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

Overview of the project

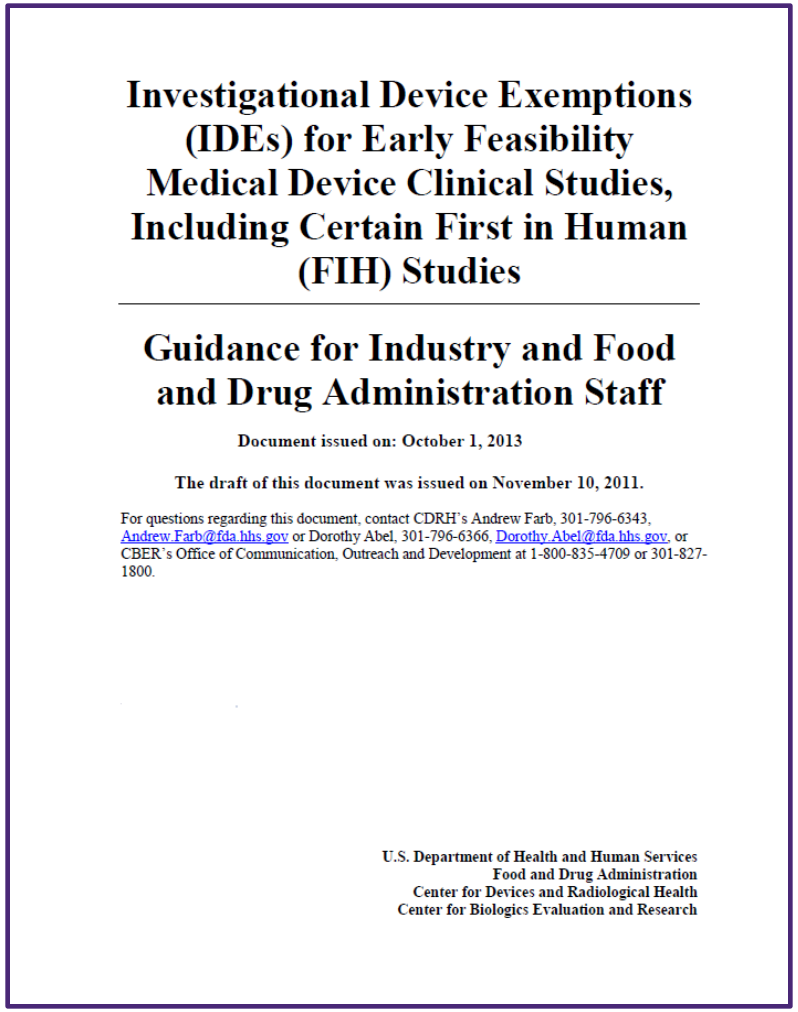
Helen Banks, Luisa Buzelli (Bocconi University)

16 July 2024

Agenda

1. Context of the HEU-EFS project
2. Project's goals, objectives and stakeholders involved
3. Structure of the project and timelines
4. Focus on Research and analysis (WP1 & WP2)
5. Next steps
6. Q&A

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.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

WHAT?

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

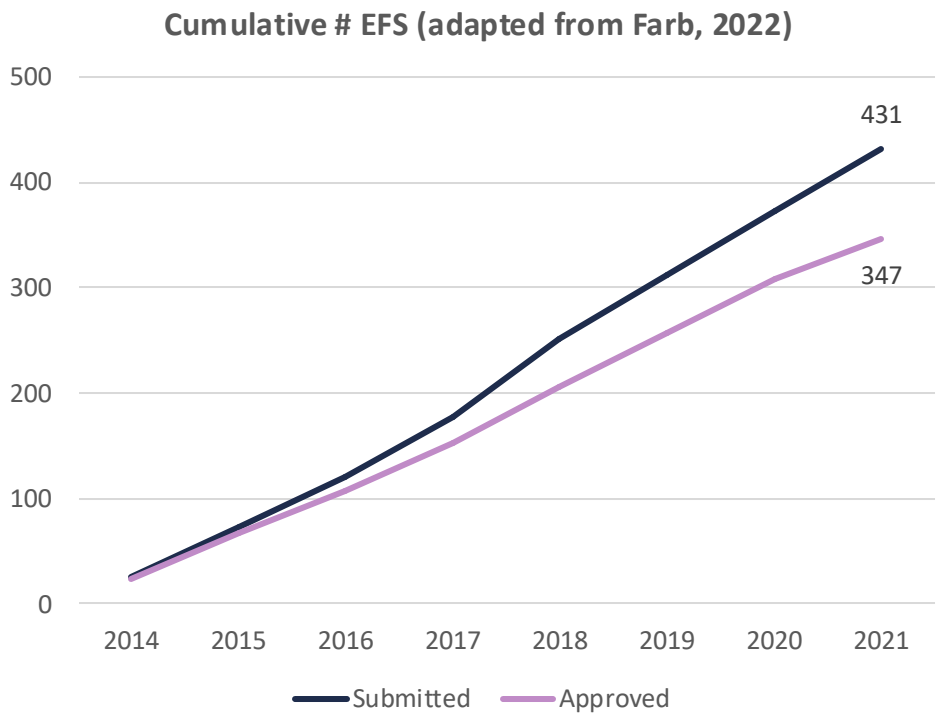
WHEN?

