innovative health initiative

HEU EFS
HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

HEU-EFS

Harmonized Approach to Early Feasibility Studies for Medical Devices in the European Union

Disclaimer

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Challenge

Bringing medical technology innovations to patients in the EU has become increasingly long and difficult.

- Rising R&D costs.
- Ever-stricter EU regulations.
- Lack of harmonised approaches in Member States for facilitating early evidence generations.

- Uncertainty for innovators.
- Decline in attractiveness of Europe.
- European patients missing out on the latest medical technology innovations.

Needs


New approaches are needed to ensure patients get a timely access to their treatment and Europe remains at the forefront of innovation.

About EFS

Early Feasibility Studies (EFS) are small clinical studies designed to gain early, relevant insights into an innovative medical technology during the development process, before starting a larger clinical investigation, that would not be possible in a non-clinical setting.

EFS are a critical initial step of a longer chain of subsequent evidence-generation phase and provide a unique opportunity to:

1. Collect relevant **data** at an early stage
2. Inform the **business case**
3. **Maximize the chances to develop innovative**, cost-effective, safe high-risk medical technologies

HEU-EFS approach

HEU-EFS will **develop and validate a robust, unified approach to allow early insights into technology evidence generation** and to make the EU a conducive environment to undertake EFS.

Acceptability will be driven by engagement of a wide network of stakeholers - universities, hospitals, contract research organizations, patient associations, health technology assessment agencies, MedTech companies and start-ups, regulatory authorities, notified bodies and professional associations.

HEU-EFS aim & objectives

HEU-EFS aims to develop an Harmonised Approach to EFS for Medical Devices in the European Union.

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 and 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.

Benefits

Patients with no or little treatment options access innovative technologies to improve prognosis & quality of life.

Payers and policymakers make evidence-based, informed investment decisions that meet patient needs and generate value for society.

Technology providers develop innovations that meet healthcare professional & patient needs.

Healthcare professionals deepen their clinical development excellence.

Patients

Health systems

Clinical & innovation excellence

HEU-EFS project facts

- 22 public and private consortium partners
- 4-year project
- €19 million grant from the Innovative Health Initiative
- Coordinated by Bocconi University
- Industrially led by Edwards Lifesciences

Consortium – public partners

HEU EFS

Bocconi

Clínic Barcelona | Universitat de Barcelona

EPF European Patients Forum

Region of Southern Denmark

Global Heart Hub

Qurasoft

Philipps Universität Marburg

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

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Gemelli

NIPH
Norwegian Institute of Public Health

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CARMAT

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

Meditrial
Digital Research Organization

Idris Oncology

Consortium – private partners

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