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

Implementing a Program for Early Feasibility Studies in Europe: Goldmine or Fool's Gold?

CO-MODERATORS:

Maria Luisa Buzelli, Bocconi University, Milan, Italy – HEU-EFS Project Coordinator

Andrea Rappagliosi, Edwards Lifesciences, HEU-EFS Private Consortium Coordinator

SPEAKERS

Marta Kerstan

Johnson & Johnson MedTech

Tom Melvin

University of Galway

Lucía Feito Allonca

Patient Advisory Group

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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: an overview

Andrea Rappagliosi | Edwards Lifesciences

Maria Luisa Buzelli | Bocconi University

Issue Panel Implementing a Program for Early Feasibility Studies in Europe: Goldmine or Fool's Gold?

ISPOR 2025 | Glasgow, 10 November 2025

Disclaimer

This project is funded by the European Union, the private members, and those contributing partners of the Innovative Health Initiative Joint Undertaking under grant agreement No 101112185. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those those of the aforementioned parties. Neither of the parties can be held responsible.

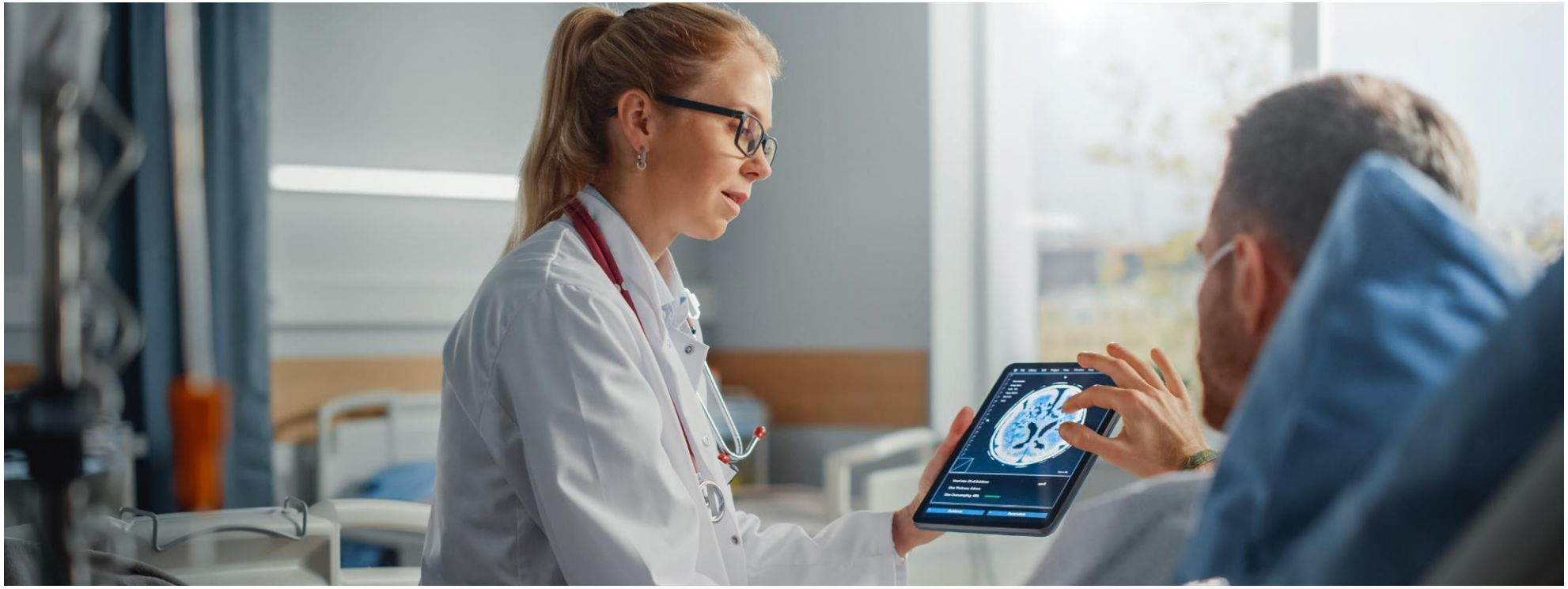
Challenges

Bringing medical technology innovations to patients in the EU has become increasingly long and difficult.

