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 or those of NICE
MDs EU Regulation
Evidence requirements

Class I
- CE
- CI
- PMCF
- PMS
- PSUR

Class IIa
- CE
- CI
- PMCF
- PMS
- PSUR

Class IIb
- CE
- CI
- PMCF
- PMS
- PSUR
- PRUR

Class III
- CE
- CI
- SSCP
- PMCF
- PMS
- PSUR

CE – Clinical evaluation
CI – Clinical Investigation
SSCP – Summary of Safety and Clinical Performance
PMCF – Post-market Clinical Follow-up
PMS – Post-market Surveillance
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 health, 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.