MT31

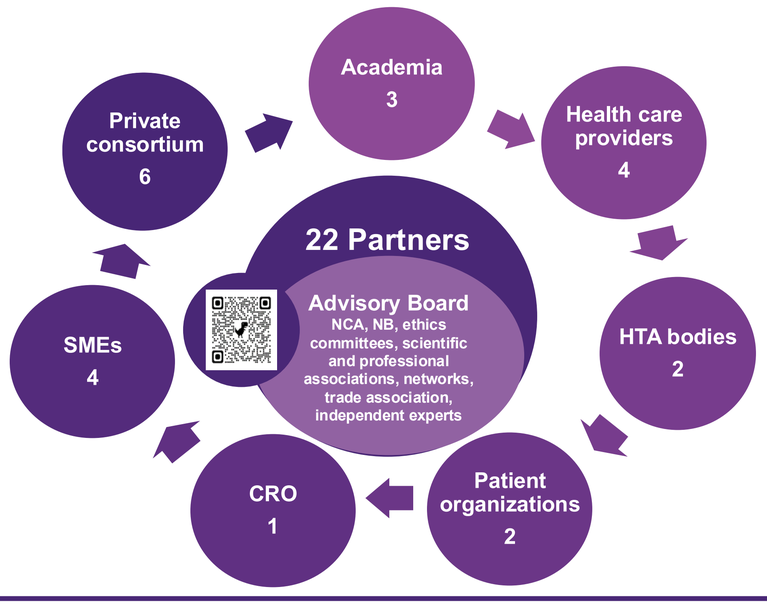
National Competent Authorities' Experiences With Early Feasibility Study Assessment: Promoting Dialogue, Supporting Sponsors, and Fostering Shared Learning to Harmonize the EU Framework

F. FACCIOLO,[1] F.L. ZURLO,[1] G. CALLEA,[1] A.H.C. POULSSON,[2] T. MELVIN,[3] F.B. MALANDRINI,[1] N. PALMINTERI,[1] M. GERAGHTY,[3] M.E. AUSTENG,[2] **M.L. BUZELLI,[1]** H. BANKS[1] and C. FEDERICI.[1]

[1] SDA Bocconi School of Management, Milano, Italy, [2] Norwegian Institute of Public Health, Oslo, Norway, [3] University of Galway, Galway, Ireland

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 insufficient. HEU-EFS formulates recommendations to establish an EU EFS program, ensuring patient safety and enhancing EU single market competitiveness.



OBJECTIVE

This study explored the experiences of National Competent Authorities (NCAs) during EFS assessments to identify processes, stakeholder roles, and timelines that could inform the development of a harmonised framework for EFS in the EU.

METHODS

Data collection: Online focus groups with 8 representatives from 4 NCAs. Focus groups topics included:

1. Experiences with EFS-like studies
2. Dialogue between NCAs and sponsors of EFS
3. Challenges to and opportunities for harmonisation
4. Efficiency of EFS applications evaluation
5. Ethics approval

Data analysis: Thematic analysis using deductive coding based on interview topics and questions.

RESULTS

6 main themes emerged from the focus groups:

Lack of formal EFS definition and homogeneous assessments across NCAs

*"the **MDR doesn't use the term EFS**." "**all studies were treated the same**." "We do not look at the fact if it's EFS or not"*

*"**[EFS] assessment is different** in the way we assess the data and monitor the patient." "We follow [EFS] with the higher grade of vigilance." "we can have **specific recommendations**."*

Poor documentation quality and limited evidence on novel devices challenge EFS validation / evaluation

*"**Challenges** during the validation and evaluation [are] the **organisation and the composition** of the submissions."*

*"Another [challenge] is if it is a completely **new design**." "there are **no guidance** about […] **tests have to be performed** in order to say the design is safe to go to clinical testing."*

Dialogue improves assessment efficiency and speed through NCA adaptability and sponsor cooperation

*"when there was a scientific advice, the solution and **the assessment [was] quicker [and] easier for both sides** [NCA and sponsor]." "If [sponsors] are cooperative, they basically speed up our evaluation."*

*"There's **different types of scientific advice**." "we **are open to what sponsors want** because the needs of sponsors can be very different."*

Shared learning in Coordinated Assessment pilot can pave the way for unified EFS assessment in the EU

***"[Coordinated Assessment]** is important for us [NCAs] to learn the practices of our colleagues and share [our practices] with them."*

*"We need harmonisation, **we need to talk to each other and need more guidance or best practices on that**." "[…] but it's a way of how does that get taken on board into an **MDCG-endorsed guidance**."*

Additional data from sponsors and standardised templates address applications' missing information

*"**We required some things we usually do not require** at such kind of depth with other trials." "**[Templates] would help with all required sections** and information to be there."*

Diverse ethics approval models across EU generate struggles and underscore need for harmonized model

*"There are different approaches to ethics [approvals], and **that is a problem**." "A more **harmonised approach** to ethics [approval] would be something that I would feel **would be very helpful**."*

IDENTIFIED BEST PRACTICES: 1) Dialogue in written exchanges and/or meetings; 2) Parallel ethics committee review

CONCLUSIONS

NCAs reported a lack of a harmonised approach to EFS. Promoting dialogue with sponsors, supporting their preparedness, and encouraging shared learning among NCAs are essential to inform a harmonised EU EFS framework.

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.

Co-funded by the European Union