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

Origins and Objectives

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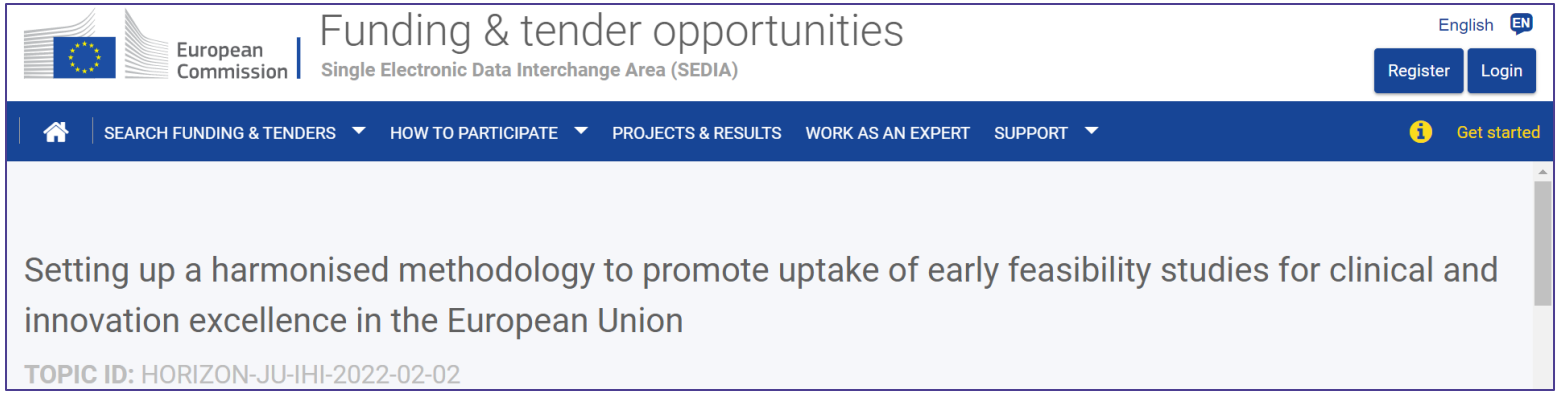
MedTech Europe Cardiovascular Sector Group | 8 March 2024

Context of the Project

- **EFS are provided for** in the MDR 2017/745.
- **ISO 14155:2020** introduced a taxonomy for different clinical investigation types.
- However there is no standardised **procedural framework**, **guidelines** or common **reference standards** to conduct EFS in the EU.

- Developing an **EU EFS Program** has the potential to:
  - **Benefit** patients, clinical sites & trialists, technology developers.
  - **Strengthen** EU competitiveness and attractiveness for innovation and investments.
  - **Deliver** access to innovation while maintaining rigorous assessments and preserving patient safety.



Overarching goal of the Project

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.

HEU-EFS project facts

- 22 public and private consortium partners
- 4-year project
- €19 million grant from the Innovative Health Initiative
- Coordinated by Bocconi University
- Industrially led by Edwards Lifesciences