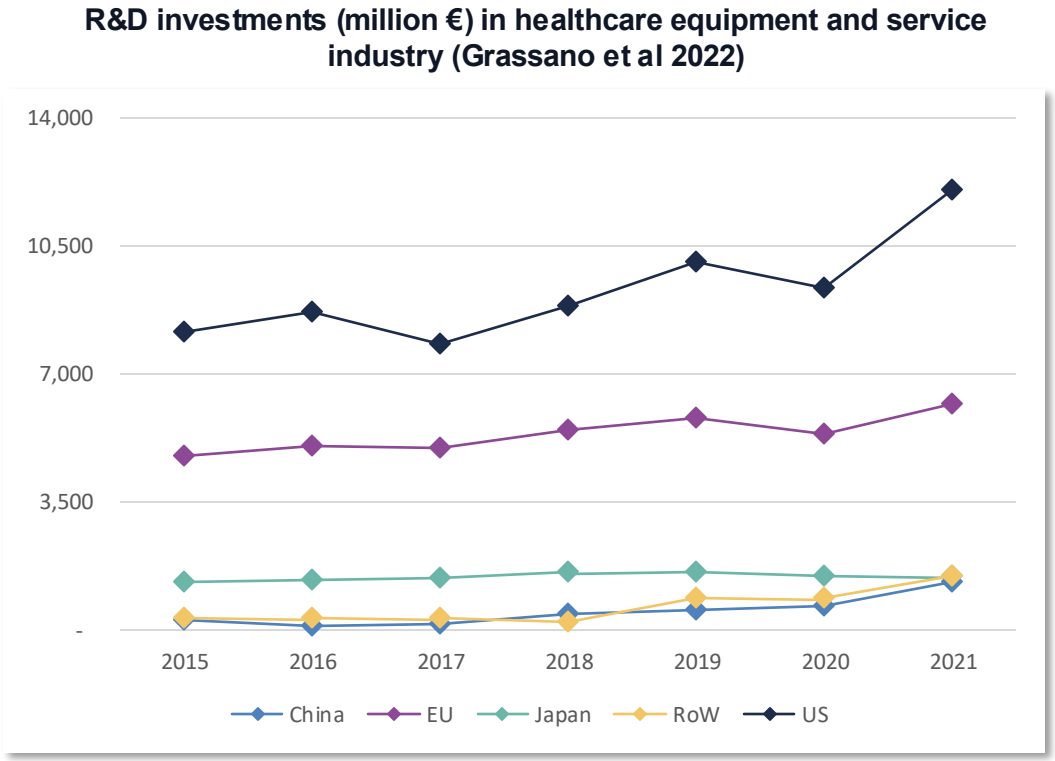
Typically, **before the device design** has been finalized, for a specific indication (e.g. innovative device for a new or established intended use, marketed device for a novel clinical application).

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 preclinical assessments or appropriate preclinical tests are unavailable.

Context: differences between USA and EU





Context: Why an EU EFS program (II)

- **MDR 2017/745** and **HTAR 2021/2282** early dialogue and life cycle approach for clinical evidence generation.
- **ISO 14155:2020** "Clinical investigation of medical devices for human subjects — good clinical practice".

