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

Origins and Objectives

Rosanna Tarricone & Giuditta Callea (PIs | Bocconi University), Tom Melvin (WP Leader | Trinity College Dublin)

MDCG Clinical Investigation and Evaluation Working Group | 4 March 2024

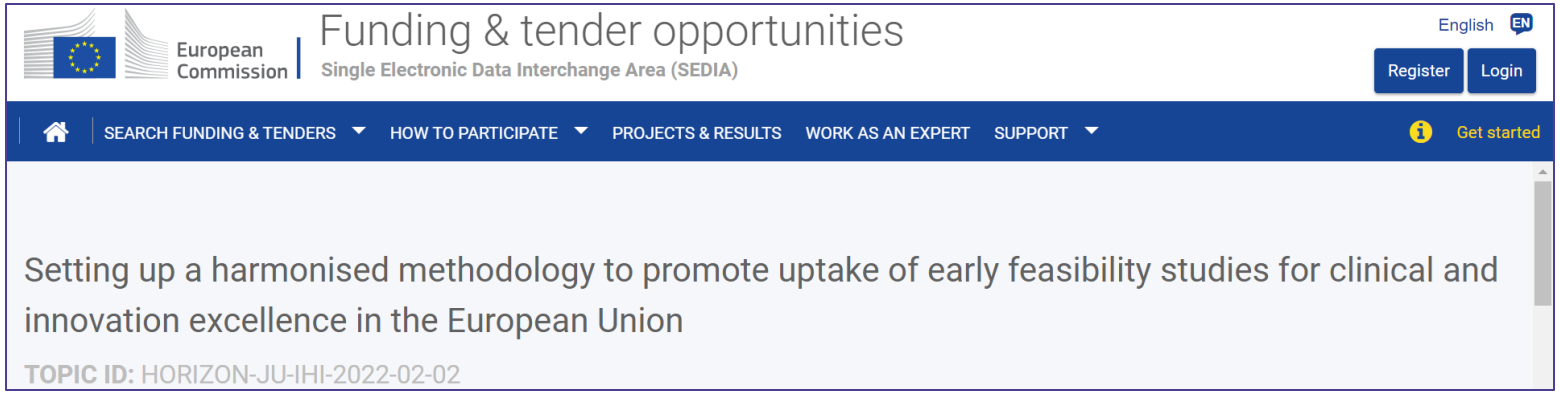
Agenda

1. Context and overarching goal of the HEU-EFS project
2. The Consortium
3. Specific objectives, WPs, timelines, outputs
4. Focus on WP1 & WP2
5. Potential for Collaboration
6. Q&A

Context of the Project

- **EFS are provided for** in the MDR 2017/745.
- **ISO 14155:2020** introduced a taxonomy for different clinical investigation types.
- However there is no standardised **procedural framework**, **guidelines** or common **reference standards** to conduct EFS in the EU.

- Developing an **EU EFS Program** has the potential to:
  - **Benefit** patients, clinical sites & trialists, technology developers.
  - **Strengthen** EU competitiveness and attractiveness for innovation and investments.
  - **Deliver** access to innovation while maintaining rigorous assessments and preserving patient safety.



Overarching goal of the Project

To formulate recommendations for the establishment of an Early Feasibility Studies Program within the European Union, with a focus on ensuring patient safety and enhancing the EU single market competitiveness.

The Consortium

ACADEMIA

- Bocconi University (leader)
- Marburg University
- Trinity College Dublin

HEALTH CARE PROVIDERS

- Assistance Publique Hôpitaux De Paris
- Fondazione Policlinico Universitario Agostino Gemelli IRCCS
- Fundació Clínic per a la Recerca Biomèdica & Hospital Clínic de Barcelona
- Odense Hospital

