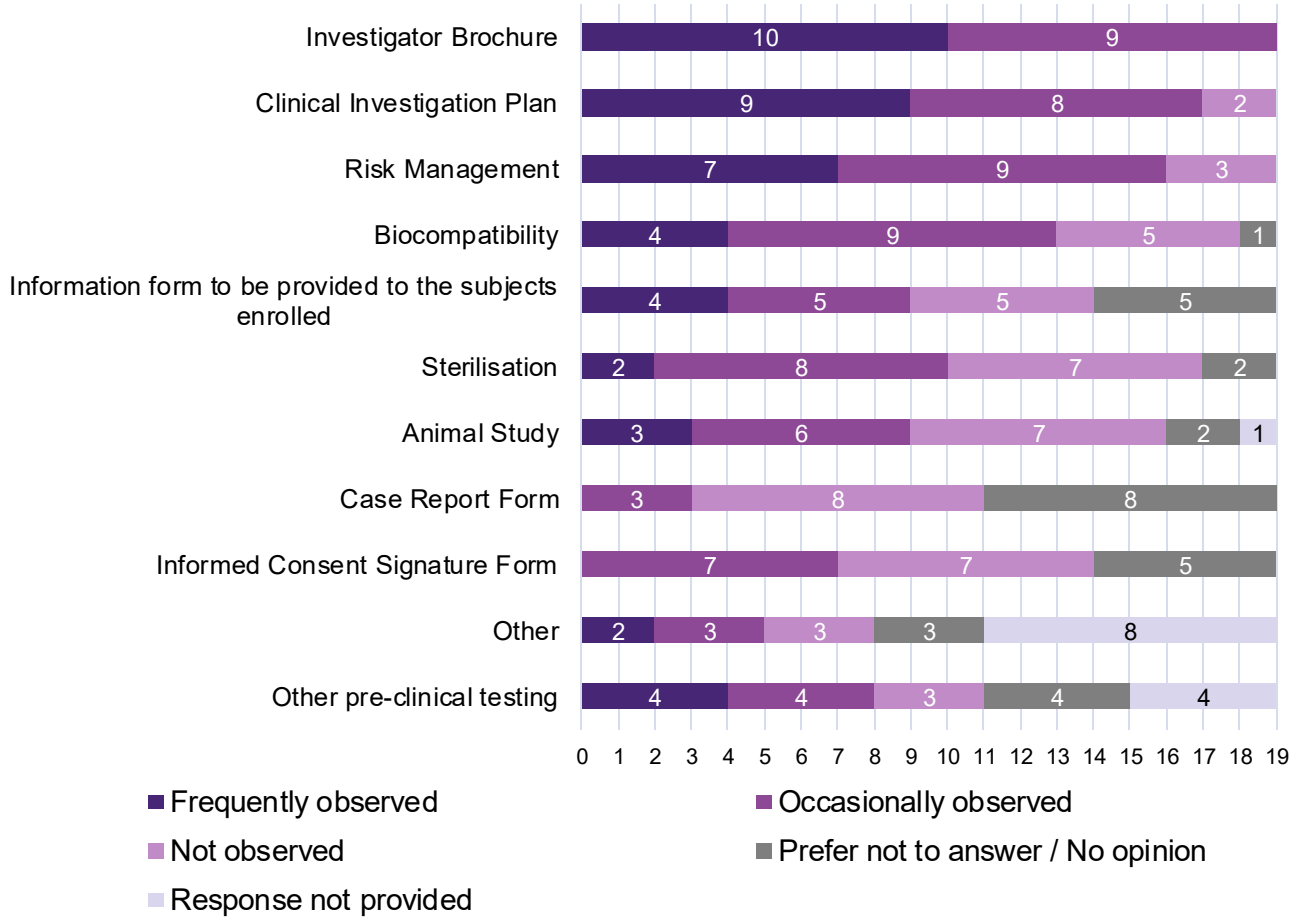
Source HEU-EFS Survey for CI sponsors (Oct-Nov 2024), n=83

