



Blinded Data Trial Analytics: Benefits and Risks in Psychiatry and Neurology Studies

Chairs:

Steve Brannan, MD

Jenicka Engler, PsyD

Disclosures

Steve Brannan

- Formerly CMO at Karuna Therapeutics
- Consultant for: Seaport, Engrail, Kynexis, EMAW, Monument, Rapport, Neurocrine

Jenicka Engler

- Dr. Engler is a full-time employee of Cronos Clinical Consulting Services, Inc., an IQVIA Business.
- Cronos provides blinded trial data analyses and clinical eligibility review as part of rater oversight and intervention services.
- Dr. Engler receives assessment scale royalties from EBAD and AIRS assessments.



Speakers

Alan Kott, MUDr

Abby Nash, MD, PhD

Colin Sauder, PhD

Todd Solomon, PhD

Steve Brannan, MD

Jenicka Engler, PsyD

Purpose of this Session

- ISCTM and many of the members here have pioneered much of the blinded analytics work being done in CNS trials.
 - ISCTM Algorithms/Flags to Identify Clinical Inconsistency in the Use of Rating Scales in Clinical RCTs Working Group led by Jonathan Rabinowitz and Nina Schooler have published articles on flags that can be used to analyze potentially anomalous trial data.
- Current work builds upon the foundation of risk-based data monitoring (RBDM) and extends to other methodologies (e.g., advanced outlier analyses, differentiation indicators, independent eligibility confirmation and sample enrichment, interim analysis).
- Importantly, both the benefits AND risks of using blinded analytics in-study to drive decision making will be discussed, as there are no silver bullets.