PED/PROs IN THE DESIGN OF CLINICAL TRIALS

ESC
Cardiovascular Round Table

Group 1. Are PED/PROs ready for use as primary endpoints in trials

- PRO on their own or followed/accompanied by clincal outcomes
- PRO as a surrogate
- Can the PRO trial be a basis for a CMA (e.g followed by a registry based safety)
- Co-primary?

- Are we discussing the sole basis of a regulatory approval – B/R (exclude considerable risk)
- What else is available/feasible (rare disease, etc) may influence how we see the value of the data we have, accept uncertainty, base safety on surrogates?
- What can you do with PRO based evidence at the payer level?
- Patient would probably want to now both outcomes – „symptoms + survival“ – patients would differ in their decisions
- Is the discussion relevant for devices?
- „What does the regulator want?“ What is important for the patient, clinicians

SO WHEN?

Surrogate OR validated tool that correctly measures relevant aspect of QoL + meaningful effect size