Challenges perceived by sponsors of CIs

- Among the identified barriers, **lack of dialogue, regulatory complexity, resource constraints, and patient recruitment challenges**, were also highlighted by the interviewed stakeholders, which identified several areas of improvements including:



Common deficiencies in sponsors application for pre-market CIs highlighted by NCA



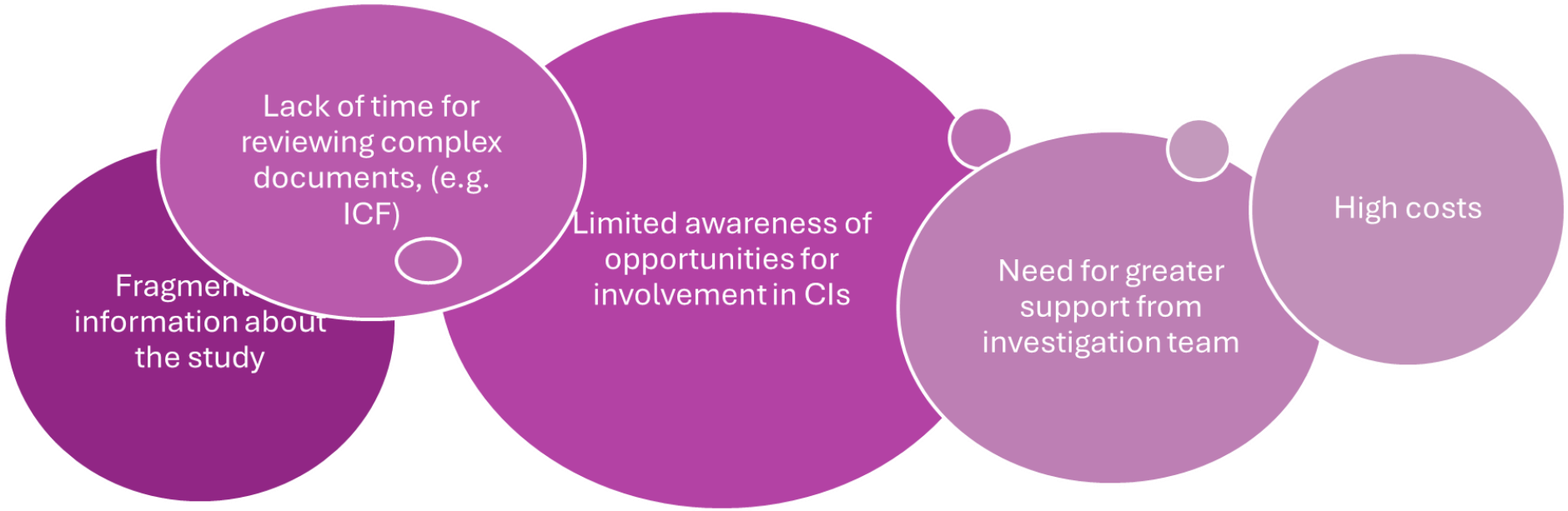
Most likely causes:

- Poor understanding of the content of standards.
- Inadequate documentation demonstrating compliance to standards.
- Price of standards.
- Lack of understanding of the CI process and applicable MDCG guidance documents.

