Global Assessment of Pre-Market Approval Pathways for Medical Devices: Highlighting the Need for Harmonization Across 55 Jurisdictions

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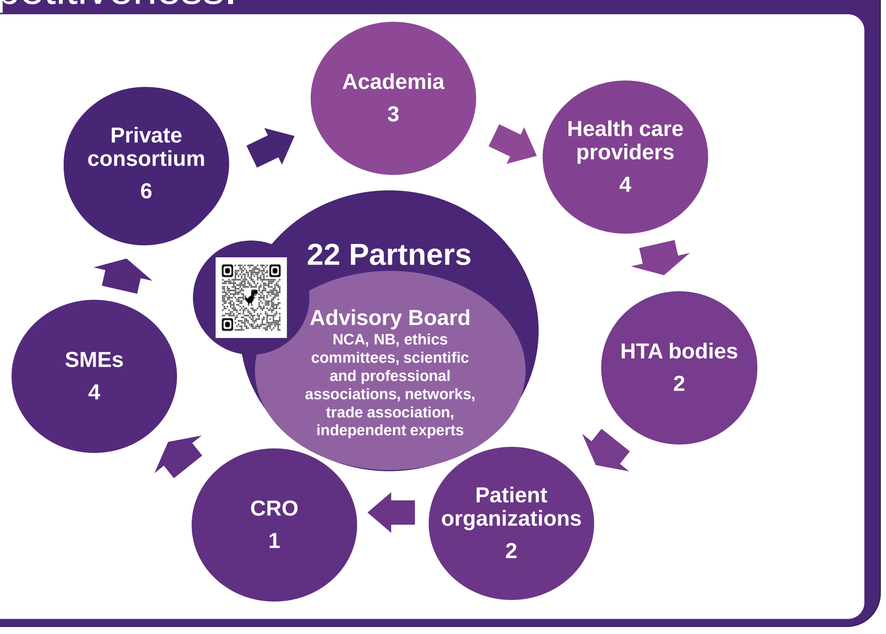
AIMS OF HEU-EFS PROJECT

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



OBJECTIVE

- Applications for pre-market clinical investigations (CI) of medical devices (MDs) follow approval pathways designed to guarantee safety and efficacy through the generation of robust clinical evidence.
- This study investigated the features of **Pre-Market Approval Pathways** (PMAP) that sponsors must consider when applying for pre-market CI approval in 55 jurisdictions.

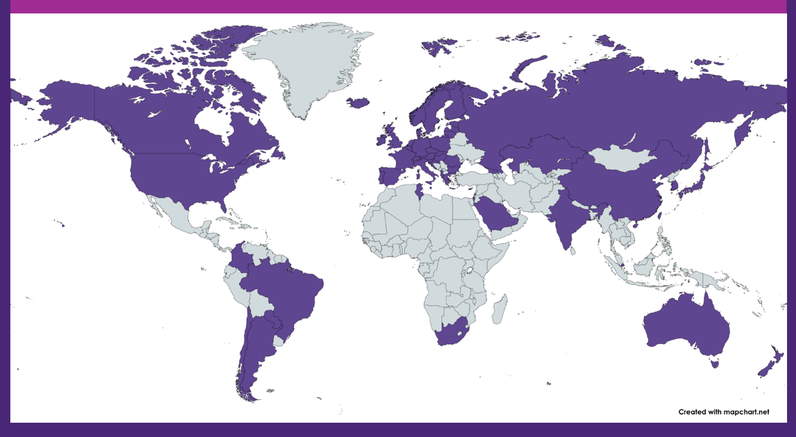
METHODOLOGY

1. Development of a comprehensive database (PMAP-DB) through systematic review of public sources.
2. Selection of 55 target countries (27 EU + 3 EEA + 25 non-EU).
3. Data collection: national legislation, approval procedures, required documentation, timelines, language of submission, submission fees, possibility to reimburse investigational MDs, existence of a performance monitoring system, and stakeholder involvement.
4. Comparative analysis of approval pathways.

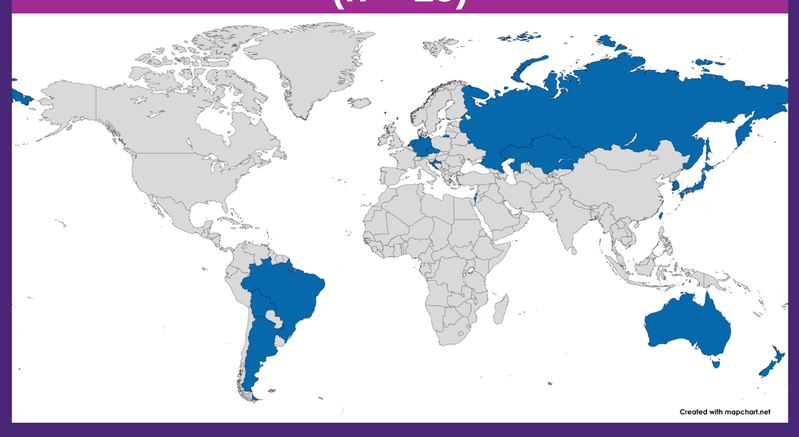
RESULTS

- High degree of accessibility of information:
  - National legislation identified in 53/55 countries (96.4%).
  - Links to competent authority websites always available (100%).
- Absence of linguistic barrier: submission permitted in English in 54/55 countries (98.2%).
- Submission procedures vary (1–6), depending on device class and characteristics.
- Different approval pathways as to interaction modes, requirements, testing, documentation, timelines, and fees.

