Clinical Trials

Course Director: Yu Shyr, PhD
Fall [3 hours credit] Shyr

Design and data analysis for clinical trials in biomedical research. Primary topics include specification of study objectives, design options, ethical guidelines, randomization, blinding, sample size determination and power analysis, interim monitoring and data analysis appropriate for parallel, crossover, nested, factorial and group allocation designs. Other topics include role of FDA in the drug approval process, adaptive trial designs, non-inferiority trials and bio-equivalence trials. Emphasis is on practical use of methods rather than formal statistical theory.

Texts & Reading:

  ISBN 978-3-319-18538-5 (hardcopy)