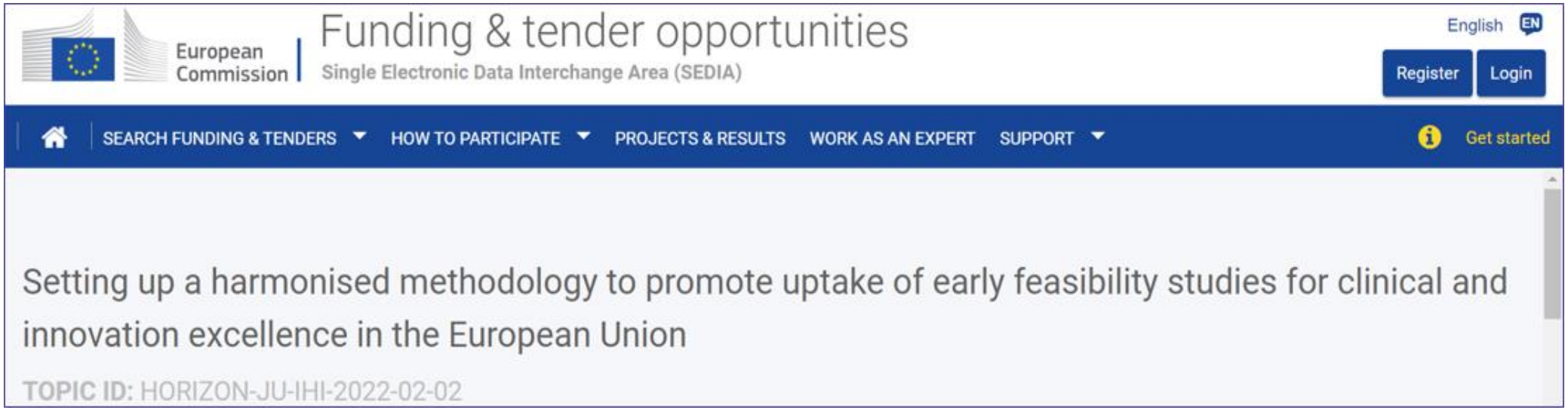
Table I.1 — Synopsis of clinical development stages (terminology can vary across geographies)

Regulatory status	Pre-market		Post-market	
Clinical development stage	Pilot stage (I.3.2)	Pivotal stage (I.3.3)	Post-market stage (I.3.4)	
Type of design	Exploratory or confirmatory (I.4.2)	Confirmatory (I.4.3)		Observational (I.4.4)
Descriptors of clinical investigations	First in human clinical investigation (I.5.2) Early feasibility clinical investigation (I.5.3) Traditional feasibility clinical investigation (I.5.4)	Pivotal clinical investigation (I.5.5)	Post-market clinical investigation (I.2.3)	Registry[a] (I.5.6) Post-market clinical investigation[a] (I.2.3)
Burden to subject	Interventional (I.6.2)			Non-interventional (I.6.3)

[a] Registry data may be used for pre-market regulatory purposes (see I.5.6), this can also apply to the post-market clinical investigation data.

- **MDCG 2021-6** – Rev 1. December 2023 Q&A regarding clinical investigation.

Call for proposals



Awarded to

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

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.

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 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

