Should patients take the leading role in the benefit-risk assessment of new technologies before their approval?

- **Leading role:**
  - Provide unique insights to overall impact
  - Challenges:
    - Risk-benefit analysis: complex process; life-cycle assessment of risk-benefit. What does statistical significance mean?; should be collective decision
    - Regulatory (safety) and method challenges (statistical interpretation skills)
    - Perspective of patient is not just subjective: challenges – representative – what constitutes risk-benefit may differ
    - Difficult to find 'average' patient in position to lead overall – model of co-chair?
    - Patient preferences not used in regulatory process currently

- **Collaborative/supportive role**
  - Hybrid decision model: include unique insights/lived experience, interpretation of data
  - Need to value contribution: needs a paradigm shift in including PRO/PED

- **Vote:** Leading role: 0: regulators/scientists: 7; Consensus 11

- **Patient leading role**: deciding outcomes/PRO in trials (incl ease of use); diversity of input; beginning and end of process (incl patient perspective in paper or separate paper); how find patients to do this and increase number of patients involved.