Source HEU-EFS Survey for NCA (Dec 2024), n=19

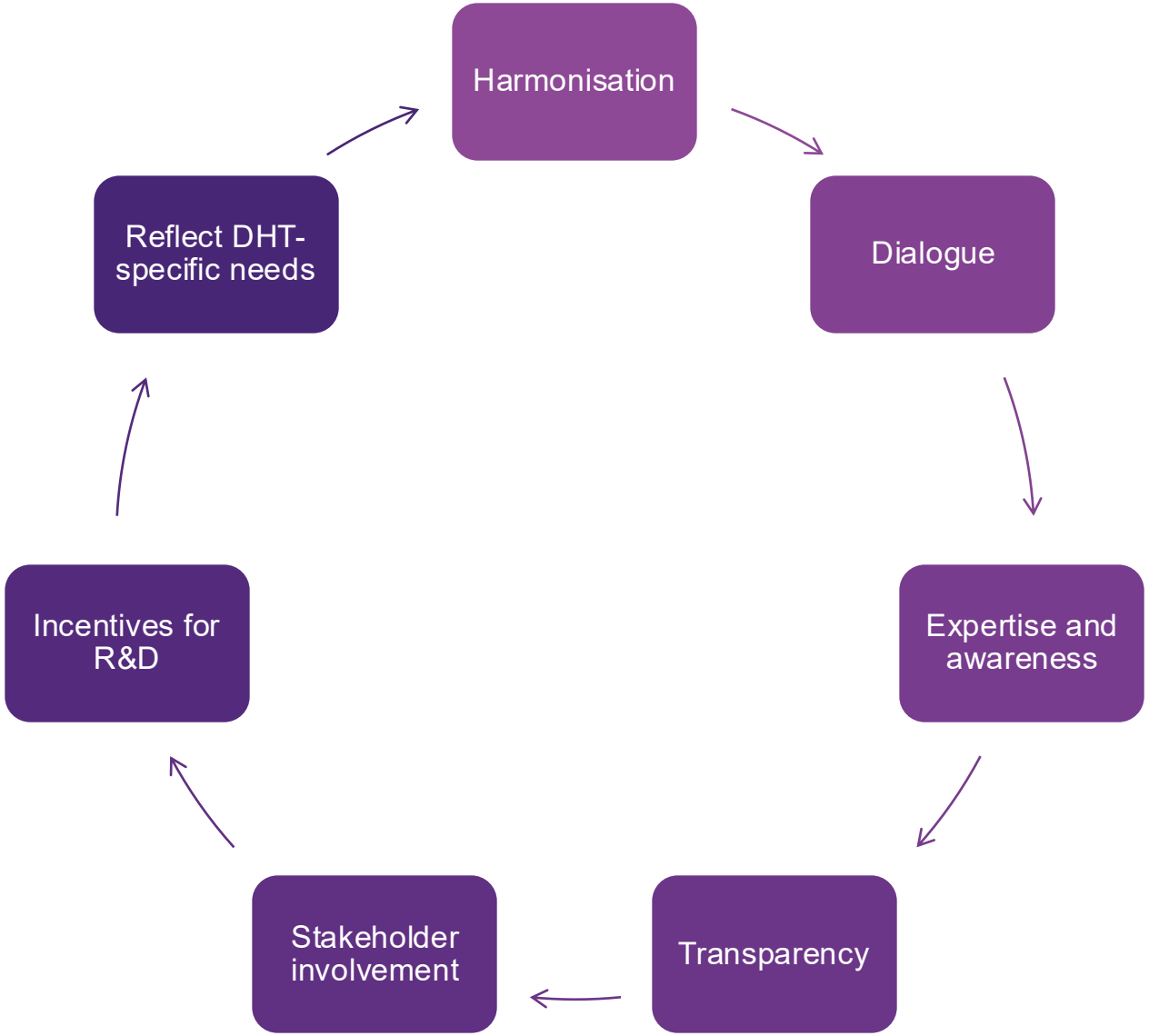
Barriers faced by patients in CIs

- Patients, when asked about the barriers faced in CIs, highlighted the following factors: **lack of accessible information, logistic challenges, post-trial concerns, limited involvement and support in CIs**.



Source Focus groups with HEU-EFS Patient Advisory Proup

Recommendations for the EU EFS Program



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Thank you!

Giuditta Callea

giuditta.callea@unibocconi.it

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innovative health initiative COCIR efpia EuropaBio MedTech Europe Vaccines Europe Co-funded by the European Union

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