REI Clinical Trial Workshop

POINTS TO CONSIDER WHEN DESIGNING A CLINICAL TRIAL

The following list includes some of the questions that should be considered in designing a clinical trial.

Research objectives:	What are the primary and secondary objectives of the trial? Have the questions been framed properly such that they can be answered by the trial you design?
Response variables:	What is (are) the primary response variable(s)? What specific endpoint will you use? Will you use direct or indirect measures, or both? What economic data should be collected for the cost-effectiveness analysis? Should the cost of complications as well as interventions be included?
Trial design:	Is a randomized controlled trial the proper design to answer the questions posed? What is equipoise? Single center or multicenter?
Masking:	Is masking feasible in this study? If so, should you use single, double, triple masking?
Sample size:	How many patients do you need to have adequate statistical power to detect important differences between groups?
Patient population:	Is there an adequate number of patients with the condition under study in your population? Will results found in your population be generalizable to the general population? Are there particular groups you want to target?
Recruitment:	How will you maximize recruitment? Do you need to advertise? Are monetary incentives necessary?
Screening criteria:	What are appropriate inclusion and exclusion criteria for potential participants in your study? Will these criteria limit recruitment?
Randomization:	What method of randomization will you use?
Safety parameters:	How will you monitor participants for the emergence of known (or unknown) adverse effects of the treatments? Is an interim analysis indicated? What are your “stopping rules?”
Data collection:	Who will develop data collection instruments? Hand-written or computerized? What approach to monitoring and quality control will be used (especially in multicenter trials)? Who will be responsible for collecting and analyzing data from multiple sites?
Informed consent:	Who will develop the informed consent document? What models are available? Who will obtain consent? How often does the IRB meet?
Baseline assessment:	What baseline history, physical and laboratory information do you want to collect prior to the intervention?

Compliance:	Will you need to educate participants to insure compliance with the treatment regimens?
Follow-up:	Is loss to follow up a potential problem? If so, how will you minimize loss to follow up? What mechanisms will be in place for short-term and long-term (if appropriate) follow up?
Data analysis:	Will you specify the type of analysis to be used at the outset of the trial? Will you use the Intention-to-Treat rule for inclusion of participants in the analysis? How will you deal with missing data?
Reporting results:	Has authorship been agreed upon in advance? Is there agreement about the journals and submission of manuscripts for publication?

CLINICAL TRIAL RESOURCES

1. Friedman LM, Furberg CD, DeMets DL: Fundamentals of Clinical Trials, 3rd edition. New York, Springer. 1998.
2. Gallin JI, Ongibene FP: Principles and Practice of Clinical Research. Burlington, Massachusetts, Academic Press. 2007.
3. Lavorsi PW, Kelsey JL: Clinical Trials. Epidemiologic Reviews. 2002:24;1-90.
4. Meinert CL: Clinical Trials: Design, Conduct, and Analysis. New York, Oxford University Press. 1986.
5. Piantadosi S: Clinical Trials: A Methodologic Perspective. Hoboken, NJ, John Wiley & Sons. 2005.
6. Straus SE, Richardson S, Glasziou P, Haynes RB: Evidence-Based Medicine (Third Edition). New York, Churchill Livingstone. 2005.
7. Domanski M, McKinlay S: Successful Randomized Trials, A Handbook for the 21st Century. Philadelphia, Lippincott, Williams &Wilkins. 2009
8. Shulz, KF, Grimes DA: The Lancet Handbook of Essential Concepts in Clinical Research. Edinburgh, Elsevier. 2006.