HTA AGENCIES

- AGENAS, Italy
- NIPH, Norway

PATIENT ORGANISATIONS

- European Patients' Forum
- Global Heart Hub

CRO

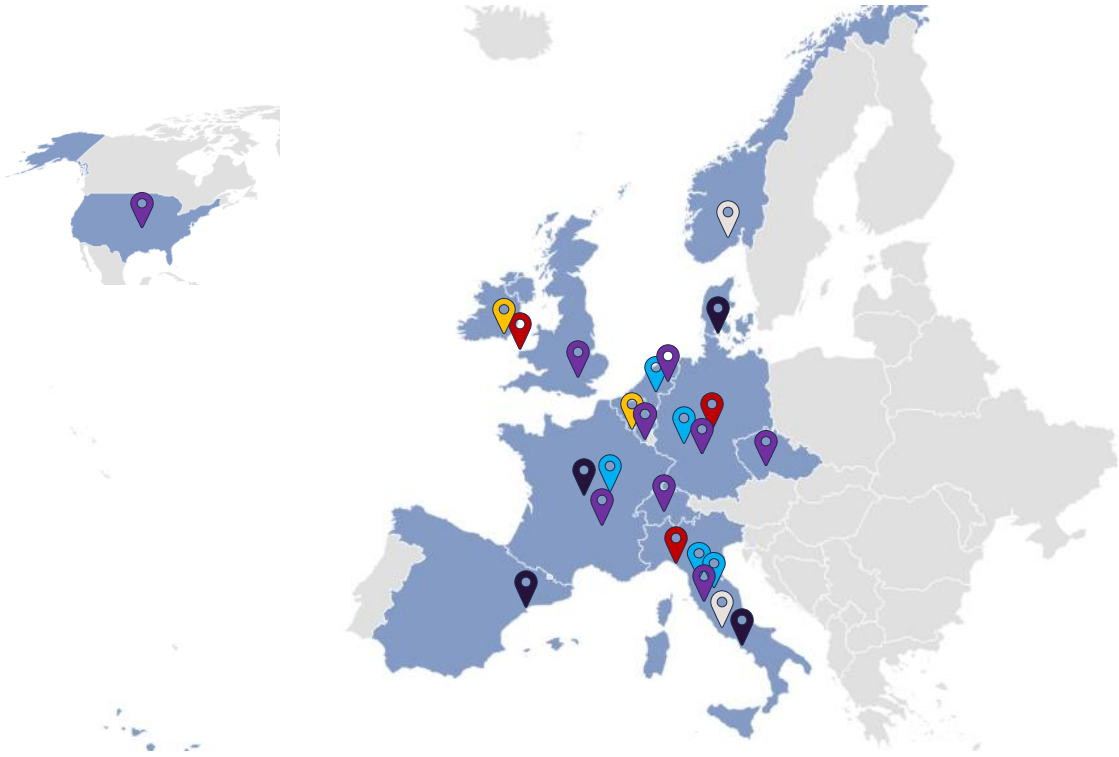
- Meditrial

SMEs

- Carmat
- Newronika
- Idris Oncology
- Qurasoft

TECHNOLOGY DEVELOPERS

- Edwards Lifescience (coordinator)
- Abbott
- DePuy Synthes
- Medtronic
- Philips
- WL Gore



External Advisory Board

COMPETENT AUTHORITIES

- Pietro Calamea, Italian Ministry of Health
- Donal O'Connor, HPRA
- Mariana Madureira and Judite Neves, INFARMED

NOTIFIED BODIES

- Team-NB
- IMQ

MEMBERS OF ETHICS COMMITTEES

- Gry Dahle, Chair of the Norwegian National Ethical Committee
- Carlo Petrini, President of the Italian National Coordination Center of Ethics Committees

PROFESSIONAL ASSOCIATIONS

- EACTS
- ESC
- EFORT
- IFMBE /EAMBES

NETWORS

- IDEAL-D

TRADE ASSOCIATION

- MedtechEurope

INDEPENDENT EXPERTS

- Amie Smirthwaite

Specific objectives

1. Conduct research and analysis on state of play of regulatory framework and characteristics and impacts of pre-market programs.
2. Build a sustainable network of stakeholders to promote the implementation of EFS in the EU.
3. Develop a sound, widely applicable, harmonised EU methodology and recommendations to uptake EFS.
4. Undertake pilot use cases to test the proposed methodological framework.
5. Develop instruments to monitor the performance of the EU EFS program.
6. Implement a dedicated, sustainable, open access, informative online portal dedicated to EFS and disseminate the project results and recommendations.

