

ISCTM Adaptive Design Working Group Dinner Meeting

16 February 2016

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History of the ADWG Deliverables to Date

- Initial educational session with Judith Quinn
 - February 2011
- Simulations
- Posters
- Publications
- Scientific Sessions

- Autumn Meeting 2012
 - Adaptive vs traditional design to evaluate the efficacy via change from baseline in the total Positive and Negative Syndrome Scale (PANSS) score for Compound X
- Annual Meeting 2014
 - Can we effectively study in the Veteran's Affairs (VA) system a novel anti-psychotic treatment compared to an active treatment, where time and sample size are unlikely to be sufficient to prove a reduction in the key endpoint of a reduced hospitalization rate.
 - Can we improve our chances of success by considering an additional endpoint (treatment failure) and analyzing sub groups (young / old in disease and with / without a history of substance abuse) where there maybe a greater effect?

- Turkoz, et al. *Adaptive versus Traditional Design Approaches to Target Dose Estimation*
– 2012

- [Adaptive Design Applied to Identification of the Minimum Effective Dose in Schizophrenia: Simulations of Scientific and Commercial Value](#)
 - T Parke , V Dragalin, I Turkoz, O Marchenko and V Haynes
 - Therapeutic Innovation & Regulatory Science January 2014 48: 41-50
- [ISCTM: Implementing Phase 2 Dose Finding Adaptive Clinical Trials](#)
 - T Parke
 - European Neuropsychopharmacology Volume 21, Issue 2, February 2011
- [An Introduction to Adaptive Designs and Adaptation in CNS Trials](#)
 - V Dragalin
 - European Neuropsychopharmacology: February 2011 (Volume 21, Issue 2)

- Scientific Session During 2015 Annual Meeting
 - Two educational presentations:
 - When is AD Useful in NS -Tom Parke
 - Overview of AD Methodology – Vlad Dragalin
 - Presentation and discussion of real world examples
 - Phase 2 Sleep Study – Margaret Moline
 - Phase 2 Alzheimer’s Disease – Andy Satlin
 - Phase 2 Migraine Study – Ron Marcus

- Based on feedback obtained in evaluations of scientific sessions
- Based on survey sent to society members

SERIES OF WEBINARS
SESSION PROPOSAL FOR FEBRUARY 2017

Structure

- Three in 2016
- 75 minutes to include questions
- Topics based on feedback received
- Combine with recommendations on publically available tutorials (i.e. YouTube)
 - Resource list
 - To be distributed prior to the Webinar
 - Follow up with a scientific session at the 2017 meeting
 - ◆ Will provide further discussion on topics raised
 - ◆ Panel to include experts, researchers, clinicians, regulatory and senior executives

Possible designs in a specific therapeutic area:

- Alzheimer's Disease
- Schizophrenia
- Parkinson's

Discuss:

- Objective of trial
- Different design options (including traditional)
 - Pros/cons of each design
- How will you proceed internally to have study approved and funded
- *Incorporate real world example*

Sequential Parallel Comparison Design

- Ibo and Pilar
- *Real world examples*
 - Have conducted 2 studies utilizing SPCD (anxiety and depression)
 - Discuss FDA feedback

Feasibility Assessment

- Process of presenting Adaptive Design internally to decision makers
- How do you convince decision makers Adaptive Design is the best choice?

Lesson learned session

- Avoiding failure – what works, what doesn't
- Logistics
- Necessary steps prior to initiation of an adaptive design trial

- Conduct in May, September, early December
- Determine best time of day
- Would be recorded
- Can do a panel for each presentation to include statistician, operations, etc.

- ISCTM Members
- Open to a larger group
 - Based on currently available mailing lists
 - Consider fee structure
 - Limit for a webinar would be 100 attendees

- Would be sent via the webinar
- Answer on call as time and topic allow
- Carry some over to Scientific Session at Annual Meeting

- Incorporate ideas generated this evening
- Final decision:
 - Dates and times
 - Topics
 - Speakers
- Send out notification to ISCTM members and other mailing lists
- Begin series of Webinars
- Begin planning for scientific session Feb 2017

Questions


