# How to increase effectiveness of the EU regulatory medical device evaluation system?

*Priorities for further reform?*

Group 6

ESC Cardiovascular Round Table - 18 April 2024

ESC
European Society of Cardiology

# Problem

- **Europe can’t be a follower, we need to lead!**
  - FDA first strategy by startups, SMEs and larger companies
  - European investigators aren’t part of major studies anymore
  - Question of historical research center move from Europe
- **NB are a business**
- **Opacity & reproducibility of process and outcomes**

# Questions

- **What can we change?**

# Solutions

- **Overarching**
  - Process is too scattered with NB – we need 1 reference point
- **Short term**
- **Mid term**
- **Long term**

# Short term solutions

- **Dialogue (e.g. Breakthrough designation in US)**
- **Mandate a time-line for processing application**
- **Prioritize**
  - Devices already approved by FDA, Japan, etc.
  - Define what submissions to prioritize (ESC, expert panels)

# Mid term solutions

- Clear criteria for evaluation
- Early consultation with Expert Panels
- Allow for iteration (expedited process if core is unchanged)
- Solutions for Orphan Medical Devices
- Process for expedited review for specific devices
- Regulations on cost of certification - NB
- Mandate an open, reproducible process
- Involvement in MDCG
- Regular dialogue with EMA

# Long term solutions

- **Data**
  - Harmonized datasets
  - High-quality registries
  - Make them mandatory!