Structure of the Project

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

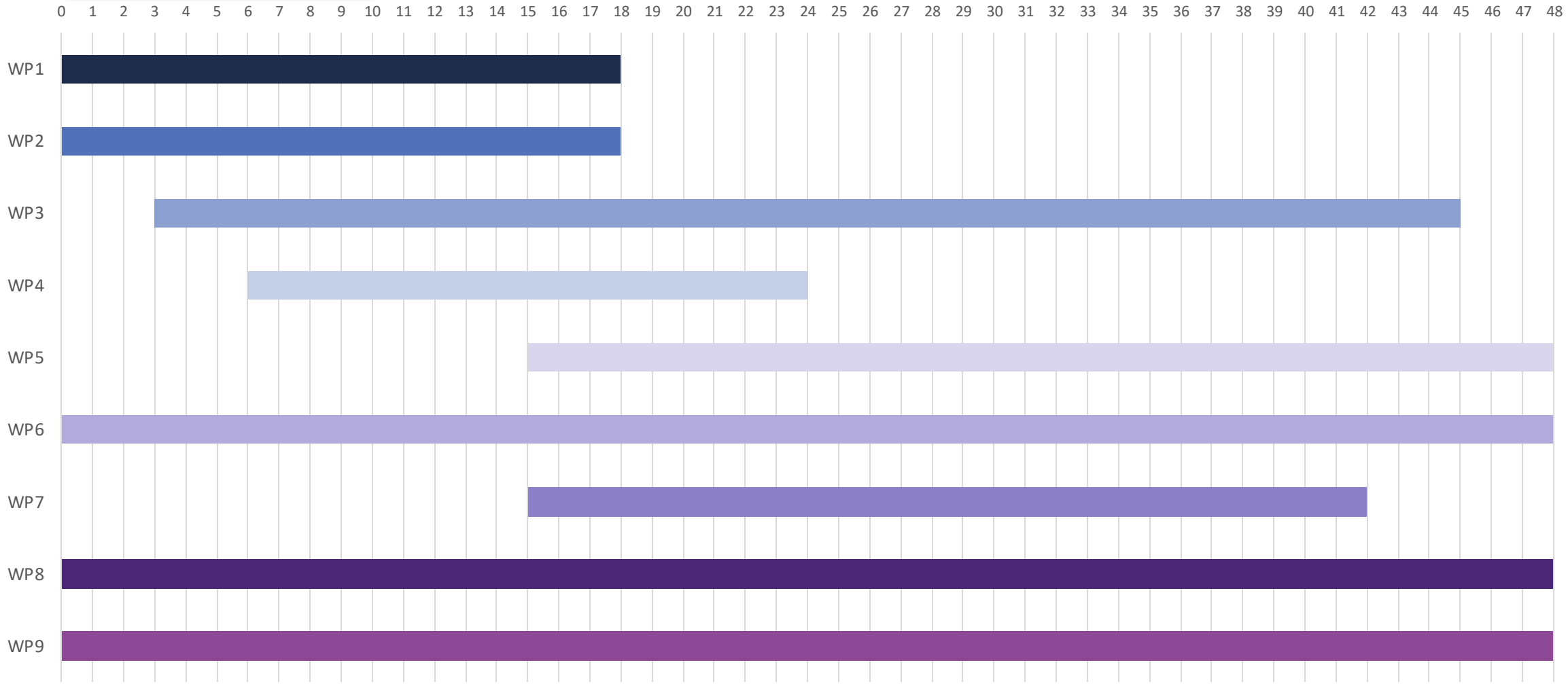
WP governance: a public private partnership

WP	Leader	Co-leader
WP 1 Research and analysis on state of play of pre-market programs and implementation barriers to EFS	Bocconi	DePuy Synthes
WP 2 Research and analysis on regulatory framework and organization of clinical evidence generation programs in the EU	Trinity College Dublin	Assistance Publique Hôpitaux de Paris
WP 3 Methodology development: rationale, processes, and procedure	NIPH	Bocconi and Edwards Lifesciences
WP 4 Methodology development: evidence requirements, data, and statistical tools	Meditrial	Abbott
WP 5 Methodology development: EU EFS program monitoring system	Bocconi	AGENAS
WP 6 Methodology development: ethical and legal aspects	Bocconi	Edwards Lifesciences
WP 7 Testing the methodology: pilot use cases	Edwards Lifesciences, Medtronic and Abbott	Fondazione Policlinico Agostino Gemelli
WP 8 Web portal, dissemination, exploitation, and communication	Edwards Lifesciences	Bocconi
WP 9 Scientific supervision and project management	Bocconi	

