

# Statistical Methods in Clinical Trials

Summer 2009, first 5-week session

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*Time:* MTWR 5:30 – 7:45 pm      *Room:* MC 3.610  
*Instructor:* Michael Baron      *E-mail:* mbaron@utdallas.edu  
*Office:* ECSN 3.912      *Phone:* 972-UTD-6874  
*Internet:* <http://wwwpub.utdallas.edu/~mbaron/6390clinical.html>  
*Office hours:* Thursday 12:30 - 1:30 pm in ECSN 3.912  
MTWR 5:00 - 5:30 pm in MC 3.610

*Main text:* *Group sequential methods with applications to clinical trials*  
by C. Jennison and B. Turnbull, Chapman & Hall/CRC, 2000

*Prerequisite:* STAT 4351/4352 or 5351/5352 or equivalent courses in Probability  
and Mathematical Statistics at a senior undergraduate or graduate level

Course outline:

1. Four phases of clinical trials. Introduction, concepts, rules, policies (Chap. 1, notes).
2. Introduction to sequential methods (Chap. 1, 18, lecture notes). Wald's sequential probability ratio test. Stopping boundaries. OC and ASN.
3. One-sided and two-sided tests in clinical trials (Chap. 2–6). Pocock, O'Brien-Fleming, Wang-Tsiatis tests. Unified (information) approach.
4. Statistical inference with interim analysis in clinical trials (Chap. 6–9). Error spending functions. Repeated confidence intervals.
5. Group sequential methods for binary data and survival data (Chap. 11–13)
6. Multiple comparisons (Chap. 15).
7. Computations for group sequential tests (Chap. 19).

Grading:

4 Quizzes	60 %	Weekly quizzes will cover the material of the preceding week and the corresponding homework assignment.
Homework	0 %	Homework will be assigned but will not be collected or graded. Answers will be provided, solutions will be discussed.
Final exam	40 %	A 2½-hour final exam covers the most fundamental concepts and methods learned in the course
90–100 % = A,    75–90 % = B,    55–75 % = C		

Tips:

For each quiz and exam, review all the new concepts and formulas. Try to understand the methods rather than to memorize them.

For efficient use of exam time, prepare a brief summary of important statistical tools you may need for the exam. Arrange it on a single sheet of paper in the most convenient way.

Although you are allowed to collaborate while doing the homework, you have to show your own work in class. Therefore, a serious attempt to do all the problems and a thorough