The Consortium

ACADEMIA

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

HEALTH CARE PROVIDERS

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

HTA AGENCIES

- AGENAS, Italy
- NIPH, Norway

PATIENT ORGANISATIONS

- European Patients' Forum
- Global Heart Hub

CRO

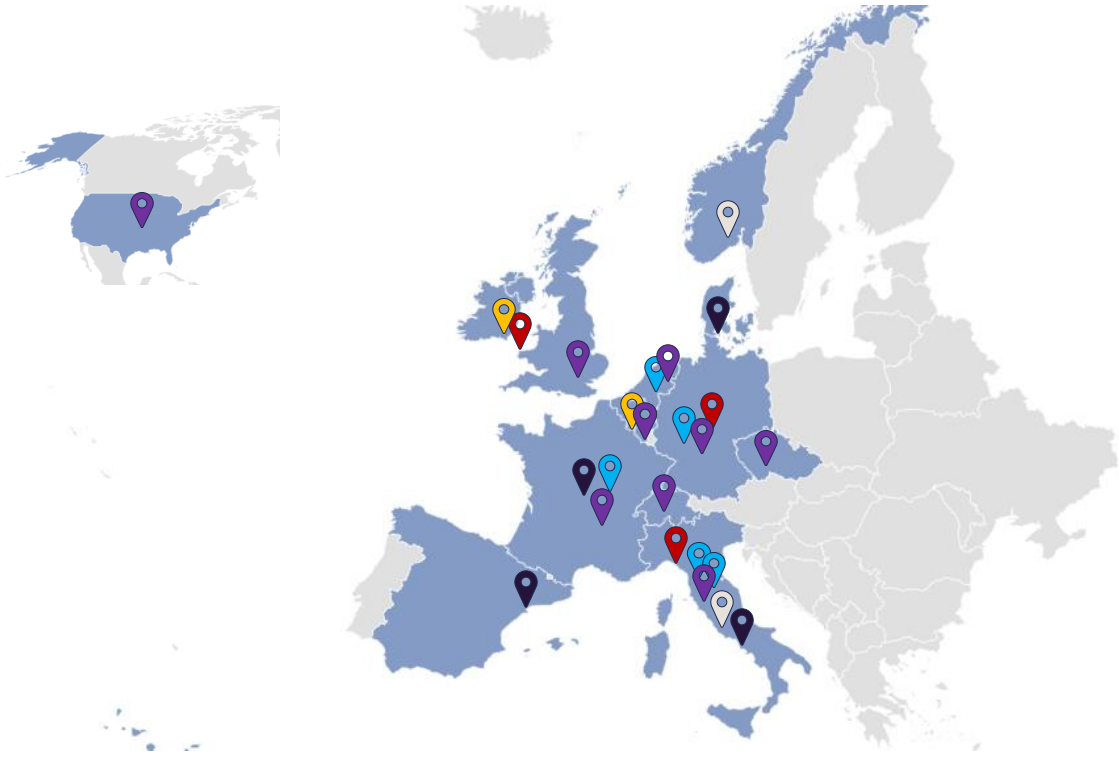
- Meditrial

SMEs

- Carmat
- Newronika
- Idris Oncology
- Qurasoft

TECHNOLOGY DEVELOPERS

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



External Advisory Board

COMPETENT AUTHORITIES

- Pietro Calamea, Italian Ministry of Health
- Donal O'Connor, HPRA
- Mariana Madureira and Judite Neves, INFARMED

NOTIFIED BODIES

- Team-NB
- IMQ

MEMBERS OF ETHICS COMMITTEES

- Gry Dahle, Chair of the Norwegian National Ethical Committee
- Carlo Petrini, President of the Italian National Coordination Center of Ethics Committees

PROFESSIONAL ASSOCIATIONS

- EACTS
- ESC
- EFORT
- IFMBE /EAMBES

NETWORS

- IDEAL-D

TRADE ASSOCIATION

- MedtechEurope

INDEPENDENT EXPERTS

- Amie Smirthwaite

Specific objectives

1. Conduct research and analysis on state of play of regulatory framework and characteristics and impacts of pre-market programs.
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.

Structure of 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

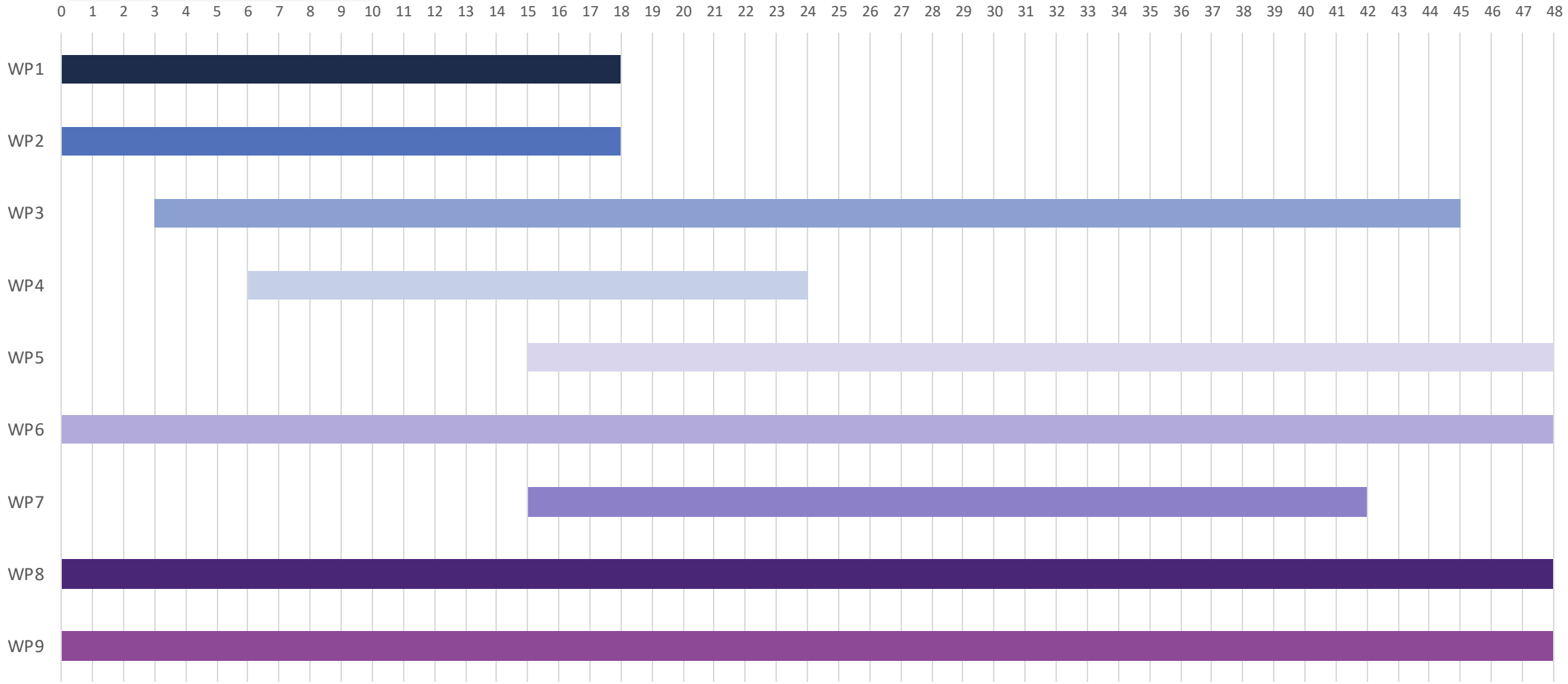
WP governance: a public-private partnership

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



Deliverables

- Guidance and recommendations on EU EFS
- Templates for clinical investigation protocol, patient informed consents, clinical site contracts, insurance agreements
- Research reports
- Databases
- Papers
- Training materials
- Online portal

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Thank you!
Questions?

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