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

Engagement of National Competent Authorities

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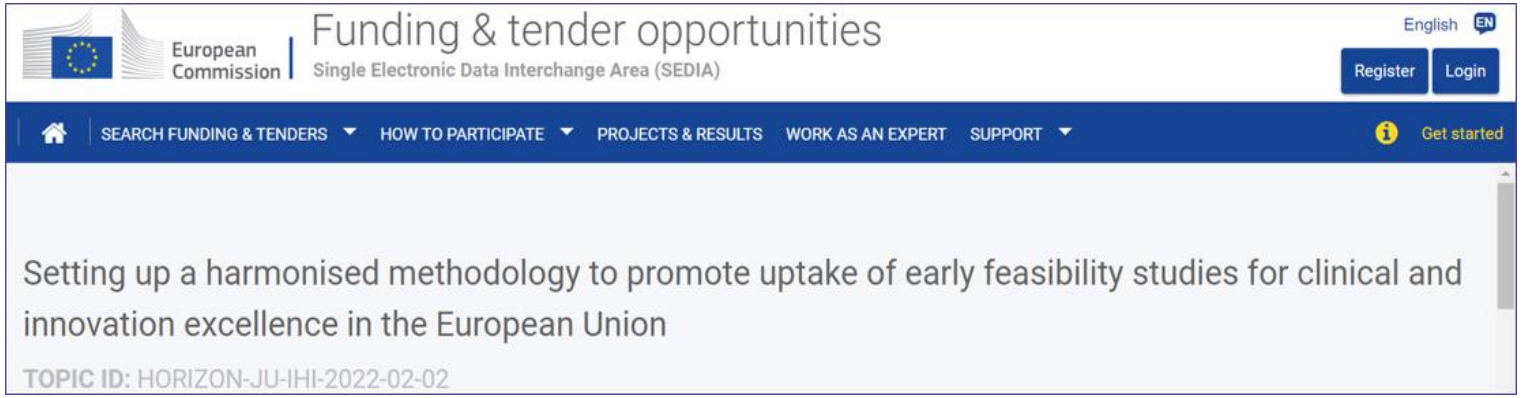
Disclaimer

The Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS) project is 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(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the parties can be held responsible for them.

Refresher on the project aims and objectives

The HEU-EFS project



AWARDED TO
Harmonised approach to Early Feasibility Studies for medical devices in the European Union – **HEU-EFS**

Overarching goal: to formulate recommendations for the establishment of an EFS Program within the EU, with a focus on ensuring patient safety and enhancing the EU single market competitiveness.

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

The HEU-EFS Community

HEU-EFS Consortium

- Bocconi University
- Trinity College Dublin
- Philipps University Marburg
- Assistance Publique Hôpitaux de Paris
- Policlinico Universitario Fondazione Agostino Gemelli
- Fundació Clínic per a la Recerca Biomèdica (FCRB)
- Odense Hospital - Region Syddanmark
- AGENAS - Agenzia nazionale per i servizi sanitari regionali
- Norwegian Institute of Public Health
- European Patients' Forum
- Global Heart Hub CLG
- CARMAT
- IdrisOncology BV
- NEWRONIKA SPA
- Qurasoft GmbH
- Meditrial Srl
- Abbott
- Edwards Lifesciences
- DePuy Synthes - Johnson & Johnson
- Medtronic
- Philips
- WL Gore

