Adaptive Design Publicity Paper Subteam
Chair: Thomas Laage
Members: (end slide)
Formed October, 2014

• Mission: Creative publicity for AD through publication in the medical literature

• Themes to attract journal editors and readers
  – Emphasis on ethical aspects of AD trials (John Loewy)
  – Paper would still need to cover all aspects of AD

• Possible target journals
  – DIA journal (Therapeutic Innovation and Regulatory Science) – already an audience familiar with the topic
  – Clinical Trials (Society of Clinical Trials publication) – long review time
  – More general medical journals such as New England Journal of Medicine – ethics and personalized medicine emphasis
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• Tentative Submission Dates
  • April/May, 2015
• Group Assignments
  • Nitzan Mekel-Bobrov will provide summaries of adaptive designs negotiated with FDA by his group
  • John Loewy will review other journal possibilities and to write a brief introduction that would highlight the ethical issues involved
  • Sandeep Menon – research target journal possibilities
  • Li Chen – obtain Chris Coffey’s recent paper on adaptive trial design barriers and opportunities (done)
  • Eva Miller – obtain Nitan Patel’s webinar about AD and economics in an AML trial
  • Tom Laage –
    • Review issue of clinical equipoise wrt changing information available during AD trials and ethical responsibilities involved for PI and DSMB
    • Review recent KOL presentations for good examples of ethical situations
    • Draft outline of paper
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Subteam Deliverable:
• A paper that will publicize the advantages of AD, with an emphasis on the ethical aspects

Meeting Schedule:
• Monthly

Needs:
• Is there a best way to have teleconferences?
Adaptive Design Publicity Paper Participants:

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