ISCTM Adaptive Design Working Group
Dinner Meeting

16 February 2016
Judy Kando
Ron Marcus
Deliverables to Date

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

• **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 Sessions

• 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
Next Steps

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

SERIES OF WEBINARS
SESSION PROPOSAL FOR FEBRUARY 2017
Webinars

**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
Proposed Topics

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

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
Logistics

- 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.
Attendees

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

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

• 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