BIOS 752 Design and Analysis of Clinical Trials, Fall 2016

Instructors: Anastasia Ivanova, Associate Professor of Biostatistics
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Lectures: Tuesday and Thursday, 12:30 PM to 1:45 PM, Room 2305 MCG

Learning objectives: The main objective of the class is to introduce methods for designing and analyzing clinical trials.

Help sessions: Tuesday 2:00 PM to 3:00 PM, location Hooker 0015, except on 10/4 and 10/25 the location is MC 1303

Assessment: 1) MIDTERM EXAM (worth 40% of final grade); You can bring a total of 2 pages (one-sided) of letter size (8.5 × 11 in) of supporting materials to the exam.
2) FINAL PROJECT (worth 25% of final grade); The grade for the final project includes the grade for your presentation plus the grades for the two quizzes. You should be present on both presentation days, otherwise your final project grade is 0. Quizzes are open book. The time and location of the final presentation is Dec TBA, noon-3pm at location TBA.
3) HOMEWORK (worth 35% of final grade). Collaboration among students on homework assignments is allowed, but only in the form of discussion of the homeworks. Copying or simply dividing up assignments among collaborating students is not allowed. Questions concerning homework assignments can be addressed to the course instructor.

Course assistants: Jon Rosen jdrosen@live.unc.edu. The course assistant will be grading the homework assignments.

Course prerequisite: BIOS 660; BIOS 661 or equivalent.

Lecture notes: https://sakai.unc.edu/portal/site/bios752_2016


Schedule of lectures (subject to change)

L1, 8/23  Why do we need clinical trials? Hormone replacement therapy.
L3, 8/30  Phases of drug development. Design of dose-finding trials with toxicity endpoint.
L4, 9/1   Design of dose-finding trials with toxicity endpoint (cont).
L5, 9/6   Methods for Phase 2 trials in non-life-threatening diseases.
L6, 9/8   Phase 2 trials in oncology.
L7, 9/13  Misconduct in Clinical Trials. Dr Richard Zink
L8, 9/15  Sample size determination.
L9, 9/20  Sample size determination. Randomization.
L10, 9/22 Covariate adjustment. Dr Gary Koch
L11, 9/27 Randomization.
L12, 9/29 Randomization. Dr Bahjat Qaqish
L13, 10/4 Multiplicity.
L14, 10/6 Multiplicity
L15, 10/11 Multiplicity.
L16, 10/13 Multiplicity. Dr Gary Koch
L17, 10/18 Bioequivalence and non-inferiority trials. Dr Sonia Davis
10/20    FALL BREAK
L18, 10/25 Sequential methods.
L19, 10/27 Sequential methods.
L20, 11/1 Sequential methods.
L21, 11/3 Sequential methods. Data monitoring committees.
L22, 11/8 Crossover studies. Factorial design.
L23, 11/10 Trials in orphan diseases. Dr C.Q. Deng
L24, 11/15 EXAM
L25, 11/17 Missing data Dr Sonia Davis
L26, 11/22 Prevention trials (or other topic).
11/27    THANKSGIVING
L27, 11/29 Bayesian methods (or other topic).
L28, 12/1 Analysis of adverse events. Dr Richard Zink
L29, 12/6 Final Project Presentation

Final exam, 12/? at noon    Final Project Presentation (room TBA)
The Honor System

The University of North Carolina at Chapel Hill has had a student-administered honor system and judicial system for over 100 years. The system is the responsibility of students and is regulated and governed by them, but faculty share the responsibility. If you have questions about your responsibility under the honor code, please bring them to your instructor or consult with the office of the Dean of Students or the Instrument of Student Judicial Governance. Your full participation and observance of the honor code is expected.

Four general responsibilities under the Code. The Instrument of Student Judicial Governance, which contains the provisions of the Honor Code, states that students have four general responsibilities under the Code:

1. Obey and support the enforcement of the Honor Code;
2. Refrain from lying, cheating, or stealing;
3. Conduct themselves so as not to impair significantly the welfare or the educational opportunities of others in the University community; and
4. Refrain from conduct that impairs or may impair the capacity of University and associated personnel to perform their duties, manage resources, protect the safety and welfare of members of the University community, and maintain the integrity of the University.

Plagiarism. Plagiarism in the form of deliberate or reckless representation of another's words, thoughts, or ideas as one's own without attribution in connection with submission of academic work, whether graded or otherwise.

Authorized vs. Unauthorized Collaboration. All academic work in this course, including homework, quizzes, and exams, is to be your own work. It is your responsibility if you have any doubt to confirm whether or not collaboration is permitted.

Unauthorized devices and materials. Electronic devices including calculators are NOT allowed during exams. Internet use is NOT allowed in the classroom.

Consequences. Under the Instrument of Student Judicial Governance, the usual sanction for a first time academic offense is suspension for one academic semester and a failing grade.

Additional Information. Additional information is available from the Office of the Dean of Students, or the Honor System http://honor.unc.edu.