

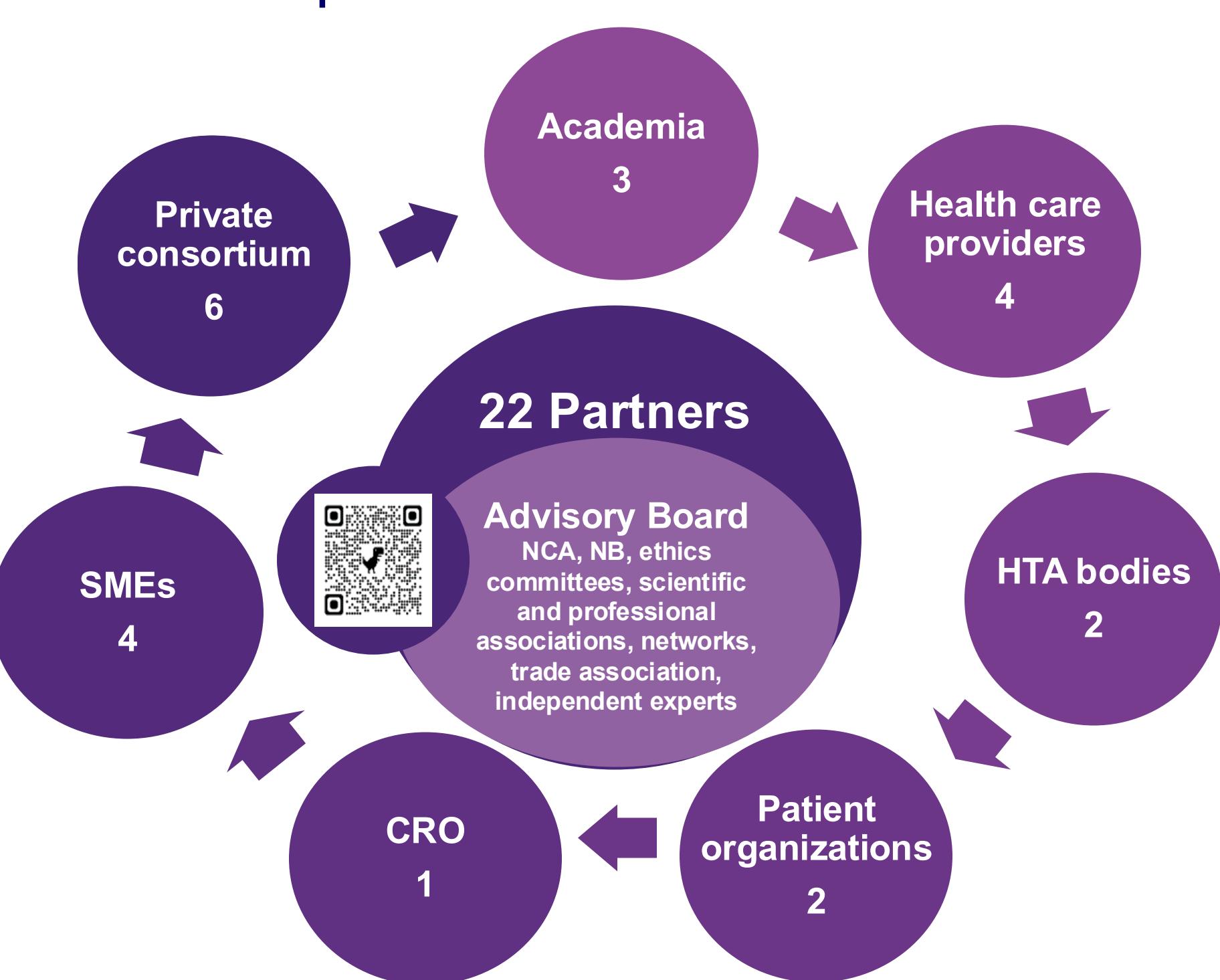
# National Competent Authorities' Experiences With Early Feasibility Study Assessment: Promoting Dialogue, Supporting Sponsors, and Fostering Shared Learning to Harmonize the EU Framework

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## 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

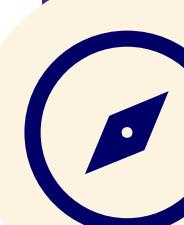
**Data collection:** Online focus groups with 8 representatives from 4 NCAs. Focus groups topics included:

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."*



### 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."*



### 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."*



### 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."*



### 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."*



### 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.