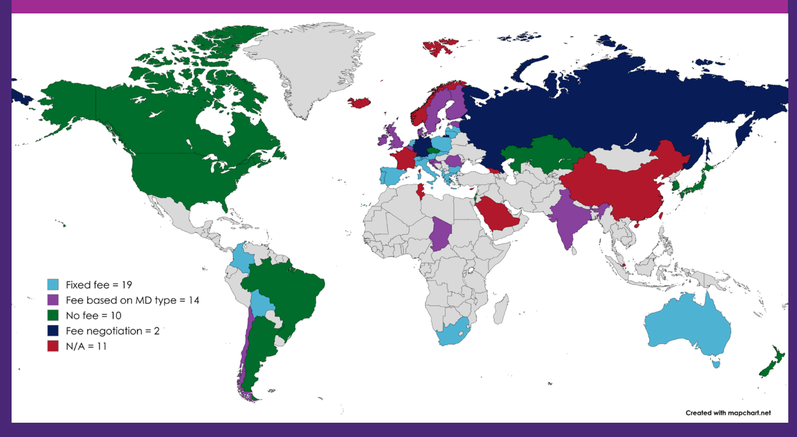
Country coverage (n = 55)



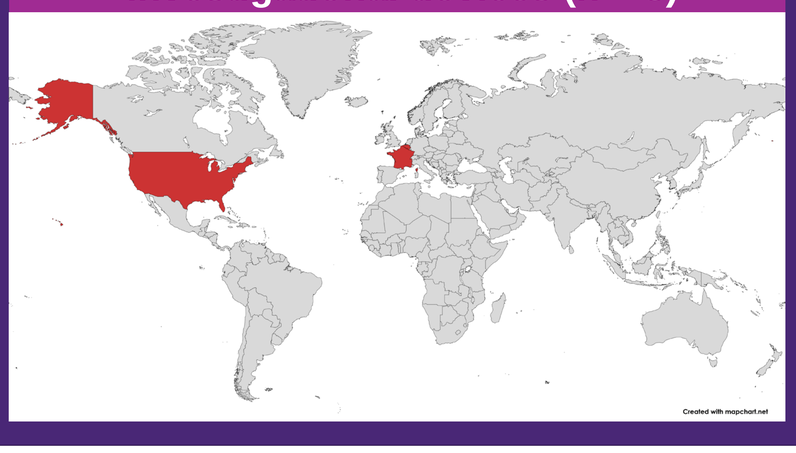
Existence of a CI public database (n = 15)



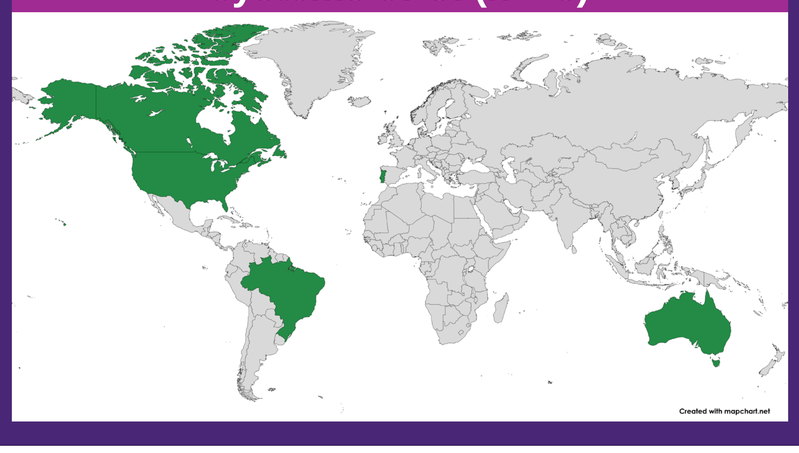
Type of submission fee



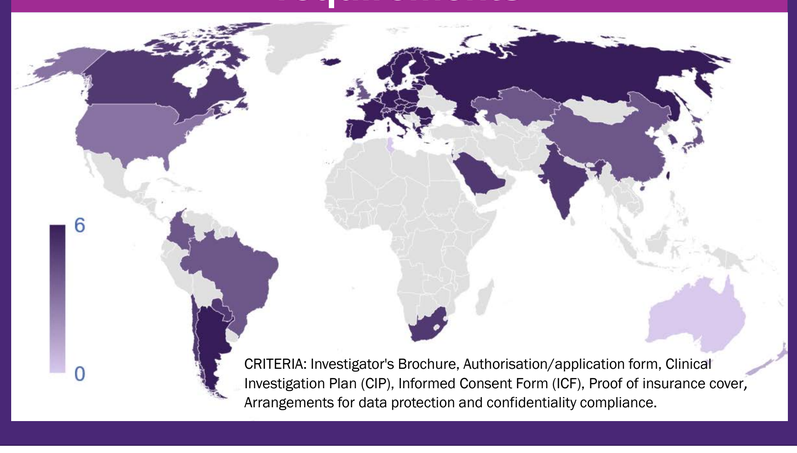
Possibility to reimburse investigational devices (n = 3)



Existence of performance monitoring systems of CI (n = 5)



Compliance with MDR Annex 15 requirements



CONCLUSIONS

The significant variability in PMAP across jurisdictions highlights the need for urgent harmonization to streamline global market access for MDs. Improved alignment and standardization of approval pathways will facilitate more efficient and consistent regulatory processes, benefiting both sponsors and patients worldwide.

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