innovative health initiative

HEU EFS

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

How to win and manage a Horizon project – the case of HEU-EFS

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RIS4SEB Consortium meeting

Milan, 9 September 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.

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Horizon Europe IHI Joint Undertaking

Horizon Europe IHI JU

- **Goal**: Translate health research and innovation into tangible benefits for patients and society and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research.
- **Partners**:
  - The EU (represented by the European Commission).
  - Lifescience industries:
    - COCIR (medical imaging, radiotherapy, health ICT and electromedical industries);
    - EFPIA (biopharmaceutical industry);
    - EuropaBio (biotechnology industry);
    - MedTech Europe (medical technology industry);
    - Vaccines Europe (vaccine industry).
- **Established** in 2021.
- **Type of call**: single stage or two stage.
- **Website**: IHI Joint Undertaking

IHI specific objectives

SO1	SO2	SO3	SO4	SO5
• Contribute towards a better understanding of the determinants of health and priority disease areas.	• Integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users.	• Demonstrate the feasibility of people-centred, integrated healthcare solutions.	• Exploit the full potential of digitalisation and data exchange in healthcare	• Enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovation.

Examples of timelines

Basic call facts

Key facts

- Call ID: HORIZON-JU-IHI-2022-01-single-stage
- Action Type: RIA – Research and Innovation Actions
- Call type: Single stage

Call timeline

- Draft topic texts published: 20 April 2022
- Publication date: 28 June 2022
- Full proposal submission deadline: 20 September 2022
- Project start: Spring 2023

Basic call facts

Key facts

- Call ID: HORIZON-JU-IHI-2022-02-two-stage
- Action Type: RIA – Research and Innovation Actions
- Call type: Two stage

Call timeline

- Draft topic texts published: 20 April 2022
- Publication date: 28 June 2022
- Short proposal submission deadline: 20 September 2022
- Full proposal submission deadline: 28 February 2023
- Project start: Autumn 2023

IHI Work Programme 2025 - conditions for single and two stage calls

Admissibility: General Annex A of Horizon Europe Work Programme 2023-2025 shall apply.

Page limits:

- For a single-stage call: 50 pages;
- For 2 stage calls:
  - 1st stage short proposals: 20 pages;
  - 2nd stage full proposals: 50 pages.

Eligibility conditions: General Annex B.

- Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members (i.e., members of IHI JU, their constituent or affiliated entities, contributing partners).

Financial and operational capacity and exclusion: General Annex C.

Award criteria: General Annex D:

- Excellence.
- Impact.
- Quality and efficiency of the implementation.

Documents: General Annex E.

Procedure: General Annex F.

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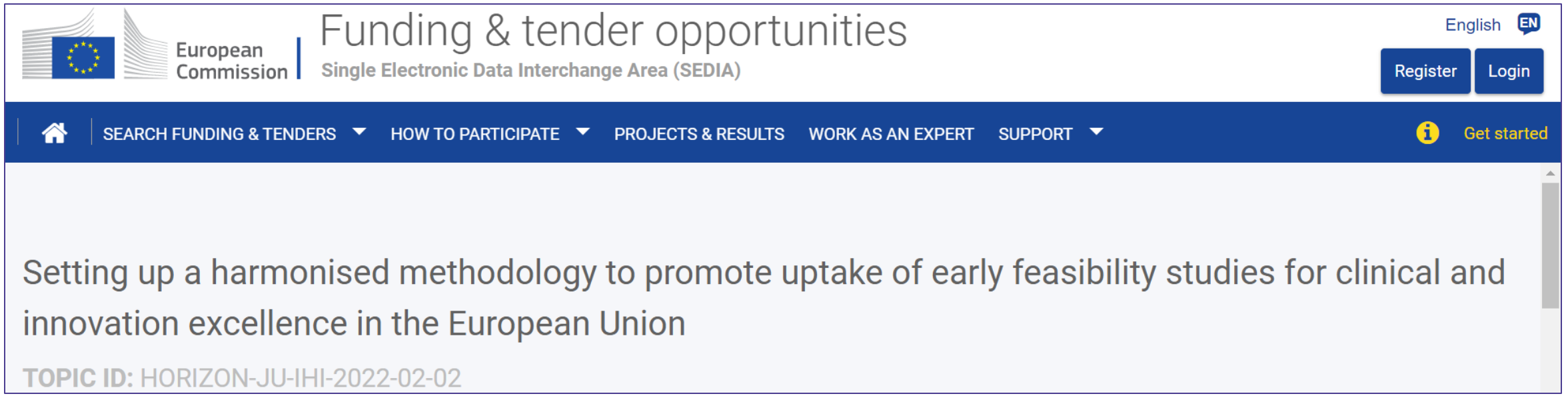
The HEU-EFS Project

call for proposals



Awarded to

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

History of the HEU-EFS Project

06/2022

HORIZON-JU-IHI-2022-02-two-stage call for proposals
"Setting a harmonized methodology to promote uptake of early feasibility studies for clinical and innovation excellence in the European Union"

