Harmonized Approach to EFS for Medical Devices in the EU

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CSI EDUCATION

DISCLOSURE STATEMENT OF FINANCIAL INTEREST

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

AFFILIATION/FINANCIAL RELATIONSHIP	COMPANY
• Employee	• Edwards Lifesciences, LLC

Co-funded by the European Union

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EARLY FEASIBILITY STUDY BACKGROUND

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

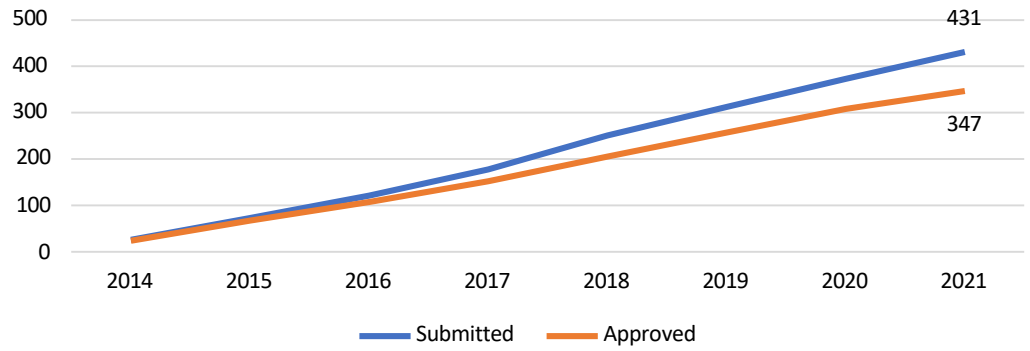
Document issued on: October 1, 2013

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

Cumulative # EFS (adapted from Farb, 2022)



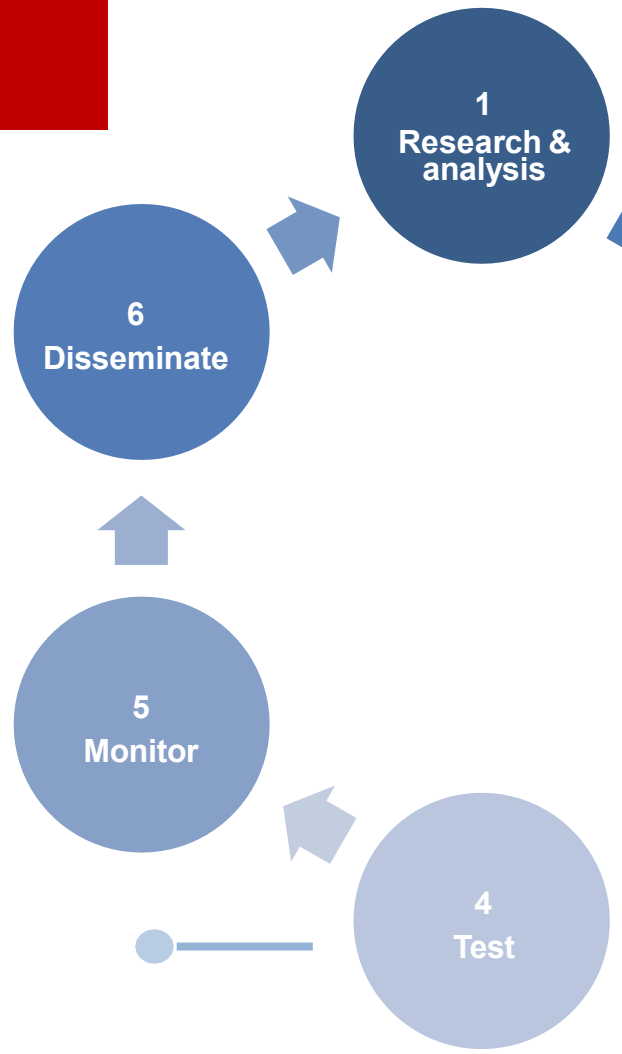
"The EU is at risk of **losing competitiveness and attractiveness** for innovation and investments."

innovative health initiative

Harmonized approach to Early Feasibility Studies for medical devices in the European Union (HEU-EFS)

OBJECTIVES

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.

