STAT 6390 – Topics in Biostatistics

Statistical Methods in Clinical Trials
Summer 2009, first 5-week session

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://www.pub.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.
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:

<table>
<thead>
<tr>
<th>4 Quizzes</th>
<th>60 %</th>
<th>Weekly quizzes will cover the material of the preceding week and the corresponding homework assignment.</th>
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</thead>
<tbody>
<tr>
<td>Homework</td>
<td>0 %</td>
<td>Homework will be assigned but will not be collected or graded. Answers will be provided, solutions will be discussed.</td>
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<tr>
<td>Final exam</td>
<td>40 %</td>
<td>A 2½-hour final exam covers the most fundamental concepts and methods learned in the course</td>
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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 understanding of the solutions is required.