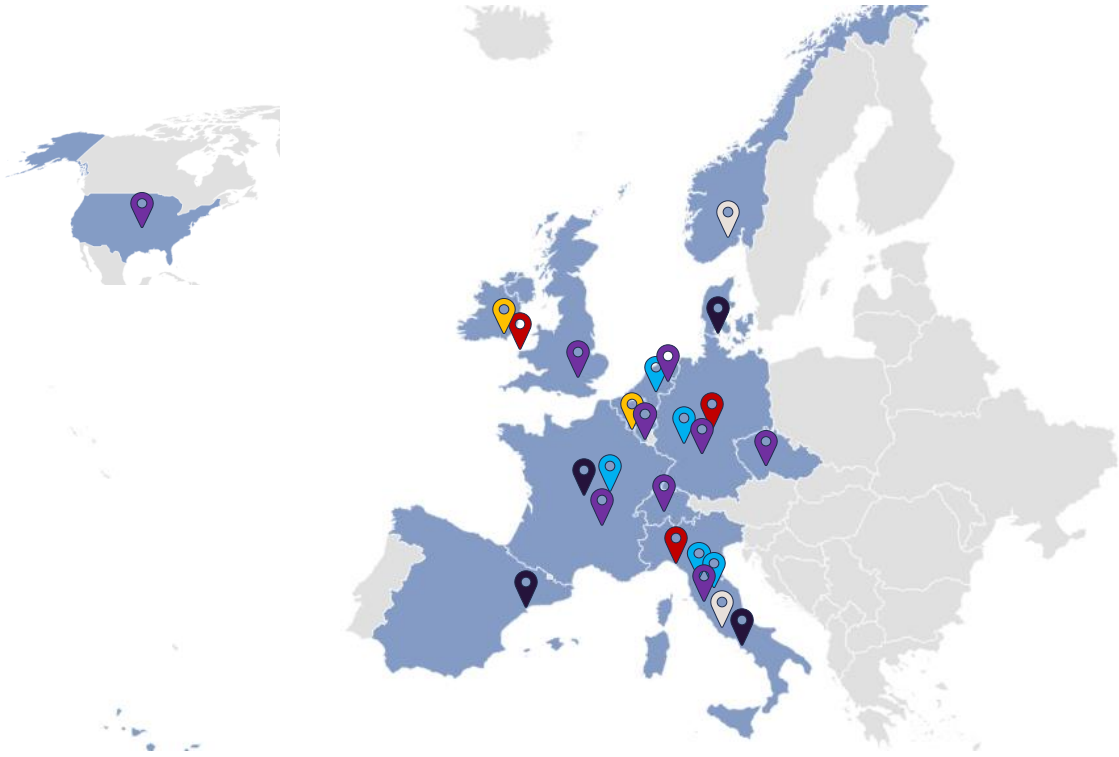
- Meditrial

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 (Ireland)
- Mariana Madureira and Judite Neves, INFARMED (Portugal)

