Challenges of pre-market clinical investigations of medical devices: a multi-stakeholder perspective

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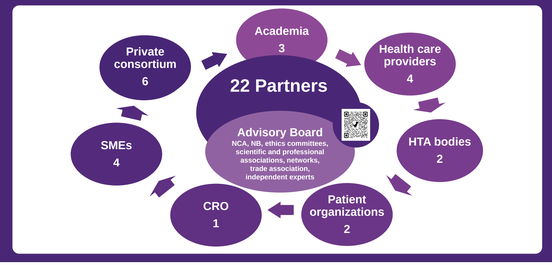
HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

AIMS OF HEU-EFS PROJECT

Formulate recommendations for the **establishment of an Early Feasibility Studies (EFS) Program** within the **EU**, ensuring patient safety and enhancing EU single market competitiveness.



INTRODUCTION & OBJECTIVE

- The **complex EU regulatory landscape** makes **early-stage clinical research challenging**, with different stakeholders facing several obstacles. EFS play a crucial role in the development of novel medical devices (MDs) before full-scale clinical trials.
- We aimed to **explore barriers and solutions to fostering EFS in the EU** by gathering **stakeholder perspectives** to improve trial efficiency and medical innovation in pre-market clinical investigations (CIs) of MDs.

METHODOLOGY

1. Online **survey for sponsors of CIs** to gather insights on challenges in pre-market CIs of MDs.
2. O**pen-ended interviews** with **health technology assessment (HTA) bodies, notified bodies (NBs), national competent authorities (NCAs) clinical sites, scientific associations, ethics committees (IEC), contract research organisations (CRO), patient representatives, sponsors of CIs** to explore key success factors for EFS, challenges and opportunities
3. Running a **focus group with the projects' Patient Advisory Board** to identify patient-reported challenges and solutions in CIs.

RESULTS

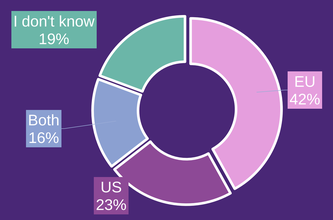
- **Survey respondents (n=83) favour the EU** for pre-market CIs mainly due to **site enrollment capacity, trialists' expertise, and quicker study timelines**, but face barriers such as **lack of stakeholder dialogue and documents approval**.

- Among the identified barriers, **lack of dialogue, regulatory complexity, resource constraints, and patient recruitment challenges**, were also highlighted by the interviewed stakeholders, which identified several areas of improvements including:

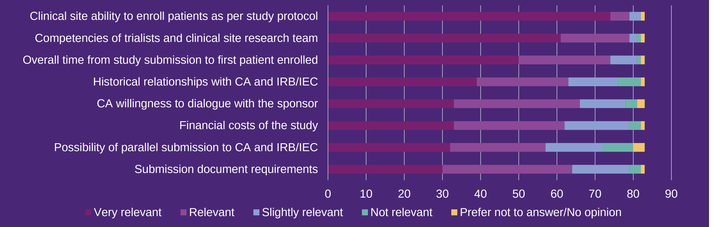
  - Early stakeholder collaboration to streamline regulatory expectations
  - Standardised guidance and templates to reduce study setup delays.
  - Specific trainings for investigators and clinical teams to develop the necessary skills for early-phase trials.

- **Patients**, when asked about the barriers faced in CIs, highlighted the following factors: **lack of accessible information, logistic challenges, post-trial concerns, limited involvement and support in CIs**.

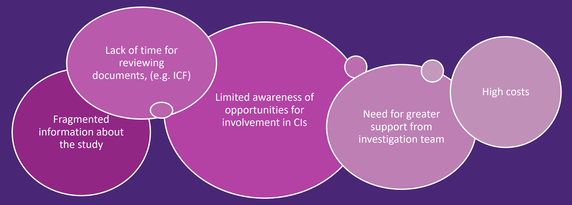
Favourite location for conducting pilot CIs



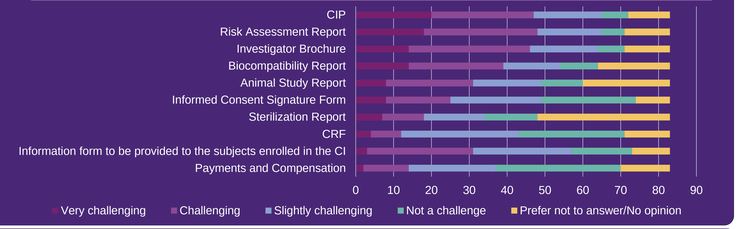
Key criteria influencing the selection of the country



Barriers faced by patients involved in CIs



Challenges of the dialogue with NCAs when managing amendments to the CI



CONCLUSIONS

When conducting pre-market CIs, stakeholders face **several barriers**, including **regulatory complexities, site capabilities, and patient recruitment challenges**. Addressing these hurdles requires multi-stakeholder **collaboration**. **Regulatory clarity, streamlined processes, and structured dialogue** are some of the measures that can ensure smoother CIs and enhance efficiency in clinical trials.

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