- Rising R&D costs.
- Ever-stricter EU regulations.
- Lack of harmonised approaches in Member States for facilitating early evidence generations.

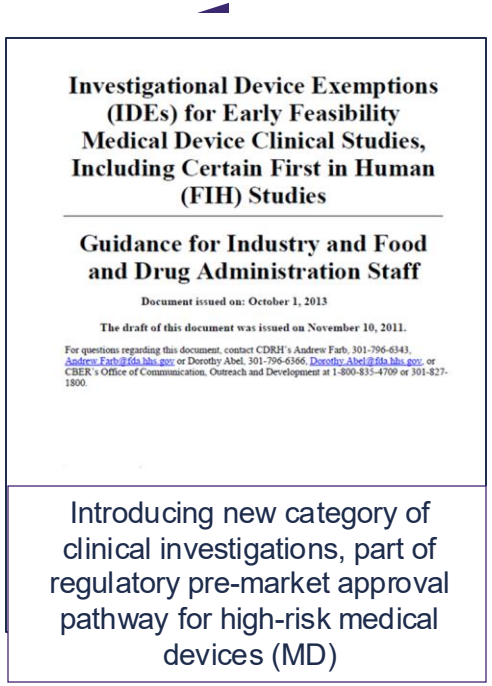
- Uncertainty for innovators.
- Decline in attractiveness of Europe.
- European patients missing out on the latest medical technology innovations.

Needs



New approaches are needed to ensure patients get a timely access to their treatment and Europe remains at the forefront of innovation.

Context: Early Feasibility Studies (EFS)



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.

Introducing new category of clinical investigations, part of regulatory pre-market approval pathway for high-risk medical devices (MD)

WHAT?

- A limited clinical investigation of a device **early in development**.

WHEN?

- Typically, **before the device design has been finalized**, for a specific indication (e.g. innovative device for a new or established intended use).

WHY?

- To **evaluate the device design concept** with respect to initial clinical safety and device clinical performance or effectiveness (if appropriate) as per intended use in a **small number of subjects** when this information cannot practically be provided through additional preclinical assessments or appropriate preclinical tests are unavailable.

EFS in the EU

- EFS provided for in the MDR 2017/745.
- ISO 14155:2020 “Clinical investigation of medical devices for human subjects” introduced a taxonomy for different clinical investigation types.
- However, no standardised procedural framework, guidelines or common reference standards to conduct EFS in the EU.

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

Project information

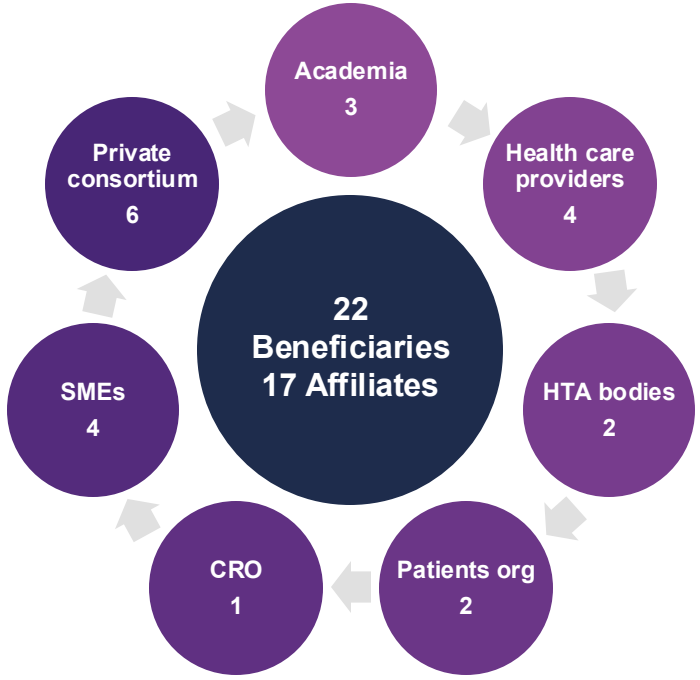
Start date: 1 October 2023
End date: 30 September 2027

