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SDA Bocconi SCHOOL OF MANAGEMENT

SETTING UP A HARMONIZED METHODOLOGY TO PROMOTE UPTAKE OF EARLY FEASIBILITY STUDIES FOR CLINICAL AND INNOVATION EXCELLENCE IN THE EUROPEAN UNION: WHAT VALUE(S)?

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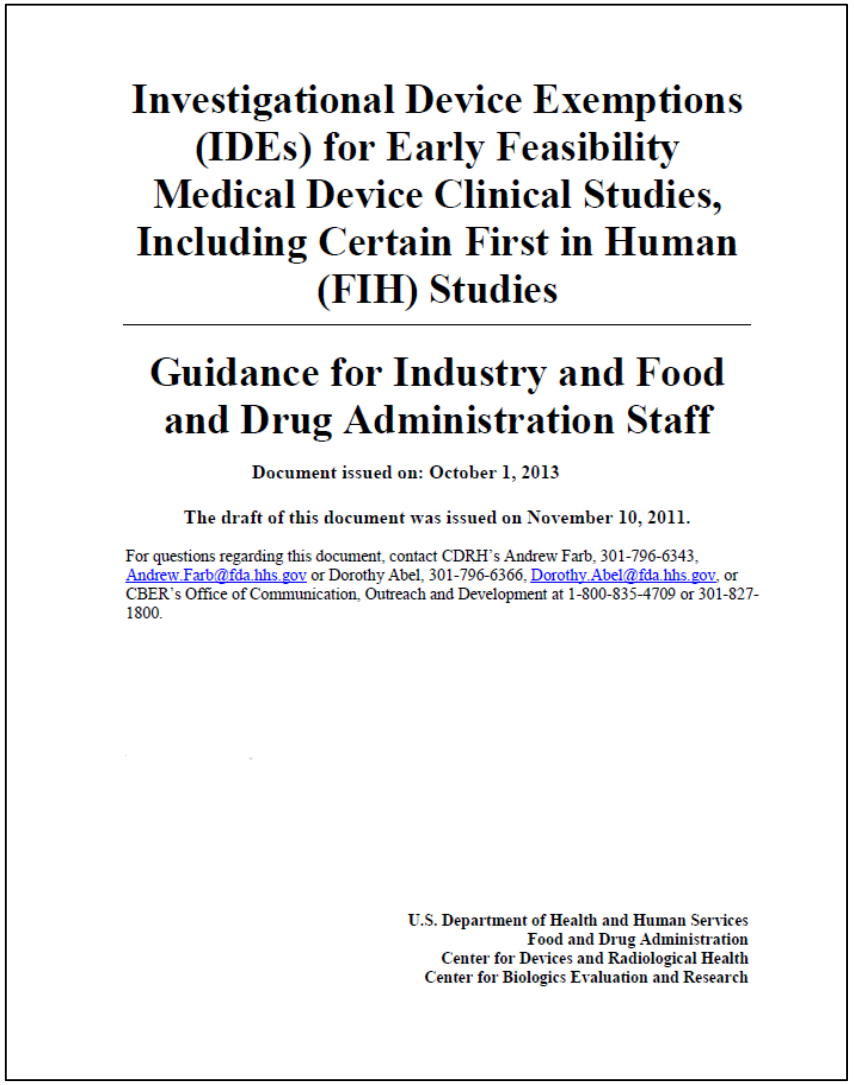
DISCLAIMER

- *Funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author only and do not necessarily reflect those of the aforementioned parties. Neither of the aforementioned parties can be held responsible for them.*

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 nonclinical assessments or appropriate nonclinical tests are unavailable. Information obtained from an early feasibility clinical investigation can **guide device modifications**. An early feasibility clinical investigation does not necessarily involve the first clinical use of a device.*

WHY AN EU EFS PROGRAM?