Timeline

Start date
1 October, 2023

End date
30 September, 2027

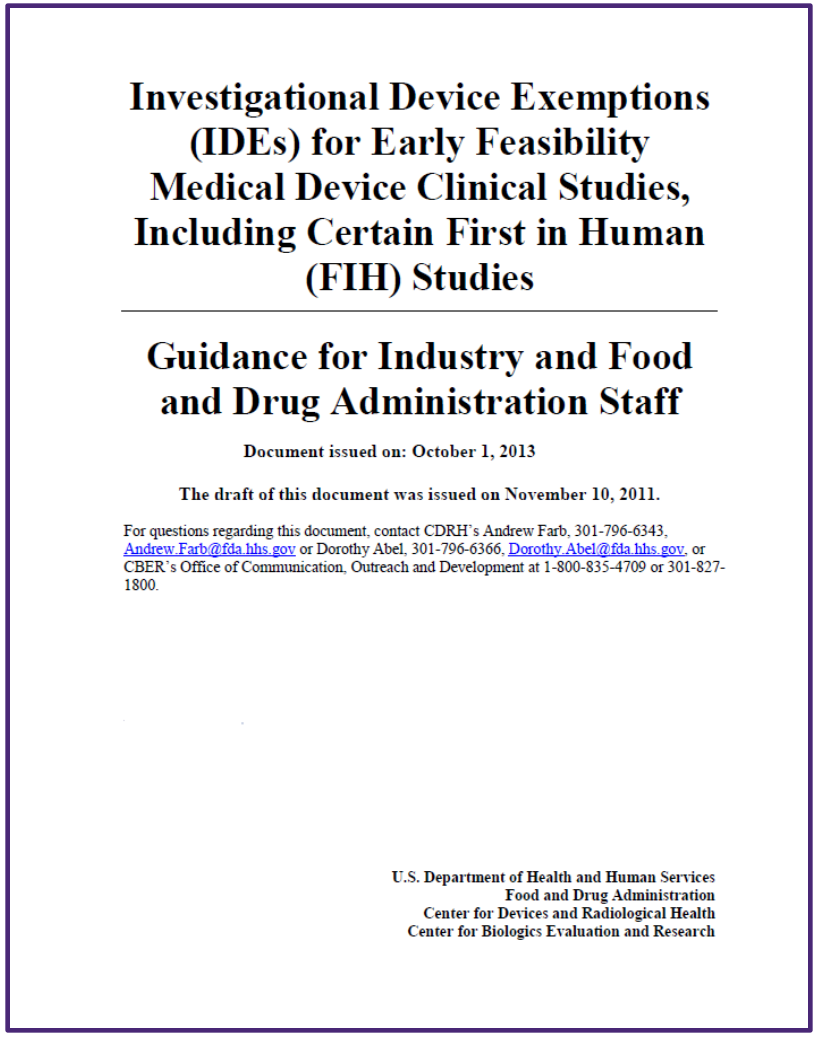


Deliverables

- Guidance and recommendations on EU EFS
- Templates for clinical investigation protocol, patient informed consents, clinical site contracts, insurance agreements
- Research reports
- Databases
- Papers
- Training materials
- Online portal