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

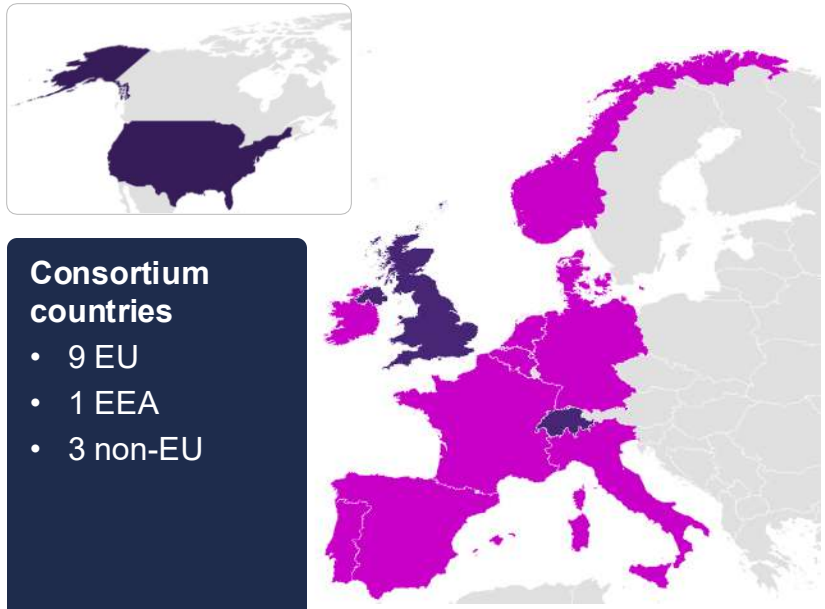
Patient Advisory Group

10 members

1
Research & Analysis:
State of Play, Barriers, Best practice

2
HEU EFS Methodology:
Process, Templates / Checklists, KPIs

3
Pilot Use-Cases:
Pilots to test & validate the methodology



Consortium countries

- 9 EU
- 1 EEA
- 3 non-EU

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		

The HEU-EFS Consortium

Expected impact

Patients

Patients with no or little treatment options **access** innovative technologies to improve prognosis & 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

Technology providers develop innovations that meet healthcare professional & patient needs.

Healthcare professionals deepen their clinical development **excellence**.

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Implementing a Program for Early Feasibility Studies in Europe: Goldmine or Fool's Gold?

