Overview and Objectives: Special Topics in Clinical Trials course will provide information on the different types of clinical trials beyond the Phase III superiority parallel group design. We will use manuscripts on special types of clinical trials to facilitate learning of concepts discussed in class.

Responsibilities:

- There will be reading assignments on selected articles and guidelines.
- Students will be assigned four written exercises that will be graded. All homework assignments will be assigned with a due date. There will be a final project which will involve writing a study protocol for a “special” clinical trial that has been recently completed or is ongoing at the University of Pittsburgh. You are encouraged to work together on class projects and homework assignments, but you should write up your results individually, i.e. very similar papers will not be accepted.
- Attendance and participation in class are required.
- Evaluation criteria will be based on completion of the writing assignments, completion of the final project, and attendance of meetings with instructors.

Course Requirements

- Class attendance 5%
- Written assignments 65%
- Final project 30%

Course Grading Scale:

For the computation of the final course grade as well as for the course assignments, the following grading scale will be used:

90 - 100 = A  
80 – 85 = B  
70 – 75 = C  
60 – 65 = D  
86 – 89 = B+  
76 – 79 = C+  
66 – 69 = D+  
< 60 = F

NOTE: Homework assignments, course information, and communication will be available at [http://courseweb.pitt.edu](http://courseweb.pitt.edu).

Other highly recommended textbooks to be used as references:
Clinical Trials: A Practical Approach, 1996, Stuart J. Pocock, John Wiley & Sons
Clinical Trials: Design, Conduct, and Analysis, 1986 Curtis L. Meinert, Oxford
Clinical Trials: A Methodologic Perspective, 2005, Steven Piantadosi, John Wiley & Sons

Course Syllabus

Date: March 3, 2010
Session 1
Meta-Analysis (including clinical trial registration) Bost
Pharmacoeconomic Studies Hanlon

Required Readings:
   Appropriate prescribing in elderly people: how well can it be measured and optimised? Lancet
   370:173-84.
   a Phase IV study? Common clinical research designs, registries, and self-reporting systems. Journal
   of Clinical Pharmacology 47:1074-1086.

Homework Assignment 1: Find an example of a meta-analysis and a pharmacoeconomic study.
Describe the studies with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design
and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary
outcome. Include the full citation and abstract for each trial. Due: Monday, March 8, 2010.

Date: March 8, 2010
Session 2
Crossover Trials Moore
Equivalence Trials Moore

Required readings:
1) Pocock Chapter 8: Crossover Trials
2) Piaggio G et al. Reporting of noninferiority and equivalence randomized trials. An extension of the
   CONSORT statement. JAMA 2006;295:1152-60.

Supplemental Readings:
4) Putt ME, Ravina B. (2002) Randomized, placebo-controlled, parallel group versus crossover study
designs for the study of dementia in Parkinson’s disease. Controlled Clinical Trials 23:111-126.
5) Stat in Med Non-inferiority trials: advances in concepts and methodology (special issue) 30 Jan 2003,
   2:165-336.
**Homework Assignment 2:** Find examples of a crossover trial and an equivalence or non-inferiority trial. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial. **Due** Monday, March 15, 2010.

**Homework Assignment 1 is due.**

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<th>Behavioral medicine interventions</th>
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<td>Emergency Medicine trials</td>
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**Supplemental Reading:**
Federal Register volume 61, no 192, page 51498 (Informed consent in emergency medical interventions)

**Homework Assignment 3:** Find examples of a behavioral medicine trial and an emergency medicine trial. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial. **Due** Wednesday, March 17, 2010.

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<td>Complementary and Alternative Medicine</td>
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**Homework Assignment 4:** Find examples of a complementary and alternative medicine trial and a surgical trial trial. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial. **Due** Monday, March 22, 2010.

**Homework Assignment 2 is due.**

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<th>Date: March 17, 2010</th>
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**Required readings:**

**Homework Assignment 5:** Find examples of a women’s health study and a pharmacoepidemiology or Phase IV study. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial. For the pharmacoepidemiology or Phase IV study, describe which type of study you consider it to be. **Due** Wednesday, March 24, 2010.

**Homework Assignment 3 is due.**
### Required readings:

1. Friedman, Furberg, and DeMets text: pp 119-122.

### Supplemental Readings:


**Homework Assignment 6:** Find an example of a group/cluster randomized trial. Describe the trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (be sure to fully describe the unit of randomization versus the unit of analysis) (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial. **Due** Monday, March 29, 2010.

**Homework Assignment 4 is due.**

### Supplemental Information:

Epidemiology of medical devices (Torrence) :

http://www.pitt.edu/~super1/lecture/lec0281/001.htm

**Homework Assignment 7:** Find an example of a medical device trial. Describe the trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. **Due** Monday, March 29, 2010.

**Homework Assignment 5 is due.**

### Homework Assignments 6 & 7 are due.