

Finding the Signal:

Strategies for achieving participant-centric trials in the face of participant-introduced validity challenges

Chairs:

- **Tim Mariano, MD, PhD, MSc** – Medical Director, Sage Therapeutics; Instructor, Dept. of Psychiatry, Harvard Medical School
- **Siân Ratcliffe, PhD** – VP & Head of Medical Writing, Clinical Development & Operations, Pfizer
- **Kari Nations, PhD** – Senior VP, CNS Clinical Development, Syneos Health; Clinical Assistant Professor, Dept. of Psychology, University of Texas at Austin

Wednesday, February 20, 2019

- **What is the evidence for and/or against the underlying assumption for a given design feature?**
- **Is that evidence spurious, or is it replicated and convincing?**
- **What is the potential impact of the design element to cost?**
- **What is the potential impact to recruitment?**
- **What is the potential impact to site engagement?**
- **How could it affect the drug/placebo separation?**
- **Would the regulators support the design feature in a pivotal trial?**

Finding the Signal - Agenda

Stakeholder	Section	Speaker
Sponsors	Case studies on how sponsors influence risks and utilize evidence/data to support decisions Discussion	Stephen Brannan Éva Köhegyi
Academia/Methods Research	Testing our assumptions: Moving from speculative to evidence-based trial design Discussion	Fabrizio Benedetti
<i>Break</i>		
Sites and Patient Advocates	Site and patient perspectives: Balancing risk mitigation with site/patient burden and acceptability Panel / Audience Q&A	Lori Davis- Facilitator Sarah Atkinson, Penney Cowan, David Walling
Regulatory	Regulatory perspective on design solutions Panel / Audience Q&A	Tom Laughren Valentina Mantua
Session Chairs	Concluding remarks	Sian Ratcliffe, Tim Mariano, Kari Nations

Thank You!
