# IP14: Evaluating Medical Devices: How does randomised clinical trial (RCT) data and real-world data (RWD) fit together?

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# Disclaimer

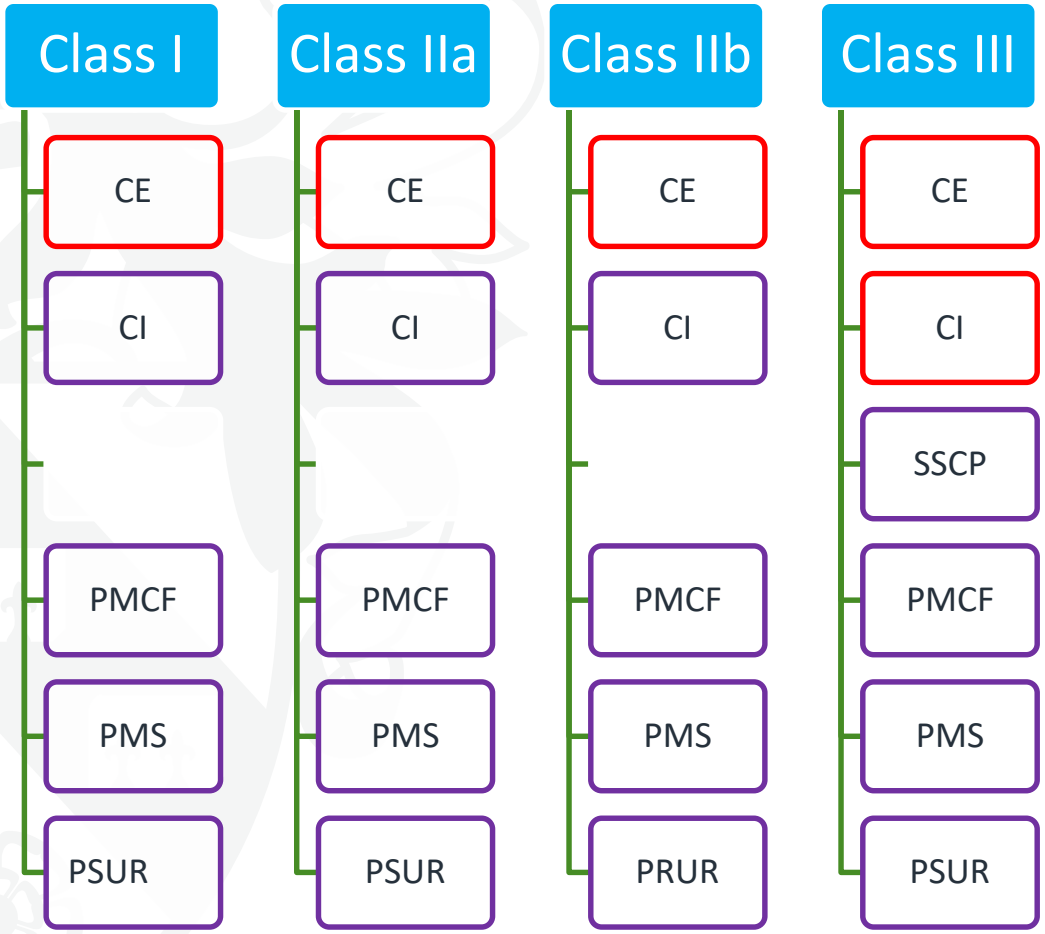
I am employed by the University of York (UK) and sit on the Medical Technologies Advisory Committee (MTAC) of the Medical Technologies Evaluation Programme (MTEP) of the National Institute for Health and Care Excellence (NICE) for England and Wales,

**however**

the **views** expressed in this presentation **are my own** and do not necessarily reflect the position of my employer of those of NICE

# MDs EU Regulation

## Evidence requirements




CE – Clinical evaluation
PMCF – Post-market Clinical Follow-up

CI – Clinical Investigation
PMS – Post-market Surveillance

SSCP – Summary of Safety and Clinical Performance
PSUR – Periodic Safety Update Report

# Performance vs Effectiveness

- Performance

ability of a device to achieve its intended purpose as stated by the manufacturer (art 2.22)

- Clinical performance

ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer (art 2.52)

- Clinical benefit

positive impact on heath, expressed as meaningful, measurable and relevant clinical outcomes, including diagnosis, patient management or public health (art 2.53)

**Source:** Regulation (EU) 2017/745

# Key Issues and Panel

- Are RCTs an appropriate vehicle for MD evaluation? Do we need to evaluate all MD with an RCT?
- How do RCT and RWD/RWE fit together?
- How MD regulation for licensing and HTA fit together?
- Panel
  - **Ms Michelle Jenks** – Project Director, York Health Economics Consortium, York, United Kingdom
  - **Prof Isabelle Durand-Zaleski** – Director of the Clinical Research Unit in Health Economics of (URC ECO) Ile-de-Franc, Hôpital de l'Hotel Dieu, Paris, France
  - **Ms Petra Schnell-Inderst** – Senior Scientist, Health and Life Sciences University, UMIT, Hall. Coordinator of EUnetHTA Task Force for HTA and Medical Device Regulation, Luwig-Boltzmann-Institute for Health Technology Assessment, Vienna, Austria.