



# Decisions, Decisions, Decisions: How Planning and Conduct of RCTs Influence Outcomes

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Chairs:

Steve Brannan, MD

Nina R. Schooler, PhD

# Disclosures

Steve Brannan

Former CMO, Karuna Therapeutics; Consulting at BMS

Nina Schooler

Advisory Board: Bristol Meyers Squibb, Boehringer Ingelheim, Teva

Consulting: Alkermes, Boehringer Ingelheim, Minerva



# Speakers

Steve Brannan, MD

Seth Hopkins, PhD

Emilio Neto, PharmD, MBA

Jerry Sanacora, MD, PhD

Steven Szabo, MD, PhD

Jane Twitchen, BSc, MBA

Dawn Velligan, PhD

David Walling, PhD

# Decisions take place at different times and levels of authority

- We are interested in the operational decisions that affect actual clinical trial conduct
  - Presenters will provide examples of decisions and their effect on outcome
- Watch for some of the following**
- Site selection
  - Trial duration
  - I/E criteria and especially changes in I/E criteria during a trial
  - Protocol amendments to design during the trial
  - Assessment frequency and participant burden
  - Recruitment strategies- e.g. how hard to push
- Presenters will offer recommendations of strategies to improve decision making that can affect trial outcome
  - Audience expertise is welcome in adding both examples and strategies

# Organization of the Session: Four groups

- Decision examples and an assessment strategy
  - Steve Brannan: Effects of decisions in prior trials
  - Seth Hopkins: Improving assessment of adverse events
- Pre-trial planning
  - Emilio Neto & Jane Twitchen: Protocol complexity, site selection and strategies for site selection and trial initiation
- Further decision examples and explicit models for balancing priorities
  - Steve Szabo: Dissecting regional differences
  - Jerry Sanacora: Model for decision making
- Site perspectives
  - Dawn Velligan: Effect of operational decisions at academic sites
  - David Walling: Effect of operational decisions at independent sites