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

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

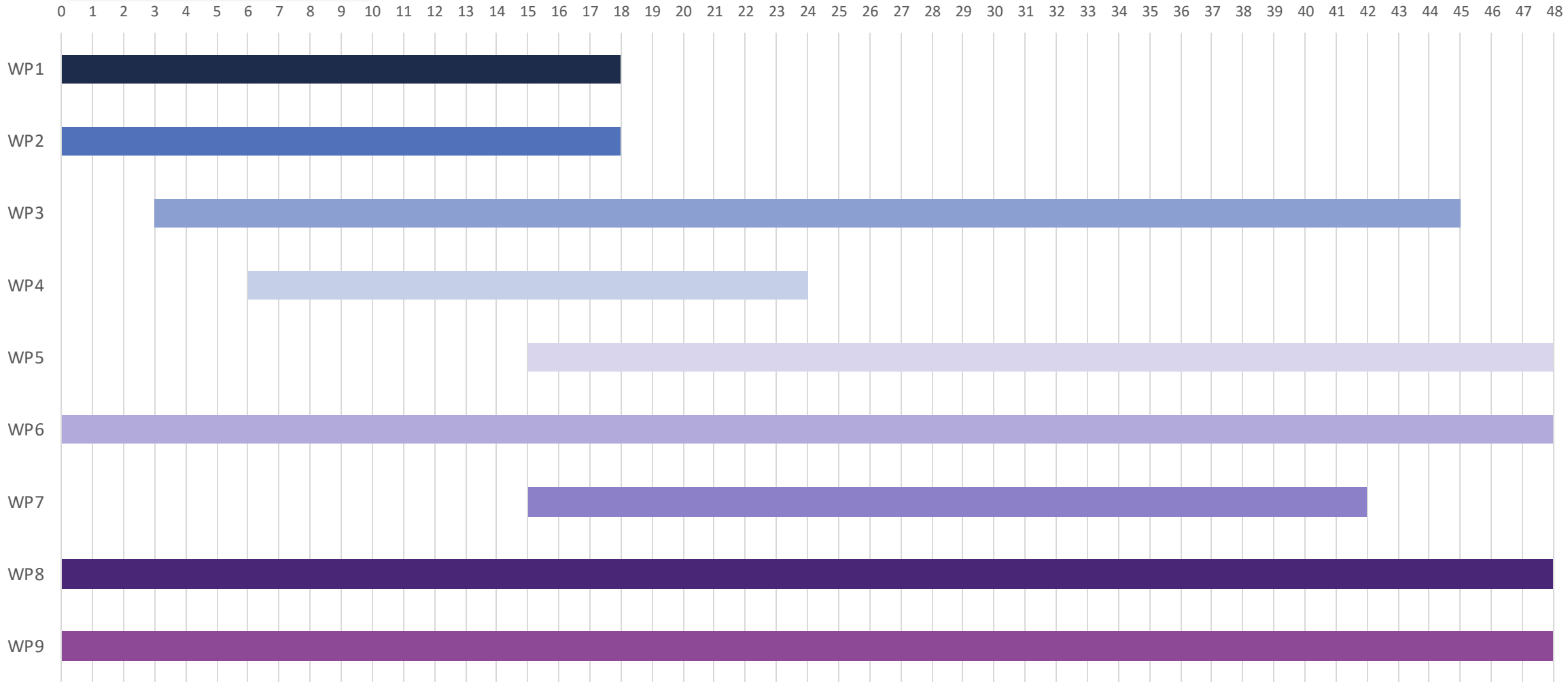
- WP 7 Pilot use cases

WP 8 Web portal, dissemination, exploitation, and communication

