

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

- Employee

COMPANY

- Edwards Lifesciences, LLC



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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

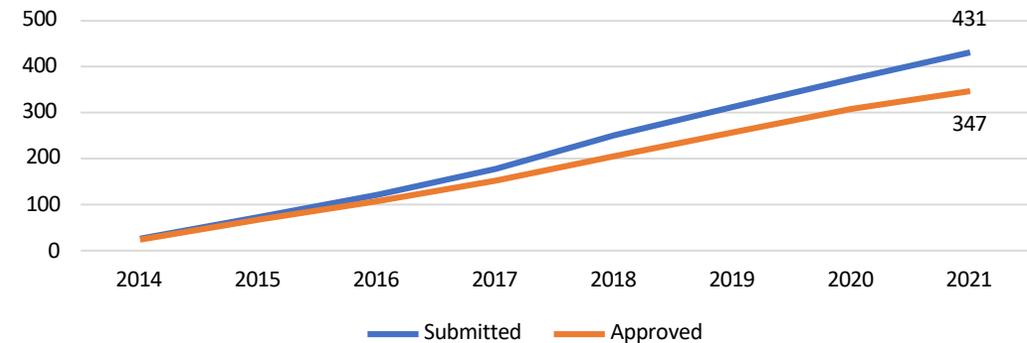
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For questions regarding this document, contact CDRH's Andrew Farb, 301-796-6343, Andrew.Farb@fda.hhs.gov or Dorothy Abel, 301-796-6366, Dorothy.Abel@fda.hhs.gov, or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

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.”



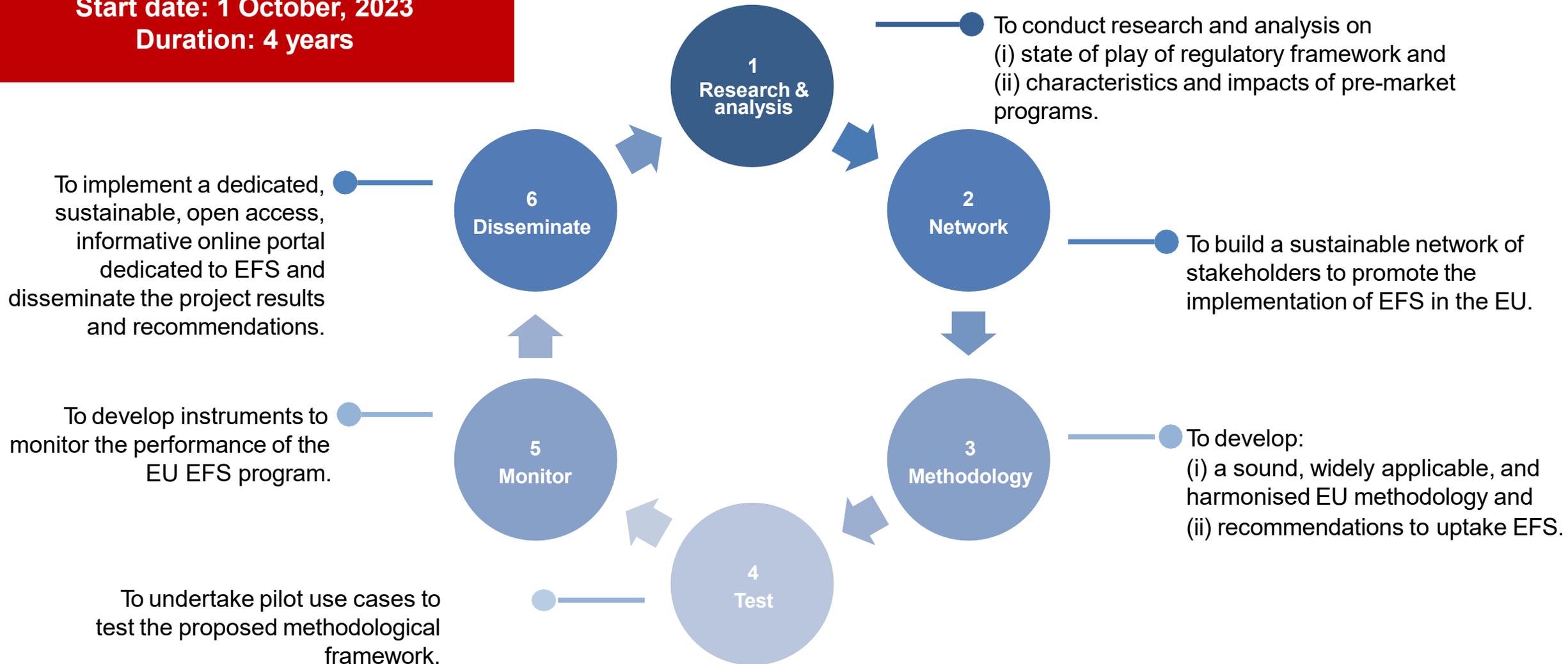
Harmonized approach to Early Feasibility Studies for medical devices in the European Union (HEU-EFS)



