

**Department of Epidemiology and Biostatistics
College of Public Health
University of Georgia
BIOS 8220
Clinical Trials
FALL 2009**

Time: Tuesday & Thursday: 2:00–3:15 pm

Location: Miller Plant Science 2102

Instructor: Xiao Song

Office: 129c Coverdell

Email: xsong@uga.edu

Tel: (706) 542-1540

Office hours: Friday, 1:30-2:30 pm, or by appointment

Course Prerequisite: BIOS 7020 or STAT 6320

Course Resources:

- Textbook: none.
- References:
 - Fundamentals of Clinical Trials, by L.M. Friedman, C.D. Furberg and D.L. DeMets;
 - Clinical Trials: A Methodologic Perspective, by S. Piantaodsi.
 - Group Sequential Methods with Applications to Clinical Trials, by C. Jennison & B.W. Turnbull.
- Lecture notes and announcements will be posted on eLearning Commons.

Course Description:

This course will introduce statistical principles and methods used in clinical trials, including phase I to IV clinical trials. Although the class will have emphasis on phase III trials, we will also discuss the feature and statistical issues in phase I and II clinical trials. For phase III trials, we will discuss ways of treatment allocation that will ensure valid inference on treatment comparison. Other topics include sample size calculation, survival analysis and early stopping of a clinical trial and noncompliance.

Course objectives:

Upon completion of the course, students will know the stages of the drug development and testing process and the steps of drug approval by the US FDA. They will become familiar

with experimental design issues that arise in clinical trials such as randomization, double-blinding, sample size determination and power analysis. Students will understand how to implement, interpret and report the results of methods of statistical analysis applicable to clinical trials.

Topical Outline

- Introduction
- Phase I and Phase II Clinical Trials
- Phase III Clinical Trials
- Sample Size Calculations
- Comparing More Than Two Treatments
- Causality, Non-compliance and Intent-to-treat
- Survival Analysis in Phase III Clinical Trials
- Early Stopping of Clinical Trials

Exams:

- Midterm (in class, open notes, Thursday, Oct 1)
- Final (in class, open notes, Friday, Dec 11, 3:30 - 6:30 pm)

Note: Exams are in class.

You must contact the instructor in advance if you are unable to take an exam at its scheduled time. Arrangements may then be made for a make-up exam.

Grades:

- Homework: 30%
- Midterm: 30%
- Final: 40%

Make-Up Policy:

Make-up exams: Generally, there are no make-up exams for this course. Make-up exams will only be offered on an individual basis and only due to personal emergencies. The student must contact the instructor before exam time in order to schedule a make-up exam.

Academic Honesty:

All academic work must meet the standards contained in “A Culture of Honesty.” All students are responsible to inform themselves about those standards before performing any academic work. More detailed information about academic honesty can be found at <http://www.uga.edu/ovpi/honesty/acadhon.htm>.

Students with Disabilities:

Students with disabilities who require reasonable accommodations in order to participate in course activities or meet course requirements should contact the instructor or designate during regular office hours or by appointment.

The course syllabus is a general plan for the course; deviations announced to the class by the instructor may be necessary.