Focus on WP1 & WP2

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.**

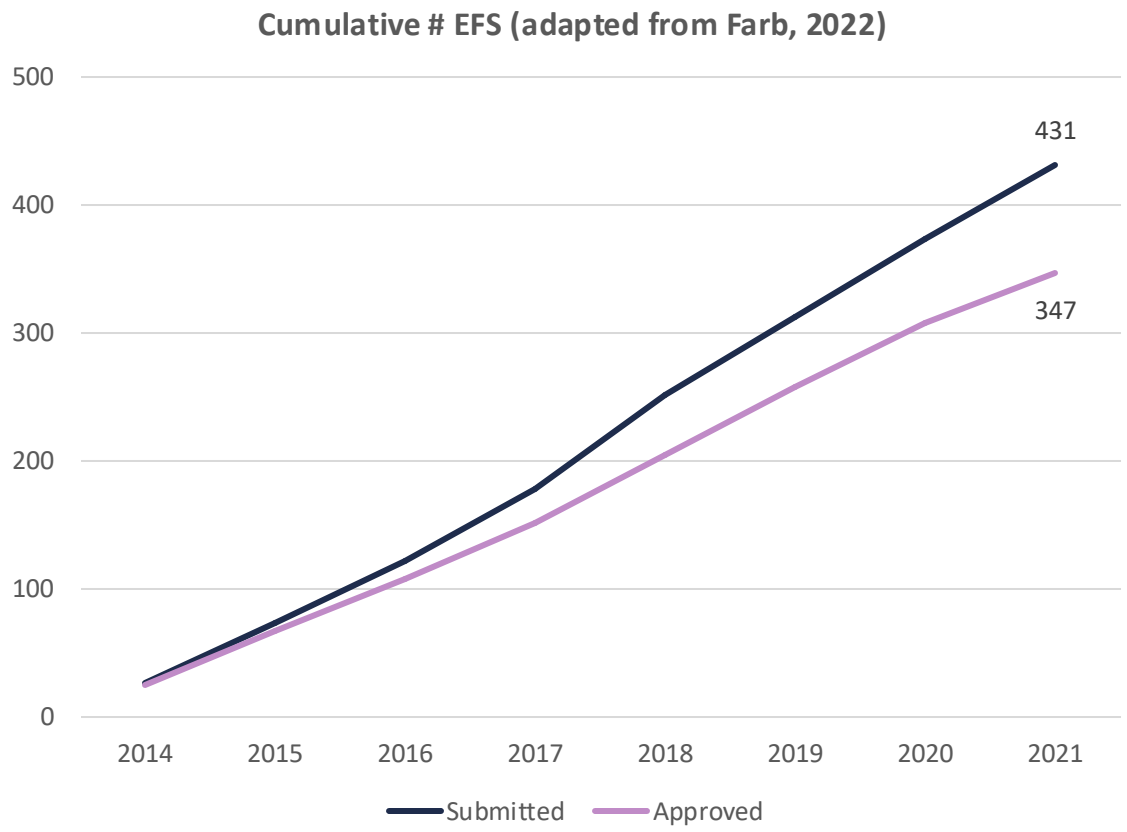
WHEN?

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.

