Discussant

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(Old) Reasons to Include PROs in Phase II Trials

- To define a response
  - When you have an MID or even an ID
    - Carbo/Taxol in ovarian cancer
- To evaluate feasibility and collect preliminary data for phase III
- To advance measurement science
  - Validate new instruments or existing instruments in new populations
  - Estimate MID in specific disease application

(New) Reasons to Include PROs in Phase II Trials

- Compare “subjective” to “objective” endpoints – need common reporting for meta-analysis
- Measure toxicity to standardize capture of MTD
- Evaluate supportive care strategies to prevent side effects (e.g., neurotoxicity)
- Evaluate rand. phase II arms on PRO
- Enable symptom cluster research

Reasons NOT to Include PROs in Phase II Trials

- Challenge to interpretation absent comparator arm
- Cost
- Competing resources