Regulatory, industry, and patient perspectives

Marta Kerstan | Johnson & Johnson MedTech

Tom Melvin | University of Galway, Ireland

Lucía Feito Allonca | HEU-EFS Patient Advisory Group (PAG) member

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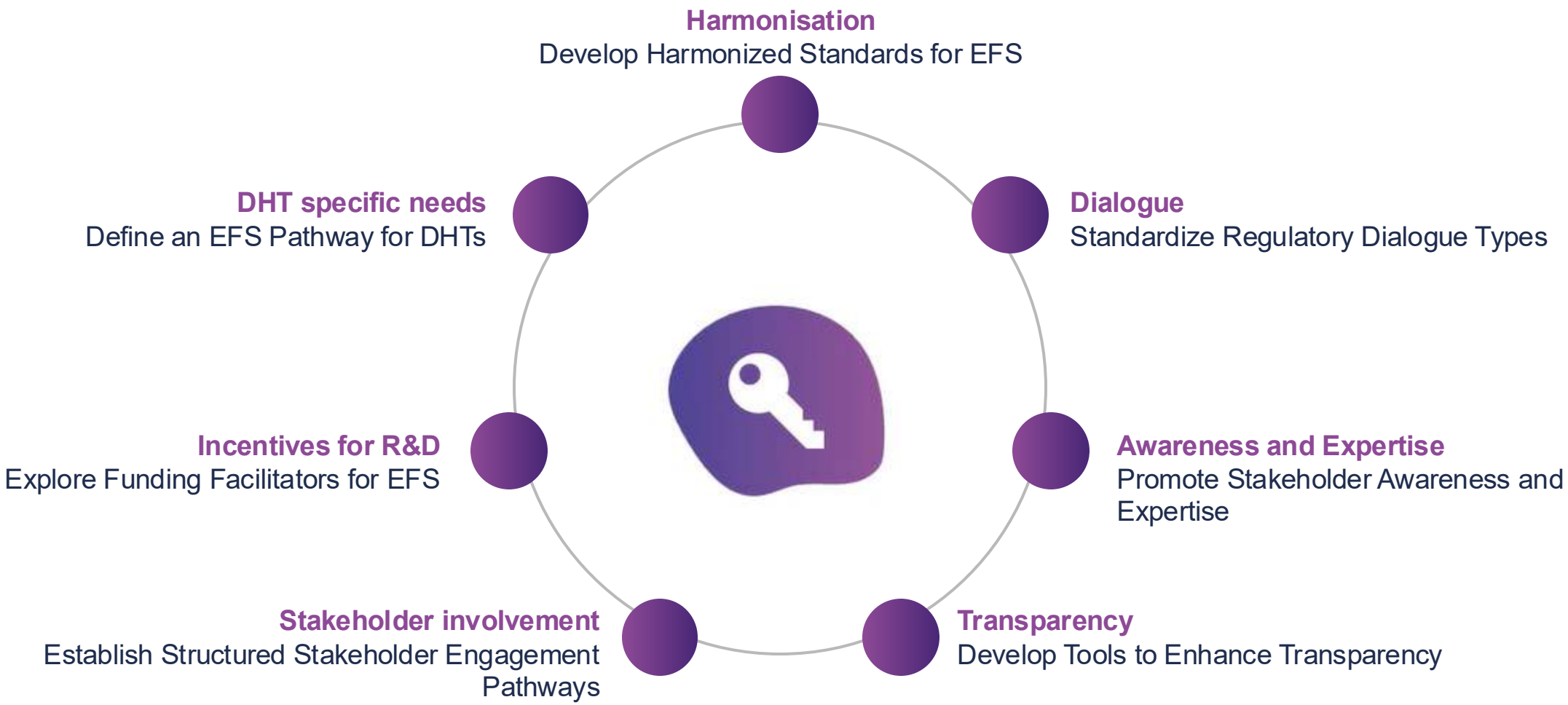
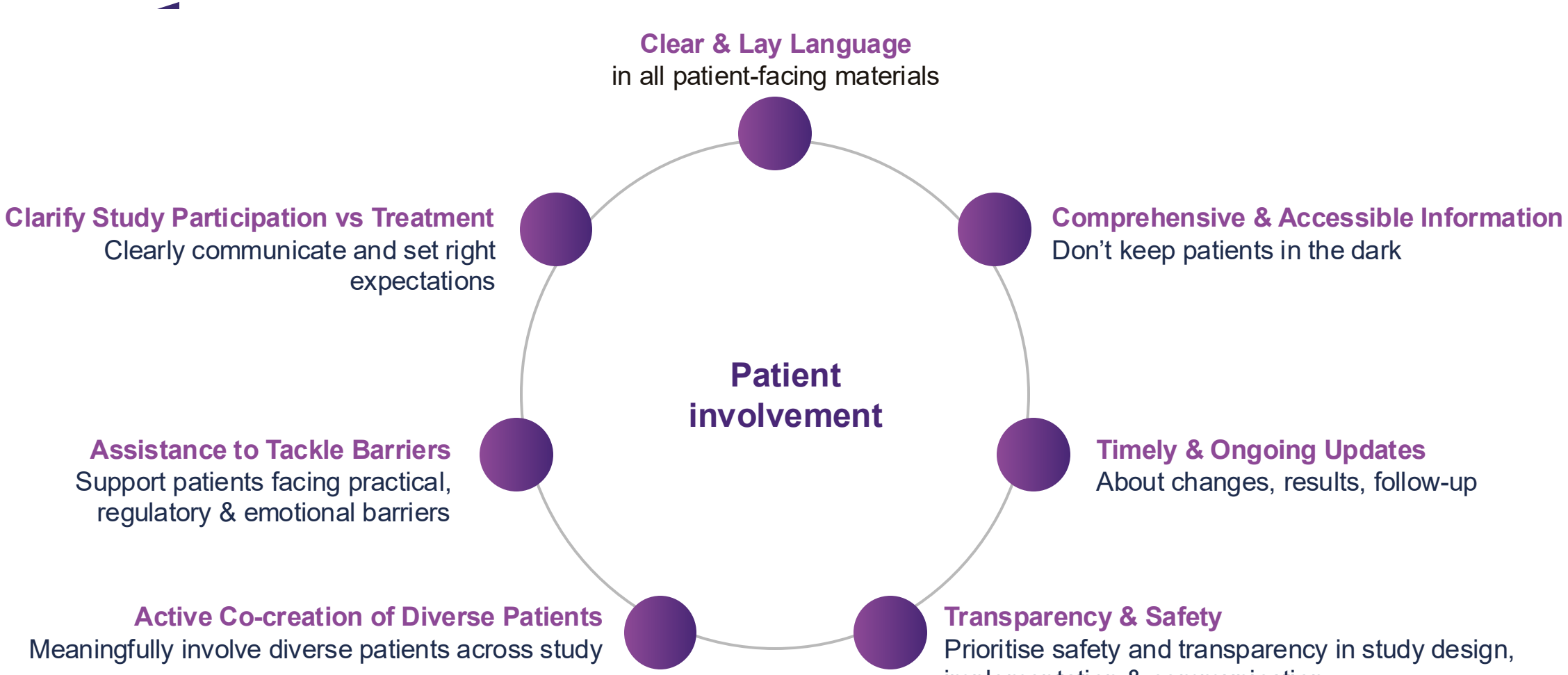
Key Recommendations



