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

**Giuditta Callea, PhD**

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- *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.*

## 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](mailto:Andrew.Farb@fda.hhs.gov) or Dorothy Abel, 301-796-6366, [Dorothy.Abel@fda.hhs.gov](mailto: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.

- **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 (L3.2)	Pivotal stage (L3.3)	Post-market stage (L3.4)	
Type of design	Exploratory or confirmatory (L4.2)	Confirmatory (L4.3)		Observational (L4.4)
Descriptors of clinical investigations	First in human clinical investigation (L5.2)	Pivotal clinical investigation (L5.5)	Post-market clinical investigation (L2.3)	Registry <sup>a</sup> (L5.6) Post-market clinical investigation <sup>a</sup> (L2.3)
	Early feasibility clinical investigation (L5.3)			
	Traditional feasibility clinical investigation (L5.4)			
Burden to subject	Interventional (L6.2)			Non-interventional (L6.3)

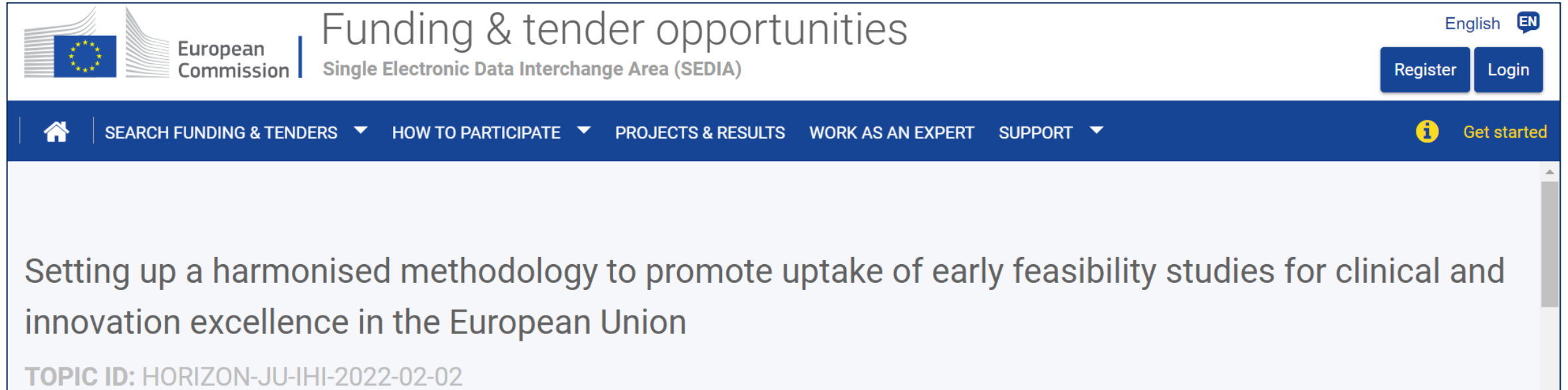
<sup>a</sup> Registry data may be used for pre-market regulatory purposes (see L5.6), this can also apply to the post-market clinical investigation data.

- **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.



The screenshot shows the top of the European Commission's SEDIA website. The header includes the European Commission logo, the text 'Funding & tender opportunities', and 'Single Electronic Data Interchange Area (SEDIA)'. There are 'Register' and 'Login' buttons, and a language selector set to 'English'. A navigation bar contains links for 'SEARCH FUNDING & TENDERS', 'HOW TO PARTICIPATE', 'PROJECTS & RESULTS', 'WORK AS AN EXPERT', and 'SUPPORT'. Below the navigation bar, the main content area displays the title of a funding opportunity: 'Setting up a harmonised methodology to promote uptake of early feasibility studies for clinical and innovation excellence in the European Union'. Below the title is the 'TOPIC ID: HORIZON-JU-IHI-2022-02-02'.

