

(Updated: September 14, 2015)

Biostatistics 619: Clinical Trials, Fall 2015 **Fridays, 10am-12pm; M1112, SPH II**

Instructor: Philip S. Boonstra, PhD

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Time: Fridays, 10am–12pm

Location: M1112, SPH II

There will be no class on Nov. 27 (Thanksgiving Break)

Office Hours: Tuesday (3-4pm) and Thursday (2-3pm).

You can probably catch me at other times, too.

Course Description: This course is designed for individuals with a strong quantitative background (emphasis on strong and quantitative) that are interested in the scientific, policy, design and management aspects of clinical trials.

Textbooks: *None required.* Some material covered in lectures will be based on content from:

- Optional {
- Cook, TD and DeMets, DL (Editors) *Introduction to Statistical Methods for Clinical Trials*, 2nd ed. (2007)
 - Friedman, LM, Furberg, CD, and DeMets, DL. *Fundamentals of Clinical Trials*, 4th ed. (2010) **This is available for free electronically via UM's subscription to Springer Link.**
 - Piantadosi, Steven. *Clinical Trials A Methodologic Perspective*, 2nd ed. (2005)
 - Crowley J and Hoering A (Editors) *Handbook of Statistics in Clinical Oncology*, 3rd ed. (2012)

Throughout the semester, I will also make available relevant papers via CTools.

Co/pre-requisite: At a minimum, you must have taken or be concurrently enrolled in a class on distributional theory, on the level of Biostat601. However, you will get the most out of this class if you have taken or are concurrently enrolled in a class that gives a rigorous treatment of generalized linear models, e.g. Biostat651. As such, I highly recommend that first-year Biostatistics MS students defer taking this class until their second year.

Topics covered: Phase I (dose-escalation, including algorithmic and model-based designs), Phase II (early stopping, randomization, biomarkers), Phase III (randomization, interim analyses, sample size, group-sequential designs, non-inferiority

trials). Other topics as well as current issues in clinical trials that we will not have time for will be covered via group projects. Finally, we will cover how to use statistical software to simulate and analyze data from clinical trials.

Grading: Assessment will be based on 4-5 homework assignments (40%), occasional very brief, pre-announced quizzes and/or a short midterm (I haven't finalized this yet) (20%), group projects (20%), class attendance/participation (10%), and weekly feedback via Google (see next bullet) (10%).

Weekly Feedback: I want to be an effective teacher. Each week I will publish a Google poll asking you to rate the week's lecture (1-5) and optionally give me anonymous feedback. On each quiz will be a question asking if you've taken at least one weekly poll (since the beginning of the semester or since the previous quiz); you will receive the full 10% if you answer 'yes' each time.

Software: I will teach with (and, as best as I can, offer help with) the R language and environment, which is freely available at <http://cran.us.r-project.org/>.

Academic Conduct:

The faculty and staff of the School of Public Health believe that the conduct of a student registered or taking courses in the School should be consistent with that of a professional person. Courtesy, honesty, and respect should be shown by students toward faculty members, guest lecturers, administrative support staff, community partners, and fellow students. Similarly, students should expect faculty to treat them fairly, showing respect for their ideas and opinions and striving to help them achieve maximum benefits from their experience in the School.

Student academic misconduct refers to behavior that may include plagiarism, cheating, fabrication, falsification of records or official documents, intentional misuse of equipment or materials (including library materials), and aiding and abetting the perpetration of such acts. Please visit <http://www.sph.umich.edu/academics/policies/conduct.html> for the full SPH Code of Academic Integrity and further definition of these terms.

Student Well-being:

SPH faculty and staff believe it is important to support the physical and emotional well-being of our students. If you have a physical or mental health issue that is affecting your performance or participation in any course, and/or if you need help connecting with University services, please contact the instructor or the Office of Academic Affairs. Please visit <http://www.sph.umich.edu/students/current/#wellness> for more information.

Student Accommodations:

Students should speak with their instructors before or during the first week of classes regarding any special needs. Students can also visit the Office of Academic Affairs for assistance in coordinating communications around accommodations. Students seeking academic accommodations should register with Services for Students with Disabilities (SSD). SSD arranges reasonable and appropriate academic accommodations for students with disabilities. Please visit <http://ssd.umich.edu/accommodations> for more information on student accommodations. Students who expect to miss classes, examinations, or other assignments as a consequence of their religious observance shall be provided with a reasonable alternative opportunity to complete such academic responsibilities. It is the obligation of students to provide faculty with reasonable notice of the dates of religious holidays on which they will be absent. Please visit http://www.provost.umich.edu/calendar/religious_holidays.html#conflicts for the complete University policy.