Timeline

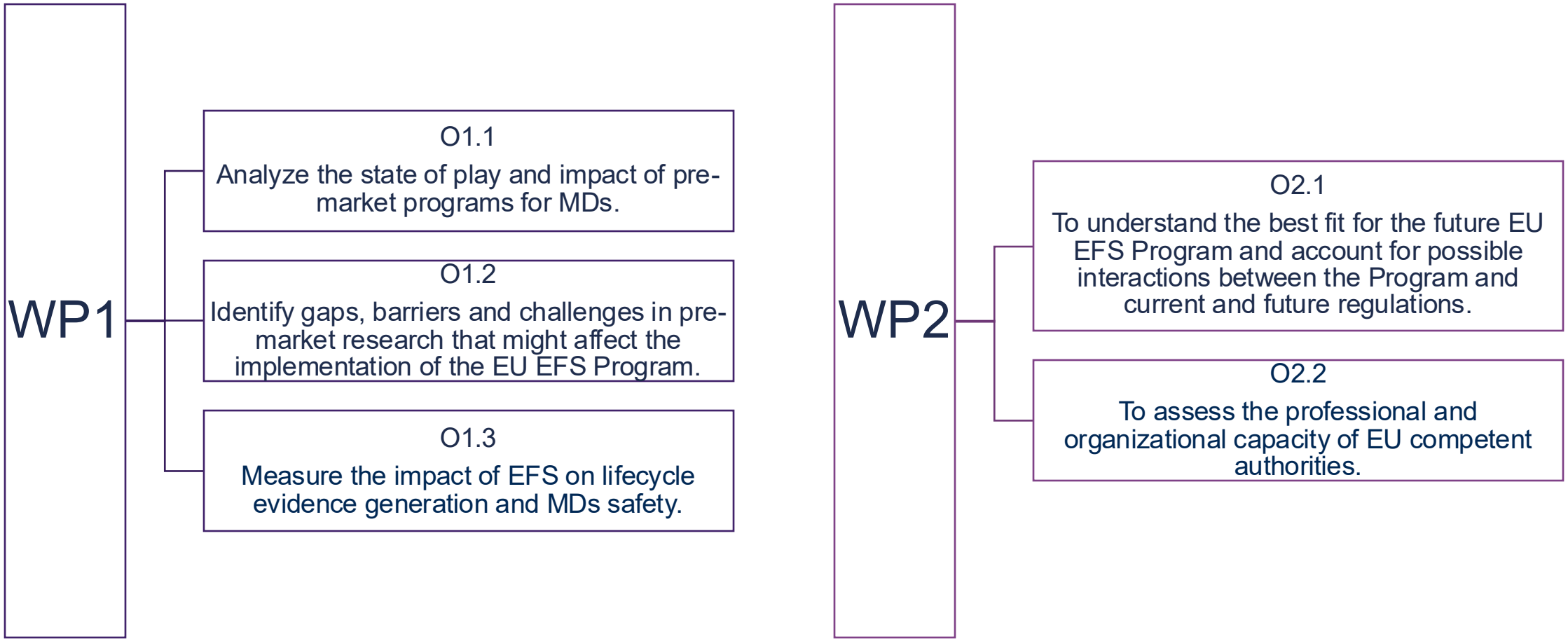
Start date
1 October, 2023

End date
30 September, 2027

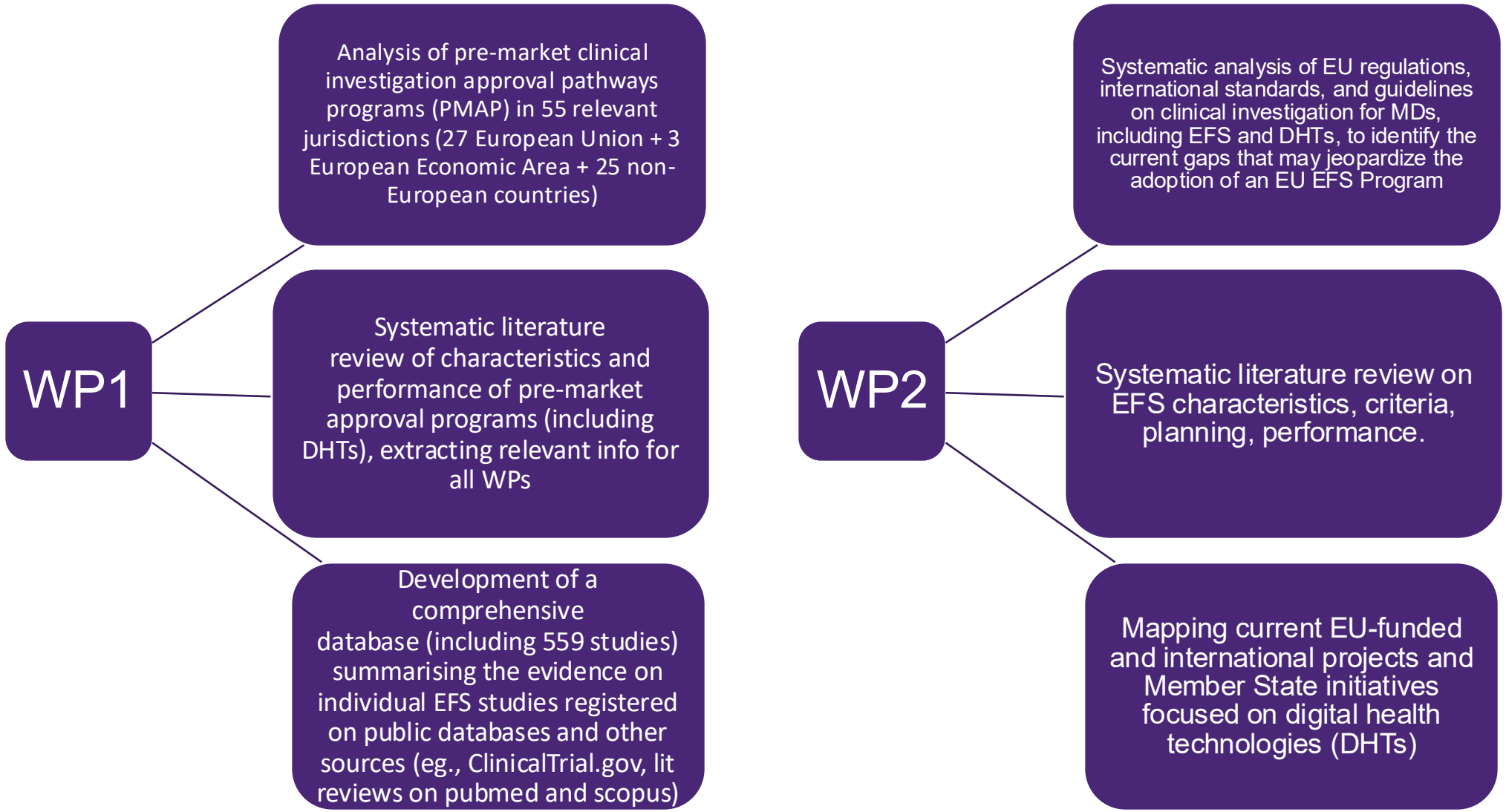


Focus on Research and analysis (WP1 & WP2)