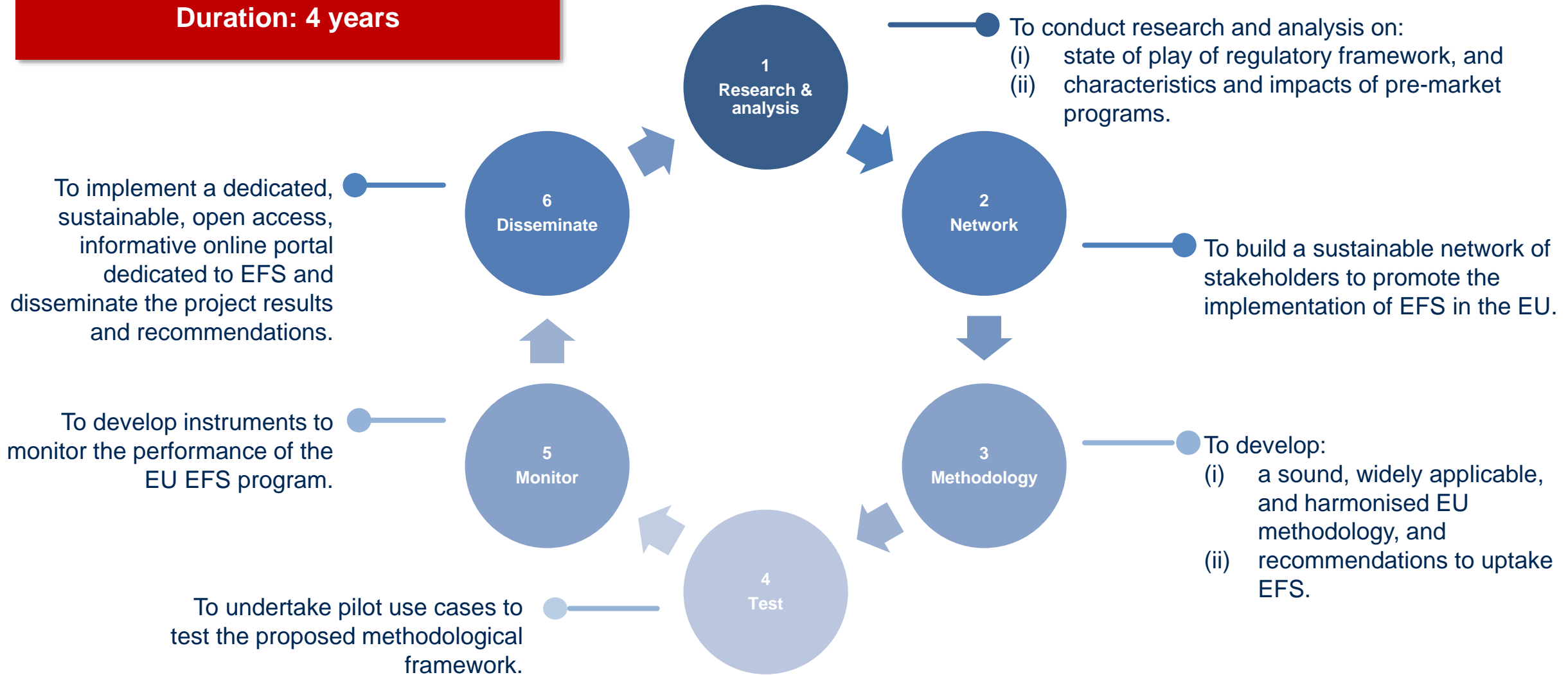


Awarded to

**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**



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

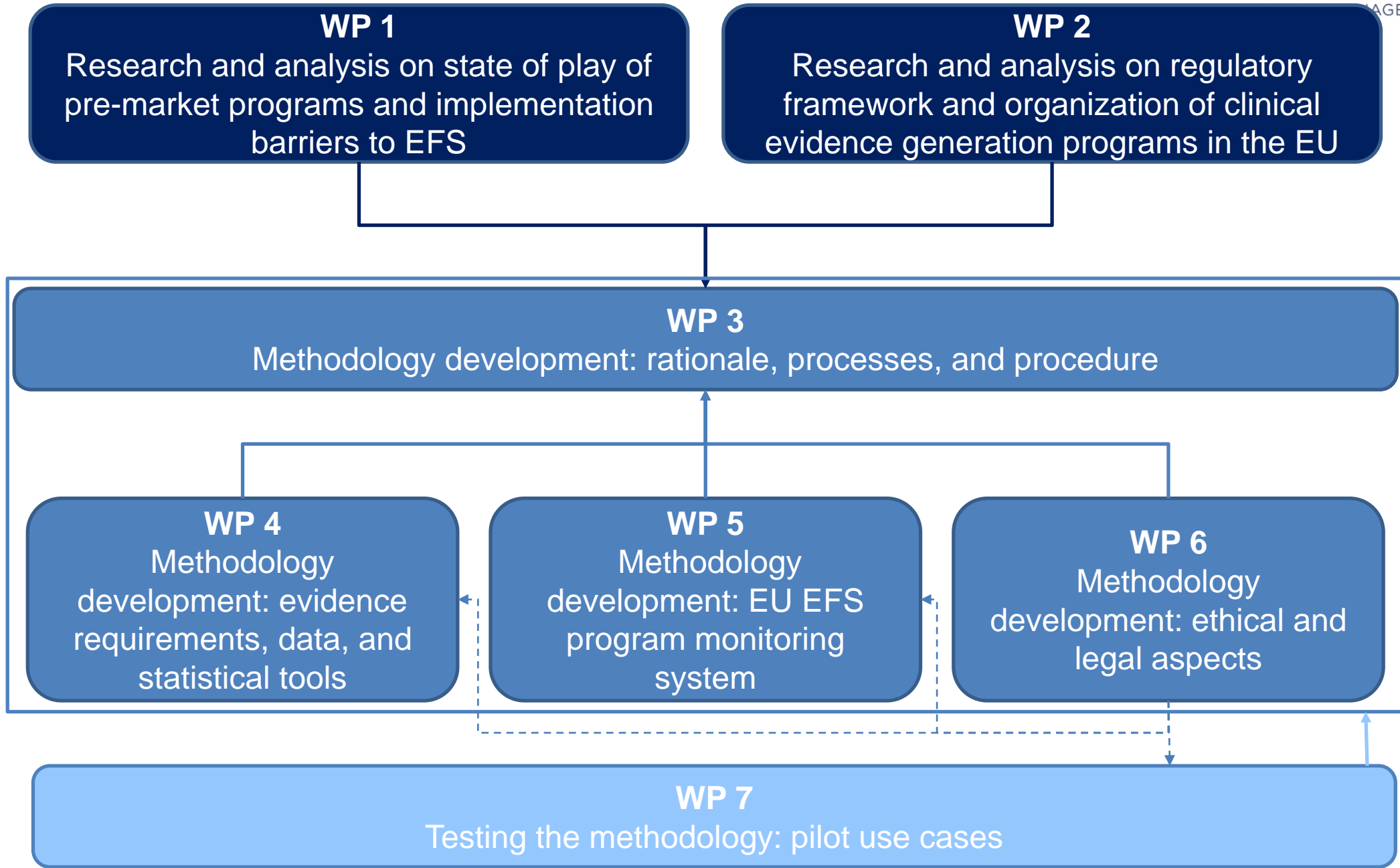
**WP 5**  
Methodology development: EU EFS program monitoring system

**WP 6**  
Methodology development: ethical and legal aspects

**WP 7**  
Testing the methodology: pilot use cases

WP 8

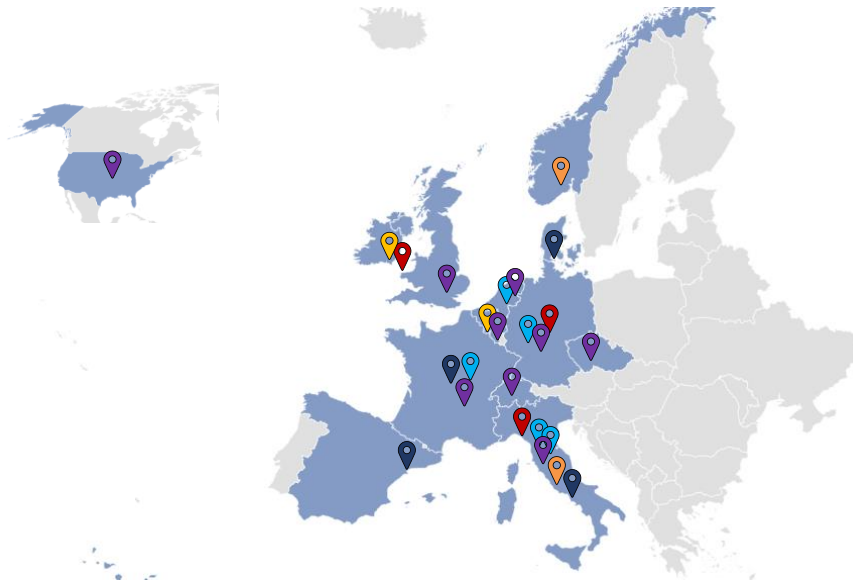
Web portal, dissemination, exploitation, and communication



# 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).



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

## Academia



## Health care providers



## HTA bodies



## Patient organizations



## CRO



## SMEs



## Technology developers





## 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



Giuditta Callea  
*Bocconi University*

### Panelists



Tom Melvin  
*Trinity College Dublin*



Kristian Kidholm  
*Odense University Hospital*



Fanny van der Loo  
*Edwards Lifesciences*

**THANK YOU!**

[giuditta.callea@unibocconi.it](mailto:giuditta.callea@unibocconi.it)