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

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Structure and timeline of the project

Start date
1 October, 2023

End date
30 September, 2027

Research and analysis

- WP1 State of play of pre-market clinical evidence generation programs and implementation barriers to EFS
- WP2 Regulatory framework and organization of clinical evidence generation programs in the EU

Methodology development

- WP3 Rationale, processes, and procedure
- WP4 Evidence requirements, data, and statistical tools
- WP5 Program monitoring system
- WP6 Ethical and legal aspects

Methodology test

- WP7 Pilot use cases

WP9 Scientific supervision and project management

WP8 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: Judite Neves, Mariana Madureira
- Italian Ministry of Health: Pietro Calamea
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- 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

WP1 Research and analysis on state of play of pre-market programs and implementation barriers to EFS

WP1 Objectives and activities

Objectives

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.

Activities

- Analysis of pre-market clinical investigation approval pathways (PMAP) in 56 relevant jurisdictions (27 European Union + 3 European Economic Area + 26 non-European countries)
- Systematic literature review of characteristics and performance of pre-market approval programs
- Development of a comprehensive database including EFS studies registered on public databases (e.g., ClinicalTrial.gov) + interviews with industry consortium members to collect their opinion and experience with EFS
- **Survey to sponsors of clinical investigations** to collect their opinion and experience on challenges faced during pre-market clinical research

Survey to sponsors of clinical investigations

The survey

Focus:

- Pilot pre-market clinical investigations (CI) that assess a medical device (MD) early in its development phase. These include first-in-human, early feasibility, and traditional feasibility clinical investigations.

Aim:

- Investigate experiences, challenges, and perspectives on planning and conducting pre-market clinical investigations for medical devices in the pilot stage of clinical development.
- Involve medtech industry in shaping the proposed framework for EFS in Europe and addressing current challenges in pre-market clinical investigations.

Participation:

- Voluntary.
- No anticipated risks associated in participating in the project.
- 7-10 minutes to complete.
- Responses anonymized and analysed in aggregate.

The survey

Distribution of the link:

- MedtechEurope
- HEU-EFS website (www.heuefs.eu) and social media.

Timeline:

- Survey open until 21 October 2024.

Anonymous link to the survey

Q&A

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

Thank you!

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