07-08/2022

Formation of HEU-EFS public consortium

09/2022

Short-proposal submitted
- 4 proposals submitted for topic (EFS)

12/2022

Evaluation results published
- 1st stage awarded by HEU-EFS consortium

12/2022

Public consortium merged with pre-identified industry consortium

02/2023

Full-proposal submitted

04/2023

Evaluation results published
- HEU-EFS consortium proposal passed 2nd phase evaluation

05-10/2023

Preparation of Consortium Agreement and Grant Agreement

Signature of Consortium Agreement and Grant Agreement

Start of the HEU-EFS project

Background

Early Feasibility Study (EFS)

WHAT?

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

WHEN?

typically **before the device design** has been finalized, for a specific indication […].

WHY?

It can be used 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 nonclinical assessments or appropriate nonclinical tests are unavailable. Information obtained from an early feasibility clinical investigation can **guide device modifications**. […]

- **Feasible** in the EU:
  - **ISO 14155:2020** Clinical investigation of medical devices for human subjects — good clinical practice.
  - **MDR 2017/745** and **HTAR 2021/2282** early dialogue and life cycle approach for clinical evidence generation.
  - **MDCG 2021-6** – Rev 1. December 2023 Q&A regarding clinical investigation.
- **Beneficial** to patients, clinical sites & trialists, technological innovation developers.

Impact and benefits of EFS

PATIENTS

- Timely access to innovative medical technologies that can address unmet clinical needs with no alternative treatment option.
- Controlled and safe access to innovative medical technologies.

COMPETENT AUTHORITIES

- Foster access to innovation while maintaining adherence to rigorous authorization process and preserving patient safety.
- Anticipate and smooth the decision-making processes thanks to early exchange of information.
- Increase the innovativeness and competitiveness of the sector.

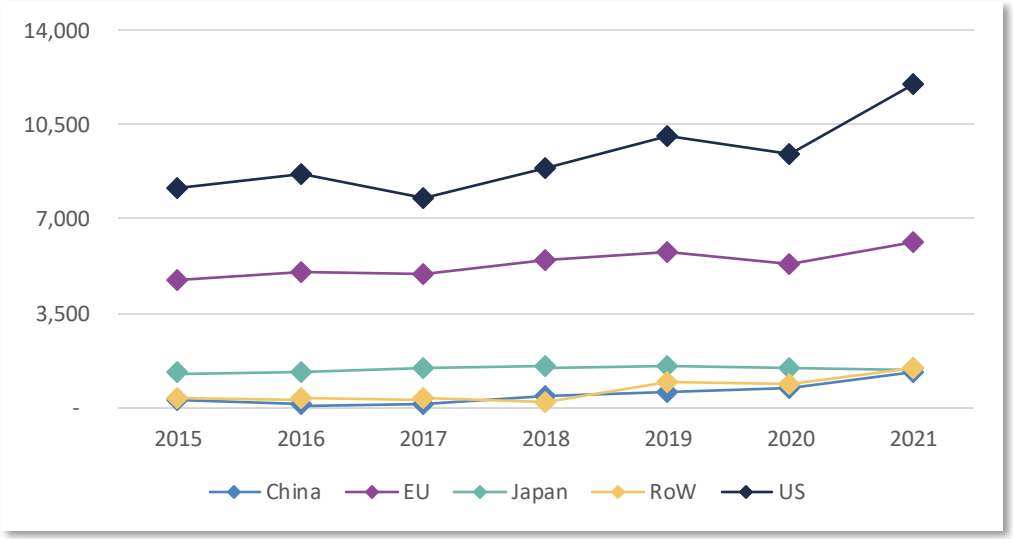
INDUSTRY

- Improve efficiency and effectiveness in technology development.
- Maximize the probability of market access.
- Maximize the probability of adequate remuneration for innovation.