- **Feasible** in the EU
  - **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)

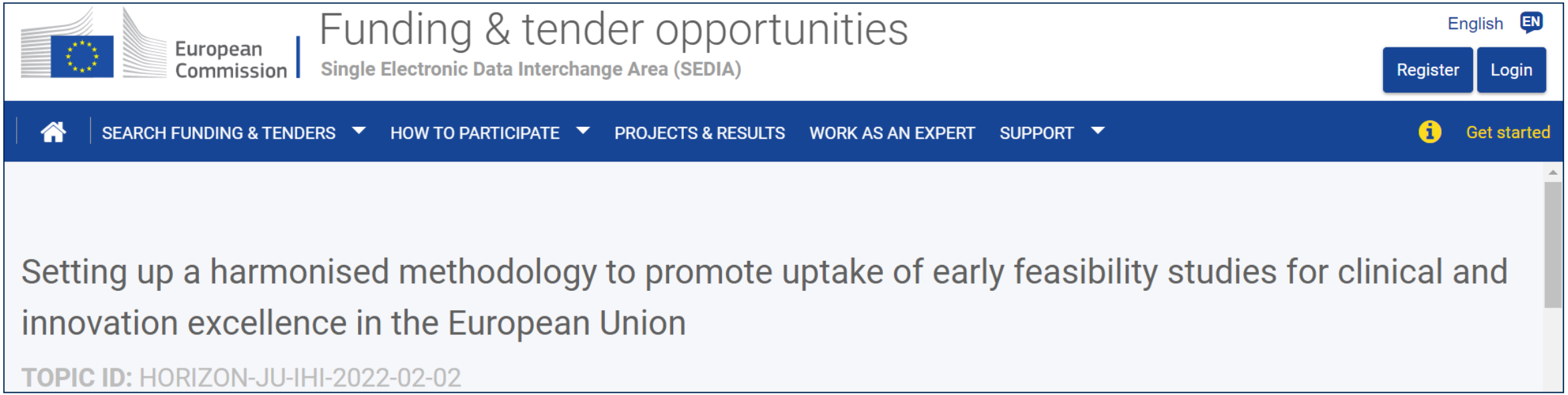
[a] Registry data may be used for pre-market regulatory purposes (see I.5.6), this can also apply to the post-market clinical investigation data.

  - **MDR 2017/745 and HTAR 2021/2282** early dialogue and life cycle approach for clinical evidence generation.
  - **MDCG 2021-6**, Q&A regarding clinical investigation.

- **Beneficial** to patients, clinical sites & trialists, technological innovation developers.
- 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.

