Sponsor Views on Harmonizing Early Feasibility Study Assessment in the EU: Early Interaction, Predictable Timelines, and Streamlined Process for Sponsor and Decision-Makers

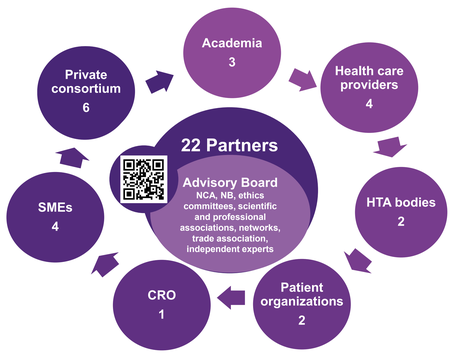
FEDERICO FACCIOLO, MS, PhD[1], ALEXANDRA H.C. POULSSON, MSc, PhD[2], MARIT ERNA AUSTENG, MD, PhD[2], FANNY VAN DER LOO, MA, LLM[3], GIUDITTA CALLEA, PhD[1]

[1] Bocconi University SDA Bocconi School of Management, Milan, Italy; [2] Norwegian Institute of Public Health, Oslo, Norway; [3] Edwards Lifesciences, Dilbeek, Belgium.

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

AIMS OF HEU-EFS PROJECT

- Early Feasibility Studies (EFS) are early clinical studies that establish proof of concept and refine device design when preclinical testing is not possible. HEU-EFS formulates recommendations to establish an EFS program in the EU, ensuring patient safety and enhancing EU single market competitiveness.



BACKGROUND

- A dedicated framework for conducting EFS is currently lacking in the European Union (EU), creating barriers to execute EFS in Europe for medical technology developers, thereby hampering innovation excellence and competitiveness in the EU.

OBJECTIVE

- As part of HEU-EFS project, this study explored the experiences of sponsors of clinical investigations with EFS assessment to inform the development of an EU-harmonized EFS framework.

METHODS

Online focus group

11 Representatives from global medical technology companies
- US (2)
- Europe (9)

Topics (and *probes*)
1. Interaction with competent authorities before and during EFS assessment (*dialogue*)
2. Harmonization of EFS assessment in the EU (*coordinated assessment*)
3. Involvement of expert panels and other EU bodies during EFS assessment (*Expert Panels, NBs)*

Thematic analysis using deductive coding based on interview topics and probes

RESULTS

Four main themes emerged from the focus groups:

Early dialogue in EFS may help clarify understanding and expectations for both sponsors and relevant authorities

Dialogue allows sponsors to explain the novel features of the device, clarify preclinical testing and level of evidence, and help authorities understand resources and expertise needed for assessment.

Evaluation of EFS remains largely dependent on individuals' expertise, capacity, and experience

The amount and scope of questions vary based on evaluators' expertise, influencing the number of rounds for questions and answers. Building recognized and trusted expertise in specific areas can help authorities.

Predictability of EFS assessment timeline is the priority for sponsors in harmonizing EFS assessment in the EU

Predictability of validation and assessment timeline is what is really important in a harmonizing EFS assessment in the EU, where the coordinated assessment was seen to offer potential to increase speed and predictability of assessment.

National authorities and ethics committees are the decision-makers yet harmonization still lags

Authorities and ethics committees approve EFS. There is openness to bring harmonization involving expert panels, even though, at the time of the focus group, it was perceived to be out of scope of the MDR.

CONCLUSIONS

- Early and ongoing engagement with government authorities – supported by clear and efficient submission and approval procedures and predictable assessment timelines – remains essential for sponsors and is key to developing a harmonized EFS framework across the EU.

Co-funded by the European Union

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.