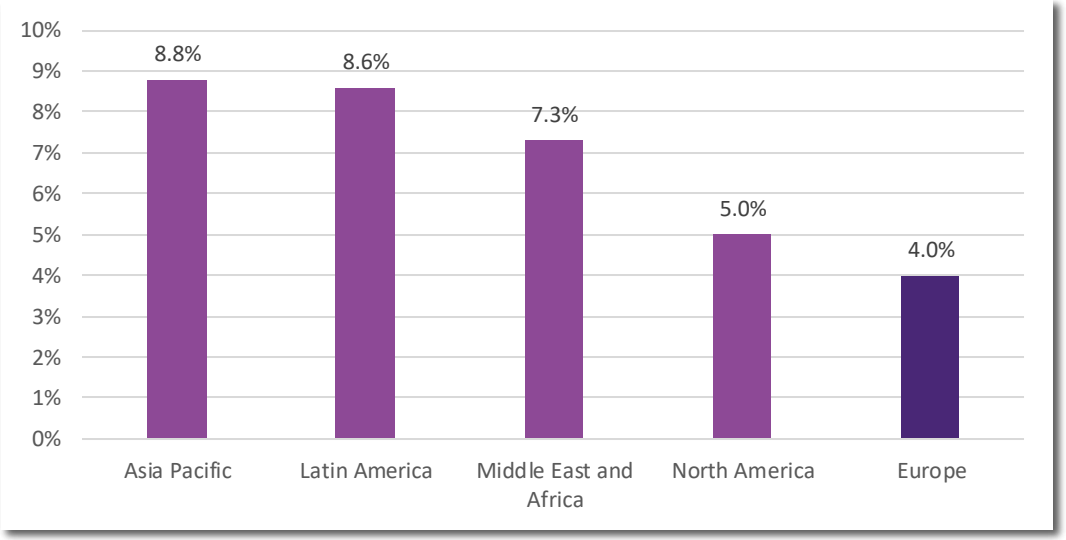
Why an EU EFS Program

- Feasible, but **no standardized procedural framework**, guidelines or common reference standards to conduct EFS in the EU.
- The EU is at **risk of losing competitiveness and attractiveness** for innovation and investments.

R&D investments (million €) in healthcare equipment and service industry (Grassano et al 2022)



Expected CAGR of the global medical technology market 2017-2022 (Statista)



Overarching goal of HEU-EFS Project

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.

Specific objectives

1. Conduct research and analysis on state of play of r**egulatory framework** and **characteristics and impacts** of **pre-market approval pathways**.

2. Build a **sustainable network of stakeholders** to promote the implementation of EFS in the EU.

3. Develop a sound, widely applicable, **harmonised EU methodology** and **recommendations to uptake EFS**.

4. Undertake **pilot use cases to test** the proposed **methodological framework**.

5. Develop instruments to **monitor the performance** of the EU EFS program.

6. Implement a dedicated, sustainable, open access, **informative online portal** dedicated to EFS and disseminate the project results and recommendations.

The Project

WP 9 Scientific supervision and project management

Research and analysis

- WP 1 State of play of pre-market clinical evidence generation programs and implementation barriers to EFS
- WP 2 Regulatory framework and organization of clinical evidence generation programs in the EU

Methodology development

- WP 3 Rationale, processes, and procedure
- WP 4 Evidence requirements, data, and statistical tools
- WP 5 Program monitoring system
- WP 6 Ethical and legal aspects

Methodology test

- WP 7 Pilot use cases

WP 8 Web portal, dissemination, exploitation, and communication

The Consortium

ACADEMIA

- Bocconi University (leader)
- Marburg University
- Trinity College Dublin

HEALTH CARE PROVIDERS

- Assistance Publique Hôpitaux De Paris (France)
- Fondazione Policlinico Universitario Agostino Gemelli IRCCS (IRCS)
- Fundació Clínic per a la Recerca Biomèdica & Hospital Clínic de Barcelona (Spain)
- Odense Hospital (Denmark)