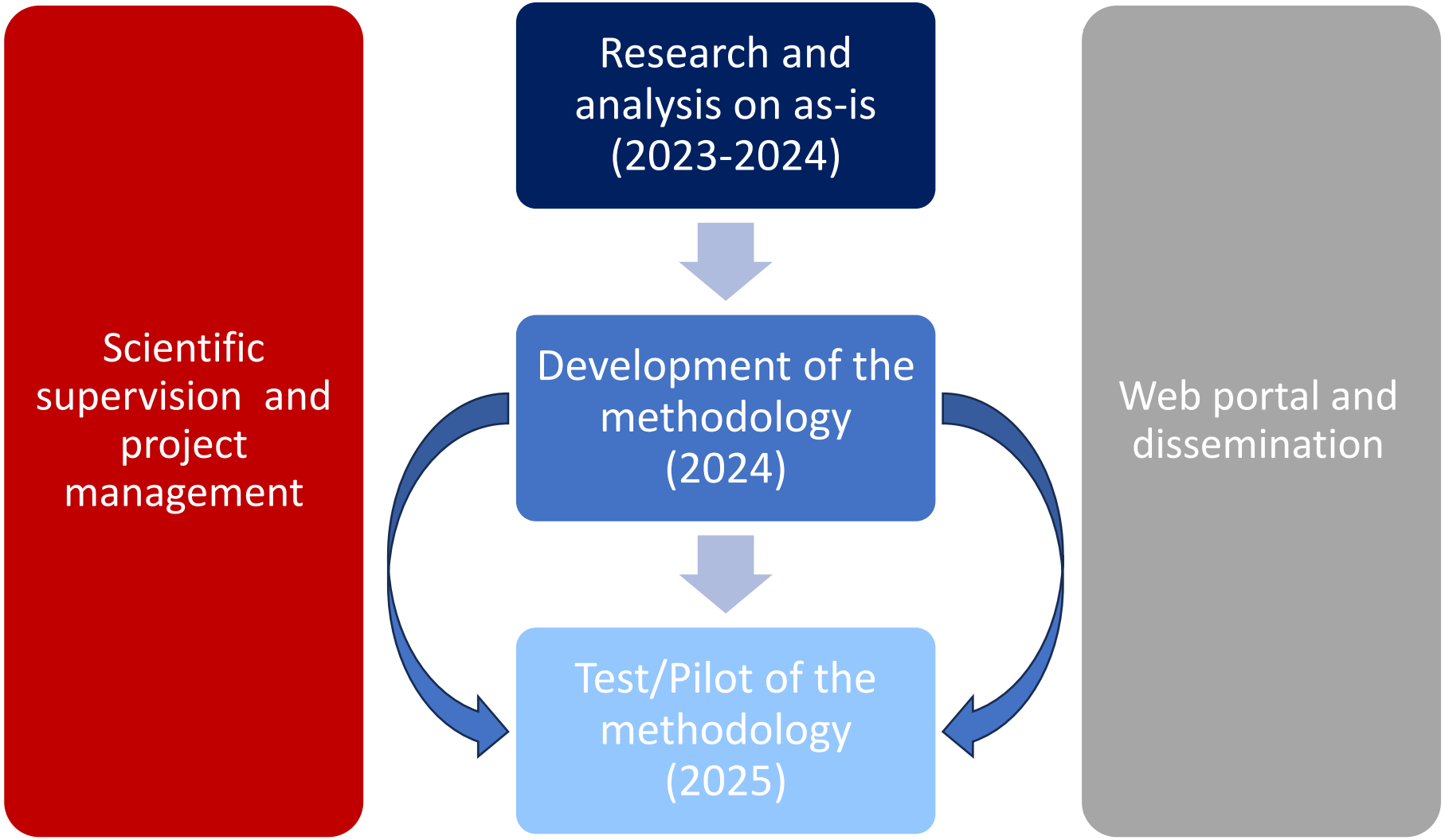
To develop:
(i) a sound, widely applicable, and harmonised EU methodology and
(ii) recommendations to uptake EFS.

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

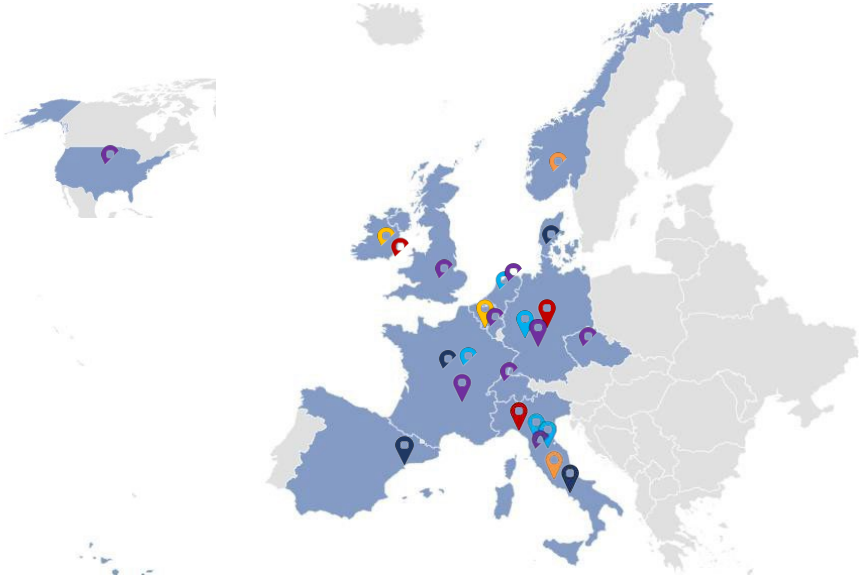
To develop instruments to monitor the performance of the EU EFS program.

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

ACTIVITIES & TIMING



CONSORTIUM COMPOSITION



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

SUMMARY

- HEU–EFS established to promote the uptake of EFS in the EU
- Cross-sectorial support and high degree of engagement across public and private stakeholders to ensure success
- Methodology to be established in 2024
- Pilot use/test cases expected in 2025
- HEU-EFS Website under construction → Future home for updates and information
- Contacts: giuditta.callea@unibocconi.it or kevin_drisko@edwards.com

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