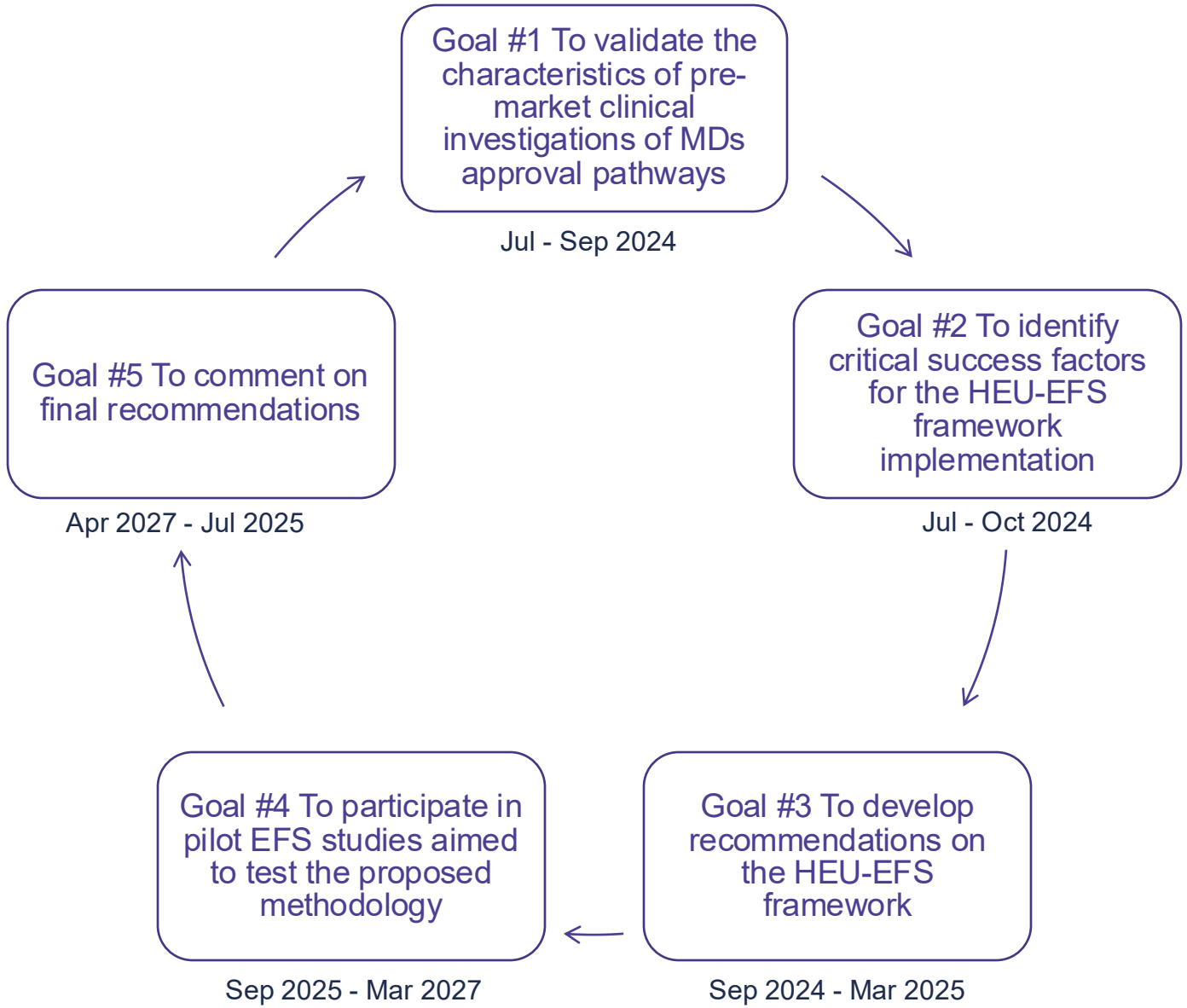
HEU-EFS Patients Advisory Group

- Diana Wong Ramos
- Jens Näumann
- Christian Pfeuffer
- Cornelia-Maria Pauna
- Dieter Wiek
- Lucía Feito Allonca
- Mireille Lasternas
- Phil Collis
- Tamool Muhamed
- Russell Wheeler

HEU-EFS External Advisory Group

- HPRA Ireland: Donad O'Connor
- INFARMED Portugal: Mariana Madureira, Judite Neves
- Italian Ministry of Health: Pietro Calamea
- TEAM-NB: Francoise Schlemmer, TEAM-NB/TUV SUD: Robert Madjno, TEAM-NB/BSI: Rachel Maed
- IMQ: Silvia Busoli Badiale
- Italian National Ethics Committee (ISS): Carlo Maria Petrini
- Norwegian National Ethical Committee for medical devices and research (REK KULMU): Gry Dahle
- EACTS: Volkmar Falk, Patrick Myers, Brendan Eley
- EFORT: Rob Nelissen
- ESC: Piotr Szymanski
- IFMBE/EAMBES: Leanardo Pecchia
- IDEAL group: Peter McCulloch
- MedtechEurope: Patrick Boisseau
- Independent Expert: Amie Smirthwaite

Goals of NCA involvement



Pre-Market Approval Pathways Database (PMAP-DB)

Pre-Market Approval Pathways Database (PMAP-DB)

