

STAT 509 Design and Analysis of Clinical Trials 2009 Fall Semester

Instructor

Vernon M. Chinchilli, PhD
Distinguished Professor and Chair
Department of Public Health Sciences, A210
Penn State Hershey College of Medicine
600 Centerview Drive, Suite 2200
Hershey, PA 17033-0855
717-531-4262 (phone)
717-531-4359 (fax)
vchinch@psu.edu (e-mail)

Course Location and Time

327 Thomas
Tuesdays 2:30-5:15 PM (includes a 15-minute break)

Course Objectives and Structure

This is a survey course that stresses the concepts of statistical design and analysis in biomedical research, with special emphasis on clinical trials. SAS 9.2 statistical software will be used throughout the course for data analysis.

Course Prerequisites

STAT 500-501, PHS 520-521, or equivalent introductory statistics courses are prerequisites. Prior knowledge of SAS is not required, but students should have some familiarity with operating a PC in a Windows environment.

Technology Needs

Students should have access to a PC with SAS 9.2 statistical software. Check the Information Technology Services webpage for public computers that currently have SAS 9.2 installed, or students can purchase a personal copy of SAS 9.2 via the PSU Microcomputer Order Center. Students also should have viable e-mail access and read e-mail regularly. ANGEL, the Penn State course management system, will be used to post course materials, such as lectures, articles, homework assignments, exams, etc. Therefore, students should have access to a computer with an internet connection and be able to read and print files.

Evaluation Methods of Course Performance

Course grades will be based on homework assignments (3/5) and a final take-home exam (2/5). Students are expected to submit assignments and take exams on time, unless there is prior approval from the instructor. Students are expected to participate in class each week.

Course Text Book

The primary text is

Piantadosi S. (2005). *Clinical Trials: A Methodologic Perspective, Second Edition*. New York, NY: John Wiley & Sons.

Additional material is taken from

Woolson RF, Clarke WR. (2002). *Statistical Methods for the Analysis of Biomedical Data, Second Edition*. New York, NY: John Wiley & Sons.

Lecture Schedule

<i>Date</i>	<i>Projected Lecture Topic</i>
08/25	Introduction; Clinical Trials as Research; Why Clinical Trials are Ethical; Contexts for Clinical Trials; Statistical Perspectives
09/01	Clinical Trials as Experimental Designs; Random Error and Bias; Objectives and Outcomes; Translational Clinical Trials; Dose-Finding Designs
09/08	Sample Size and Power – Part A
09/15	Sample Size and Power – Part B
09/22	The Study Cohort; Treatment Allocation
09/29	Treatment Effects Monitoring
10/06	Counting Subjects and Events; Estimating Clinical Effects
10/13	Estimating clinical Effects (cont.)
10/20	Prognostic Factor Analyses
10/27	Prognostic Factor Analyses (cont.)
11/03	Reporting and Authorship; Factorial Designs
11/10	Crossover Designs – Part A
11/17	Crossover Designs – Part B
11/24	Thanksgiving Holiday – No Class
12/01	Meta-Analyses
12/08	Medical Diagnostic Testing; Correlation and Agreement