EFS in the USA



US FDA launched the EFS Program in 2013 **without any change to regulation.**

Guidance

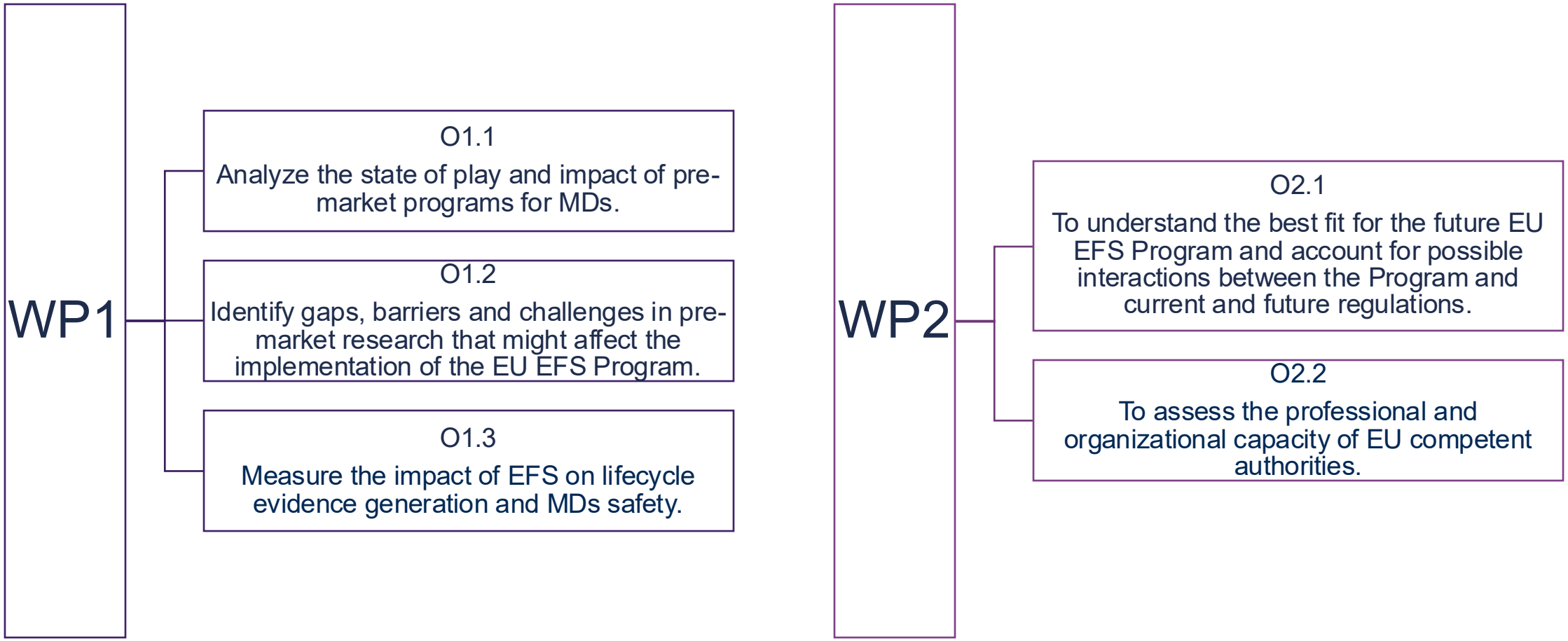
Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical studies, Including Certain First in Human (FIH) Studies

Goals of FDA Program

1. Providing the earliest and broadest patient access to beneficial medical devices.
2. Maintaining or regaining leadership in innovation.

Ref. https://www.fda.gov/medical-devices/investigational-device-exemption-ide/early-feasibility-studies-efs-program

Objectives


WP1
O1.1
Analyze the state of play and impact of pre-market programs for MDs.
O1.2
Identify gaps, barriers and challenges in pre-market research that might affect the implementation of the EU EFS Program.
O1.3
Measure the impact of EFS on lifecycle evidence generation and MDs safety.
WP2
O2.1
To understand the best fit for the future EU EFS Program and account for possible interactions between the Program and current and future regulations.
O2.2
To assess the professional and organizational capacity of EU competent authorities.

WP1 & WP2 activities

Identification of characteristics and impact of pre-market programs for MDs, including DHTs, in target jurisdictions

Identification of performance monitoring systems currently in place for pre-market programs

Identification of challenges and critical success factors of US EFS program and gaps that emerged during implementation and management of the program

Empirical investigation of EFS impact on lifecycle evidence generation and MDs safety

Investigation of the best fit for the future EU EFS Program and possible interactions between the Program and current and future regulations.

Identification of critical success factors for the EFS Program implementation with competent authorities & other stakeholders

Analysis of current competent authorities professional and organizational capacity

Development of recommendations

Methods

Scientific and grey literature review

Analysis of EU regulations, international standards and guidelines

Surveys, interviews, focus groups with stakeholders

Collection of quantitative evidence regarding EFS

Construction of case studies

Outputs

Reports

- Characteristics, gaps, and best practices of pre-market programs
- Characteristics and state of play of EFS
- EU regulatory framework and international standards
- Professional and organizational characteristics of competent authorities