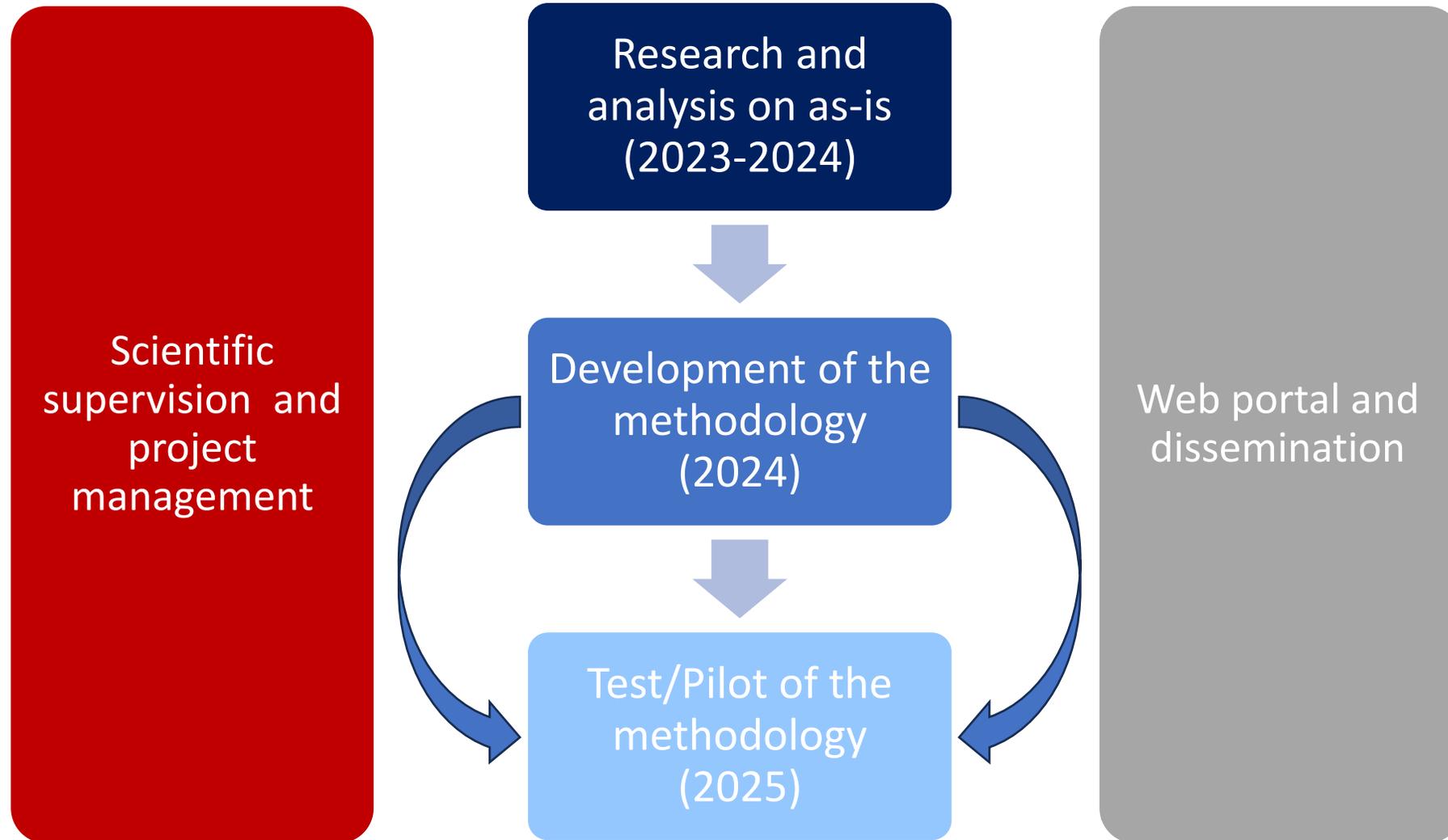
OBJECTIVES



Start date: 1 October, 2023
Duration: 4 years



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

Bocconi



Gemelli



Norwegian Institute of Public Health



Medtronic





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