

## **Clinical Trials**

Gerald Beck, PhD, Course Director  
Thursdays 7:00-9:00am

### **Course Description:**

The course will focus on the design, organization and operation of randomized controlled clinical trials and intervention studies. Topics include legal and ethical issues in design; application of concepts of controls; masking and randomization; steps required for quality data collection; monitoring for evidence of adverse or beneficial treatment effects; elements of organizational structure; sample size calculations and data analysis procedures and mistakes.

### **Student Assessment:**

Students will complete written/oral projects during the course:

1. Critique of a clinical trial
2. Design of a new clinical trial
3. Report of the results of the clinical trial (students will be supplied with "data" for their theoretical trial that they would have to analyze and report)

The final grade will be based on class participation and the three projects.

### **Topics:**

Introduction to clinical trials: Basics of clinical trials; Clinical trial roles; Bias in clinical research  
Define study questions; Define study populations  
Study protocol: Basic study designs; Superiority versus equivalence versus non-inferiority trials  
Double blind vs. single-blind versus unblinded trials: Control of bias; Use of a placebo  
Sample size/power  
Randomization  
Recruitment  
Data Collection and Quality Control; Data Management  
Adverse events  
Statistical analysis of clinical trial  
Design/Analysis issues  
Closeout and reporting of trials  
Data collection forms design  
Quality assurance  
Trial organization  
Assessing quality of life and cost effectiveness  
Designs for Phase I and Phase II studies

### **Textbook:**

Friedman, Lawrence M, Furberg, Curt D, and DeMets, David L. Fundamentals of Clinical Trials, Third Edition. Springer