HTA AGENCIES

- AGENAS, Italy
- NIPH, Norway

PATIENT ORGANISATIONS

- European Patients' Forum
- Global Heart Hub

CRO

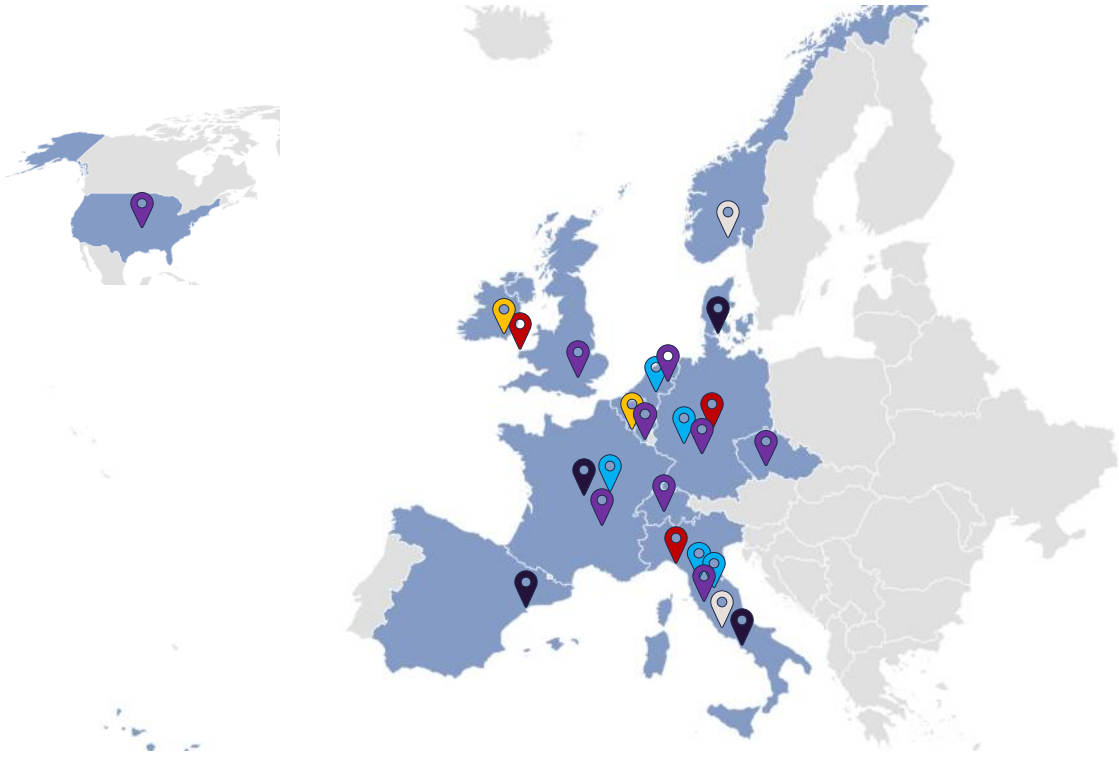
- Meditrial

SMEs

- Carmat
- Newronika
- Idris Oncology
- Qurasoft

TECHNOLOGY DEVELOPERS

- Edwards Lifescience (coordinator)
- Abbott
- DePuy Synthes
- Medtronic
- Philips
- WL Gore