Objectives for research WPs



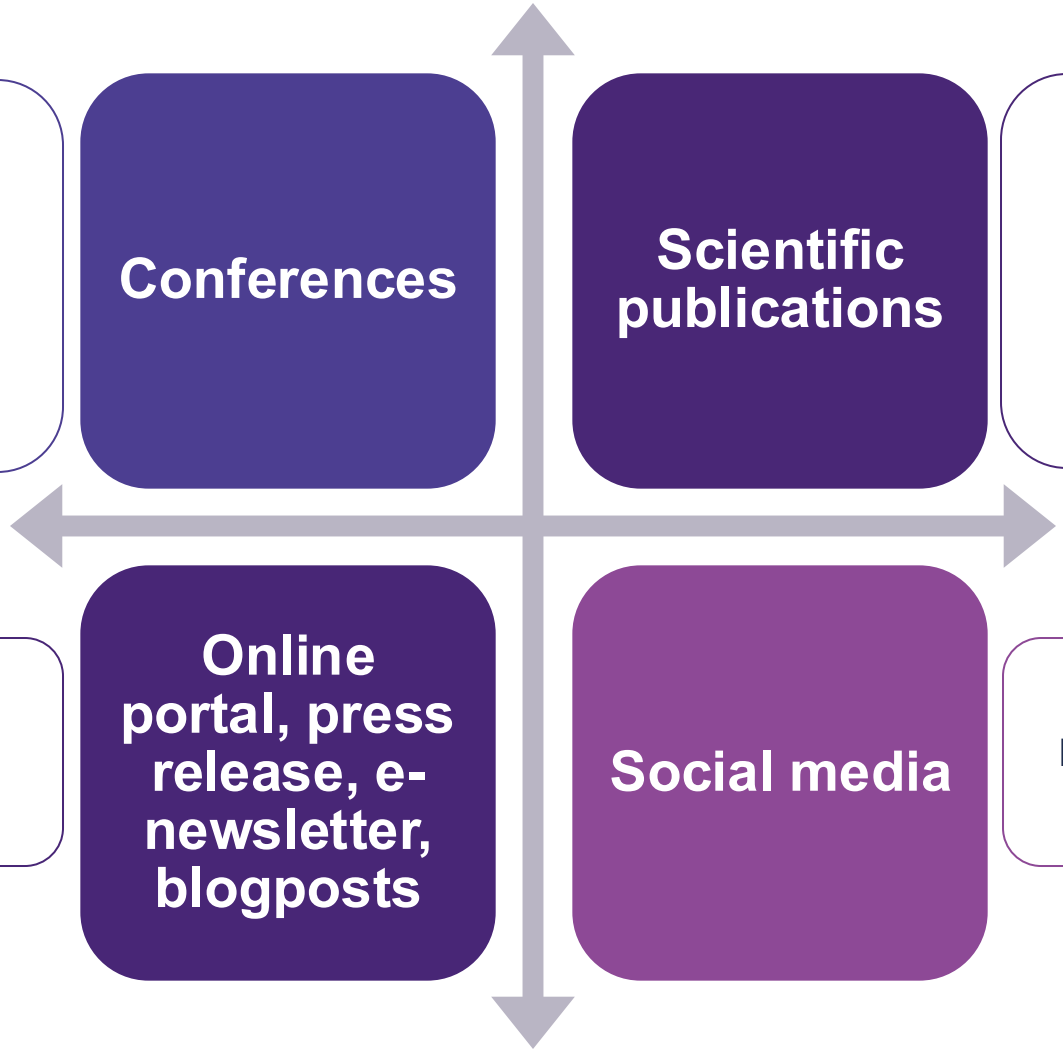
Activities conducted so far



Methodology development WPs – next steps

Definition of clear criteria	• Criteria that medical devices (MDs) must meet to be eligible for EU EFS program • Including, for instance, risk class, degree of innovation, clinical application, target patients and severity of their conditions) • Informing sponsors and regulators in a standardized manner when an EFS should be considered and what is needed to undertake this type of study
Development of a clinical investigation plan (CIP) for EU EFS	• Designed to fulfil the requirements for an EFS study in compliance with appropriate regulations
Design and implementation of a dashboard	• Ensuring harmonization with the current EU regulatory framework, which will help to monitor the performance of the EU EFS program
Assessment of any ethical and legal issues and recommendations	• Making sure that patients' safety is safeguarded, and they can benefit the most from such a program, which aims to give them earlier access to new medical devices in the 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

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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