Key Recommendations – Patient involvement & Awareness



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

Andrea Rappagliosi | Edwards Lifesciences

Maria Luisa Buzelli | Bocconi University

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HEU-EFS is launching public pilots !

Main objectives of pilots

1

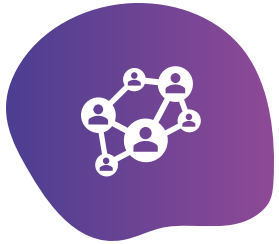
To test the HEU-EFS project methodological framework with selected pilot use-cases.

2

To recommend adjustments needed to improve the methodology.

Increase the number of pilots

Expand the patient conditions



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

Increase awareness

Call for pilots

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.

Criteria:

- Submitting in EU /EEA Country
- EFS planned submission to authorities by Nov 2026

High-risk devices (Class III and Class IIb)

- Breakthrough Device / Unmet Patients Needs
- Anatomical Understanding
- New / Expanded Intended Uses or Indications for Use for Patients

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
- Deadline 31st March 2026

Interested in finding out more?

Dedicated Webinar on Pilots on
5 December 2025, 15.00 – 16.00 CET

Follow Us on LinkedIn and subscribe to our newsletter to stay informed

@HEU-EFS

Newsletter

Call for papers

Early Feasibility Studies for Medical Devices: goldmine or fool's gold?
Submission deadline: **15 December 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.

LINK

Q&A

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COCIR
efpia
EuropaBio
MedTech Europe from diagnosis to cure
Vaccines Europe
Co-funded by the European Union

www.heuefs.eu

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Thank you!

This project is supported by the Innovative Health Initiative Joint Undertaking (JU) under grant agreement No 101112185. The JU receives support from the European Union's Horizon Europe research and innovation programme and life science industries represented by MedTech Europe, COCIR, EFPIA, Vaccines Europe and EuropaBio.

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COCIR

efpia

EuropaBio

MedTech Europe

Vaccines Europe

Co-funded by the European Union

ISPOR SESSION 043

Day and Time: Monday 10 November, 13:45 – 14:45 – **HALL 1**

Proposed agenda:

- Welcome: Luisa Buzelli (2 mins)
- Brief state of the art in the EU & relevance of the HEU-EFS project (public/private consortium): Andrea Rappagliosi (5 mins)
- Introduction to the HEU-EFS project: Luisa Buzelli (5 mins)
- Presenting perspectives and recommendations from the HEU-EFS project from regulatory, industry, and patient perspectives (30 mins):
  - Harmonisation of applications: Tom
  - Dialogue: Marta & Tom
  - Awareness and expertise: Lucia
  - Transparency: Tom
  - Stakeholder involvement: Lucia
  - R&D support: Marta
  - DHT specific needs: Tom (also mentioning Jmir paper)

- HEU-EFS project's next steps: Call for pilots (Andrea Rappagliosi); call for papers (Luisa Buzelli) (3mins)
- Q&A: (15 mins)

Slides & Upload: each speaker to add their slides to this PPT **by Wednesday 5 November.**
Luisa responsible for PPT upload on ISPOR website

Where to meet on Monday: Speaker Ready Room at conference centre, 11.15am
If you arrive after lunch - directly in Hall 1 at 13.15