CALL FOR PROPOSALS

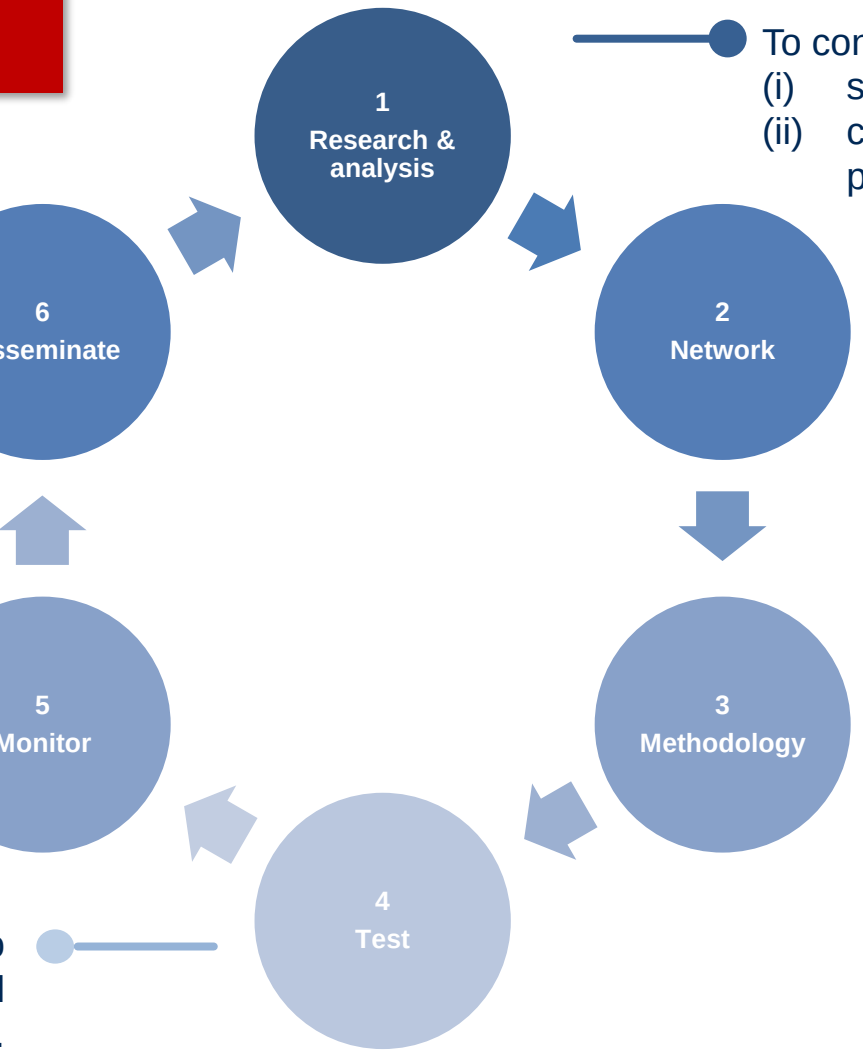


Awarded to

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

OBJECTIVES OF HEU-EFS PROJECT

Start date: 1 October, 2023
Duration: 4 years



To conduct research and analysis on:
(i) state of play of regulatory framework, and
(ii) characteristics and impacts of pre-market programs.

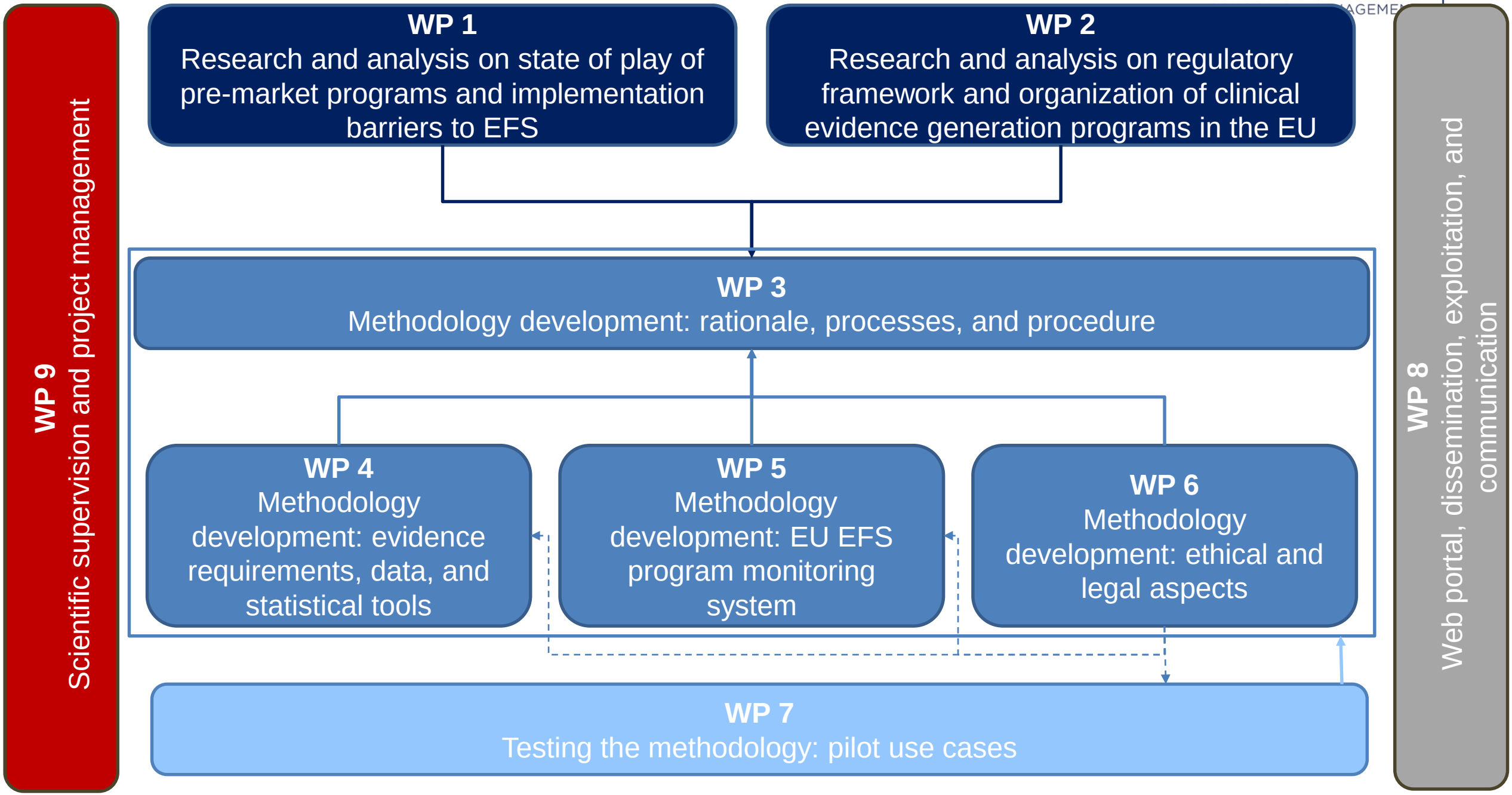
To build a sustainable network of stakeholders to promote the implementation of EFS in the EU.