OBJECTIVE

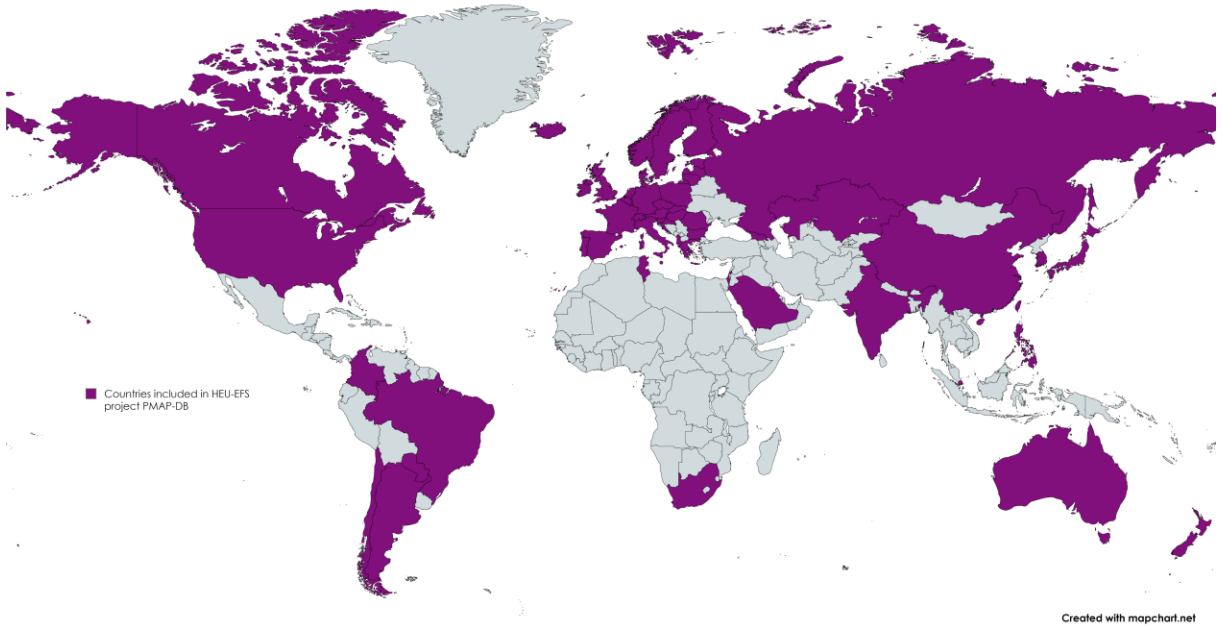
- Understand the current status of **pre-market clinical evidence generation for MDs** to:
  - Gain a solid understanding of the strengths, weaknesses and opportunities of current pre-market approval pathways;
  - Identify areas for improvement;
  - Provide recommendations on best practices.

FOCUS

- Application rules for pre-market clinical investigations of medical devices.

TARGET COUNTRIES

55 COUNTRIES
EU (27), EEA (3), Non-EU (25)



METHODOLOGY

Design PMP-DB → Data collection from public sources and compilation of PMAP-DB → Pilot validation and interviews with NCAs member of AB → Validation → Interviews with NCAs → Comparative analysis and recommendations

Overview of the information to be validated

General information
National reference legislation for clinical investigations of MDs
Authority in charge of managing the pre-market clinical investigations for MDs + link
Link of website dedicated to pre-market clinical investigations of MDs
Existence of a public database of pre-market clinical investigations of MDs + link
Existence of a performance monitoring system of the pre-market clinical investigations of MDs + link
Key performance indicators included in the performance monitoring system
Number of procedures for the submission of pre-market clinical investigations for MDs applications
Criterion guiding the classification of the studies
Language of submission

Detailed information regarding the procedures for submitting applications of pre-market clinical investigations of MDs
Name of the procedure for requesting the initiation of pre-market clinical investigations for MDs
Risk class of MDs covered by procedure (if applicable)
Type of MDs covered by the procedure (if applicable)
Link to the website of the procedure
Brief description of the process
Brief description of the procedural steps
Relevant timelines
Fees & currency
Standard documentation to be submitted
Patients' involvement in the design of pre-market clinical investigations for MDs (brief description and timing)
HTA bodies' involvement in the design of pre-market clinical investigations for MDs (brief description and timing)
Expert panels' involvement in the design of pre-market clinical investigations for MDs (brief description and timing)
Possibility to reimburse investigational devices in pre-market clinical investigations
Criteria in place for reimbursement of investigational devices in pre-market clinical investigations

Survey to National Competent Authorities

Survey

Document for circulation with NCAs ahead of the survey opening in Qualtrics

To understand **experience** with pilot stage clinical investigations

To understand **resources**, **recruitment** and **training needs** to assess applications for EFS

Suggested timelines

Pre-Market Approval Pathways Database (PMAP-DB)

Files with collected data have been prepared and will be circulated individually to NCAs

Suggested **2 week** turn-around for validation (until 5 September)

Survey

Document with survey questions and short explanatory text to be circulated to all NCAs

Suggested **1 week** turn-around for comments on the questions (until 29 August)

HEU-EFS Annual Meeting

Annual HEU-EFS consortium meeting

October 7-8 2024, Geneva

Results from WP1 and WP2 will be presented (7 October from 14:00 to 16:20)

WP3 (methodology for EFS) will be discussed (8 October from 8:30 to 10:00)

Remote dial-in is possible and you are very welcome to attend

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