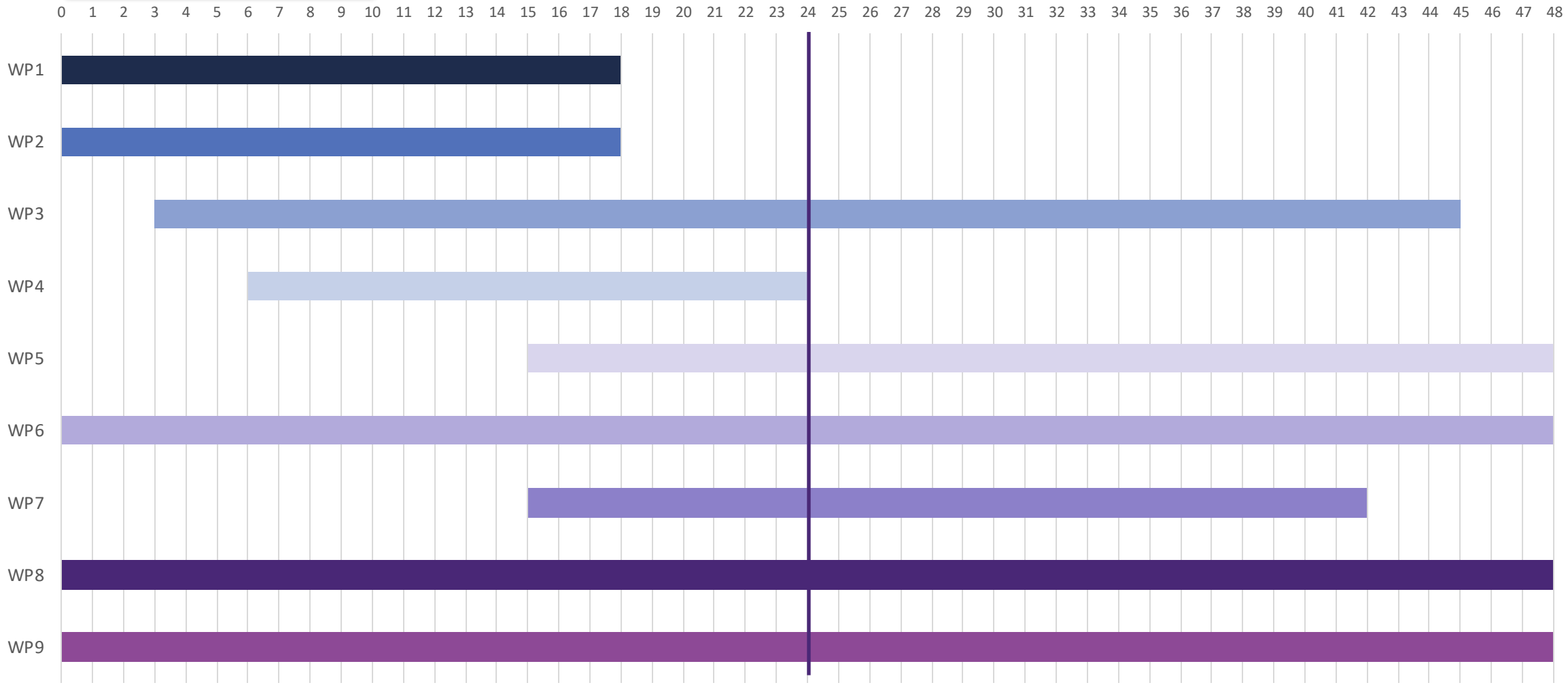
WP governance: a public private partnership

WP	Leader	Co-leader
WP 1 Research and analysis on state of play of pre-market programs and implementation barriers to EFS	Bocconi	DePuy Synthes
WP 2 Research and analysis on regulatory framework and organization of clinical evidence generation programs in the EU	Trinity College Dublin	Assistance Publique Hôpitaux de Paris
WP 3 Methodology development: rationale, processes, and procedure	NIPH	Bocconi and Edwards Lifesciences
WP 4 Methodology development: evidence requirements, data, and statistical tools	Meditrial	Abbott
WP 5 Methodology development: EU EFS program monitoring system	Bocconi	AGENAS
WP 6 Methodology development: ethical and legal aspects	Bocconi	Edwards Lifesciences
WP 7 Testing the methodology: pilot use cases	Edwards Lifesciences, Medtronic and Abbott	Fondazione Policlinico Agostino Gemelli
WP 8 Web portal, dissemination, exploitation, and communication	Edwards Lifesciences	Bocconi
WP 9 Scientific supervision and project management	Bocconi	

Timeline

Start date
1 October, 2023

End date
30 September, 2027



Governance of the project

COORDINATION BOARD

- Coordinator of Public (Bocconi) and Private (Edwards) Consortium

STEERING COMMITTEE

- WP leaders and co-leaders

CONSORTIUM

- WP contributors

EXTERNAL ADVISORY BOARD

- National Competent Authorities
- Notified bodies
- Professional associations
- Networks
- Trade association
- Ethics committees
- Independent experts

PATIENT ADVISORY GROUP

- 11 Patients

External Advisory Board

COMPETENT AUTHORITIES

- Italian Ministry of Health
- HPRA
- INFARMED

NOTIFIED BODIES

- Team-NB
- IMQ

MEMBERS OF ETHICS COMMITTEES

- Norwegian National Ethical Committee
- Italian National Coordination Center of Ethics Committees

