How to Implement the Estimand Framework in Clinical Trials – Examples, Examples, Examples

PANEL DISCUSSION

ISCTM 20th Annual Meeting ▪

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Panel

- Moderator: Elena Polverejan, PhD – J&J Innovative Medicine
- Panel:
  - Michael O'Kelly, PhD - IQVIA
  - Marc Walton, MD, PhD – MKWalton Consulting, J&J Stock
  - HM James Hung, PhD – CDER, FDA (feedback in writing)
  - Nanco Hefting, MSc, Pharm - H. Lundbeck A/S
  - Stephen Ruberg, PhD - Analytix Thinking
  - Jennifer Murphy, PhD - Biogen

Disclaimers

Views expressed by panelists do not represent the views of their employer companies/agencies

Questions - Regulatory

- What is the impact of the estimand framework to regulatory interactions, trial planning, and drug approval process?
- How could estimand choices relate to labeling language and information we provide to prescribers and patients?
- How well understood is the estimand framework by the clinical reviewers? How does the implementation of the estimand framework impact the communication between the statistical and clinical reviewers?

Questions – Implementation in Clinical Practice

- What is the status of the estimand framework implementation in clinical trial practice, from start (planning a trial, protocol development) to finish (reporting, communication, and dissemination of results in publications)? Any remaining challenges?

- Are estimand proposals driving innovation in terms of using more focused clinical questions and proposing novel ways to handle intercurrent events? Any recommendations?

- Treatment policy strategy is widely recommended by health authorities. It can be implemented only if data can be retrieved after the intercurrent events handled by this strategy. For example, how likely are patients who have discontinued treatment be followed up at the targeted clinical visit?

- Given the ICH E9(R1) estimand framework, do we need to do a better job at data collection for treatment discontinuation, other intercurrent events and study withdrawal?

Questions – Relevance to different trial stakeholders

- Do we answer in clinical trials questions relevant to prescribers and patients?

- Is there a question that is relevant to all stakeholders (health authorities, prescribers, payers, sponsors, etc.)? Can we find common ground and how can we implement it?

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