To develop:
(i) a sound, widely applicable, and harmonised EU methodology, and
(ii) recommendations to uptake EFS.

To undertake pilot use cases to test the proposed methodological framework.

To develop instruments to monitor the performance of the EU EFS program.

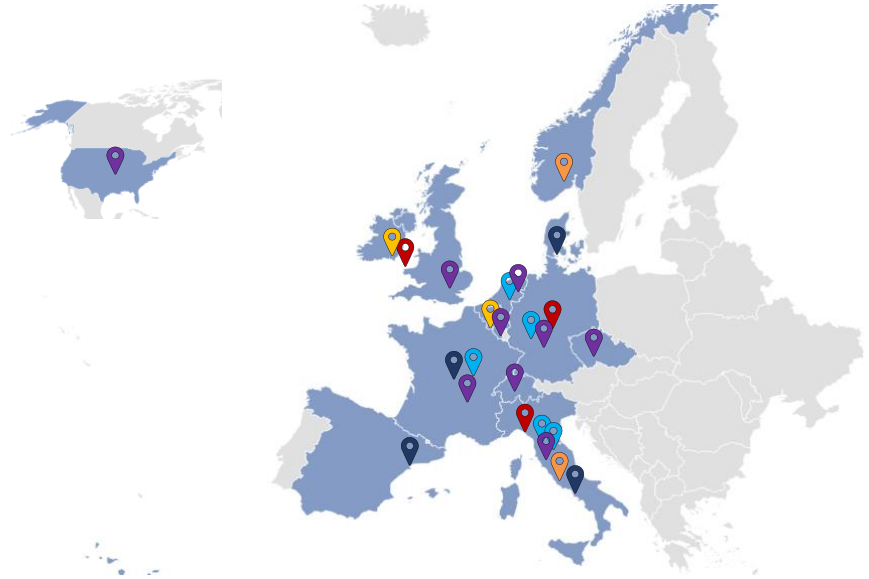
To implement a dedicated, sustainable, open access, informative online portal dedicated to EFS and disseminate the project results and recommendations.


WP 9
Scientific supervision and project management
WP 1
Research and analysis on state of play of pre-market programs and implementation barriers to EFS
WP 2
Research and analysis on regulatory framework and organization of clinical evidence generation programs in the EU
WP 3
Methodology development: rationale, processes, and procedure
WP 4
Methodology development: evidence requirements, data, and statistical tools
WP 5
Methodology development: EU EFS program monitoring system
WP 6
Methodology development: ethical and legal aspects
WP 7
Testing the methodology: pilot use cases
WP 8
Web portal, dissemination, exploitation, and communication

THE CONSORTIUM

Partners from 13 countries worldwide:

- 9 EU (BE, CZ, DE, DK, ES, FR, IE, IT, NL)
- 1 EEA (NO).
- 3 non-EU (UK, CH, US).



Academia

Health care providers

HTA bodies

Patient organizations

CRO

SMEs

Technology developers

External AB: competent authorities, notified bodies, professional associations, networks, MedtechEurope, independent experts.

Setting up a Harmonized Methodology to Promote Uptake of Early Feasibility Studies for Clinical and Innovation Excellence in the European Union: What Value(s)?

Copenhagen, Denmark ***14 November 2023, 13:45-14:45*** ***Session 230***

Moderator	Panelists		
			
Giuditta Callea *Bocconi University*	Tom Melvin *Trinity College Dublin*	Kristian Kidholm *Odense University Hospital*	Fanny van der Loo *Edwards Lifesciences*

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THANK YOU!

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