Databases

- Pre-Market Program Database

Recommendations

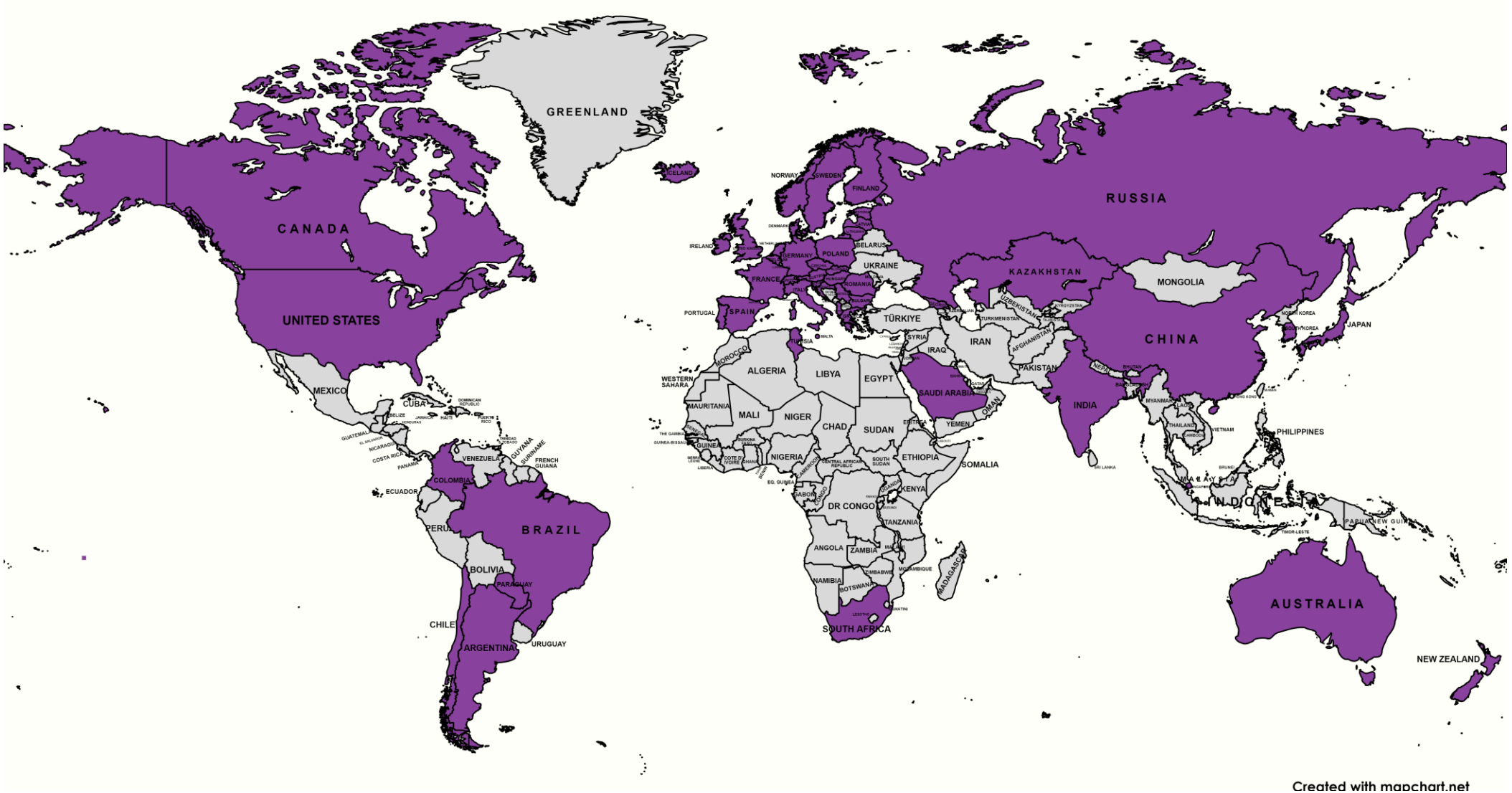
to inform the development of the EU EFS Program

Pre-Market Programs Database

General information
Country
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

Target jurisdictions



Examples of opportunies for collaboration

www.heuefs.eu @HEU-EFS @HEUEFS info@heuefs.eu

Thank you!
Questions?

This project is supported by the Innovative Health Initiative Joint Undertaking (JU) under grant agreement No 101112185. The JU receives support from the European Union's Horizon Europe research and innovation programme and life science industries represented by MedTech Europe, COCIR, EFPIA, Vaccines Europe and EuropaBio.

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