PROFESSIONAL ASSOCIATIONS

- EACTS
- ESC
- EFORT
- IFMBE /EAMBES

NETWORKS

- IDEAL-D

TRADE ASSOCIATION

- MedtechEurope

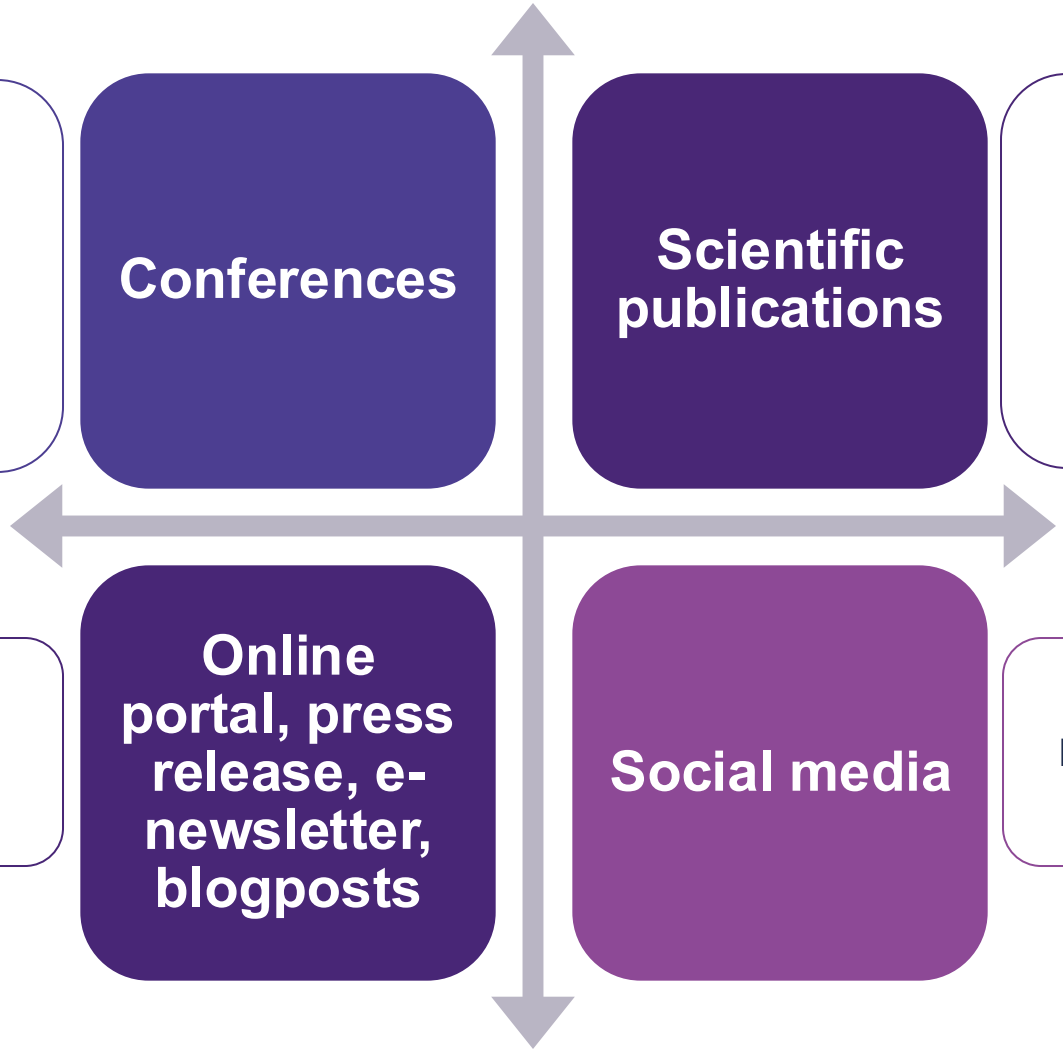
INDEPENDENT EXPERTS

- Amie Smirthwaite
- Claudia Wild
- Danielle Giroud

Deliverables

- Guidance and recommendations on EU EFS
- Templates and/or checklists for clinical investigation protocol, patient informed consents, master clinical trial agreement, and insurance agreements
- Research reports (deliverables)
- Databases
- Papers
- Online portal **www.heuefs.eu**

Communication strategies



Target groups: Policy makers, Regulators, Industry, Health economists and experts of HTA, Clinicians, Biomedical engineers, Hospitals, Scientific community and general public, Patients and citizens, Bioethicists, relevant networks

Target journals: Lancet, BMJ, Value in Health, Social Science and Medicine, Health Policy, International Journal of Technology Assessment in Health Care, European Heart Journal, EuroIntervention, and Clinical Therapeutics

'Sarfatti 25', 'Bocconi TV', Bocconi 'Knowledge'

LinkedIn, Twitter

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

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Thank you!

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