

**Graduate School of Public Health
San Diego State University
PH722: SEMINAR CLINICAL TRIALS
Fall, 2006**

Course Information

Section: 1	Schedule No.: 26246	Units:3
Time:1600 – 1840	Meeting Days: Monday	Location: HH122

Instructor

Name:	Ming Ji, PhD Assistant Professor, Epi/Biostatistics Graduate School of Public Health San Diego State University 5500 Campanile Drive San Diego, CA 92182-4162 Tel: 619-594-3454 Email: mji@mail.sdsu.edu
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Office Hours:	1400-1600 Monday or by appointment

Course Description

This seminar course is an introduction to the fundamental concepts and principles for the design, conduct, analysis and reporting of clinical trials and related statistical methods. Topics including: history of clinical trials, causal inference, study designs, randomization, blinding, sample size calculation, selection of control groups, ethics, interim analysis, statistical analysis of clinical trial data and interpretation of clinical trial results.

Prerequisite

Basic knowledge of epidemiology and biostatistics at the PH601 and PH602 levels are required. Knowledge of multivariate regression models such as multiple regression, analysis of covariance, logistic regression and survival analysis comparable to PH627 is recommended.

Course Objective

This course is aimed to familiarize the students with clinical trials, including their design, conduct, analysis and interpretation. Upon the completion of this course, the students should be able to

- Identify the characteristics of clinical trials and differentiate clinical trials from other designs in clinical or epidemiological studies
- Apply the principles to design clinical trials and write protocols
- Calculate sample size required for study designs
- Produce different randomization schemes
- Specify data monitoring and interim analysis rules
- Articulate the legal, ethical and regulatory issues in the design and review of clinical trials (such as IRB issues)
- Understand appropriate statistical analysis methods for different types of clinical trial data
- Interpret clinical trial findings appropriately
- Critically review published clinical trial results

Teaching Format

Teaching will be conducted by (1) classroom lecture by instructor and guest lecturers (2) assigned reading (3) in class representation and (4) online discussion (5) homework assignments (6) site visits to clinical trial study centers or pharmaceutical companies.

The students are expected to finish assigned reading materials before class, actively participate in lectures and online discussion, complete and turn in homework assignments in time and attend the site visits.

Evaluation and Grading

Attendance Attendance is very important since a single class meeting is 2 hours and 40 minutes. There will be no make-up lectures. Absence is only permitted for family emergency, necessary business trip and other legitimate reasons. The student who will miss a class meeting must inform the instructor prior to the class date.

Weekly Online Discussion There will also be 10 discussion topics on the Blackboard posted by the instructor. Each student is required to contribute at least three postings per topic, at least one original posting (new thread), at least two follow-up postings (comments on other people's postings). The postings should not be just opinions. Postings should have your own point of view with

supporting information or argument. They should reflect that the student has done research and analysis on the topic.

In-Class Presentation. Each student will be asked to give a presentation based on a topic in clinical trial he/she chooses. A separate list of possible topics will be available later. The order for the students to give presentation will be based on a sequence of random numbers but the first student can choose a topic first and so on. The students' presentation will be distributed evenly over the fall semester starting in October. Rescheduling is granted only under special circumstances. Each presentation should be about 30 minutes followed by a 10~15 minutes for questions and discussions. The presentation must be submitted to the instructor in electronic format after the presentation. The quality of the presentation will be based on peer-review by students as well as evaluation by the instructor on several aspects: your research on the topic such as how thorough is your literature review, your analysis of the topic such as whether you have insights, the quality of your presentation and how you respond to other people's questions.

Homework. There will be ten homework assignments. They will be available on the day of lecture and due after one week. The file names should be in the format of Name_Assign_#.doc for example, Ming_Assign_1.doc The students can submit their answer online through the Digital Drop Box on Blackboard. Late assignments can only get partial credits if they are less than 10 days late with 1 point deducted for one day delay. No credits will be given 10 days after the due date. I will review your submitted assignments and return them to you with my comments.

Grades Breakdown

Discussions: 30x10=300

Assignments 30x10=300

Attendance: 10x14=140

Presentation: 360

Total: 1000

Letter Grades:	950+	A
	900-950	A_
	850-900	B
	800-850	B_
	700-800	C
	600-700	D
	<600	F

Textbooks

Required

Fundamental of Clinical Trials. 3rd Edition by Lawrence M. Friedman, Curt D. Furberg and David L. DeMets. Springer Verlag, New York, Inc 1998.

References

1. *Clinical Trials: A practical approach*. Stuart J. Pocock. John Wiley & Sons Ltd. 1983
2. *Clinical Trials, Design, Conduct and Analysis*. Curtis L. Meinert, Oxford University Press, 1986
3. *Statistical Aspects of the Design and Analysis of Clinical Trials*. Everitt B and Pickels, A Imperial College, 2000
4. *Sample Size Tables for Clinical Studies*. 2nd Edition. Machin D, Campbell M. J and Favers P.M. Blackwell Science Inc. 1997
5. *Multivariate Analysis: A Practical Guide for Clinicians*. Katz M.H and Katz M.H. Cambridge University Press. 1999
6. *Analysis of Clinical Trials using SAS: A Practical Guide*. Alex Dmitrienko, Geert Molenberghs, Christy Chuang-Stein and Walter Offen

Online Journals

Controlled Clinical Trials

Statistics in Medicine

Both are accessible online through SDSU library website. Links are provided on the Blackboard.

Class Schedule

Dates	Topic
Sept 12	History and Introduction to Clinical Trials Sue Hollander/ Health Sciences Librarian: Information sources for clinical trials
Sept 19	Research Question/Study Population/Basic Study Designs
Sept 21	
Oct 3	Randomization and Blindness
Oct 10	Ethics and Human Subject Protection
Oct 17	Baseline Assessment / Recruitment of Participants
Oct 24	Adverse Events/Quality of Life Assessment/Sample Size Calculation
Oct 31	Guest Speaker (Dr. Greg Talavera: Recruiting Minority into Clinical Trials: The Women's Health Initiative Study) Student Presentation 1
Nov 7	Survival Analysis and Interim Monitoring Guest Lecture: Dr. Larry Shen, Director of Biostatistics, Amlyn Pharmaceutical. Phase I dose finding trials
Nov 14	Data Collection/Data Analysis/Reporting and Interpreting of Results Guest Lecture: Dr. Tony Reid TBA
Nov 21	Guest Speaker (Dr. Stephanie Brodine: Multinational Clinical Trials). Student Presentation 2
Nov 28	Site Visit
Dec 5	Guest Speaker (Georg Matt: Measurement Issues in Clinical Research) Guest Speaker (Dr. Ted Ganiats: TBA)
Dec 12	Student Presentation 3