BIOS 7431 - Statistical Issues in Drug Research and Development

Karl E. Peace

Georgia Southern University, Jiann-Ping Hsu College of Public Health, kepeace@georgiasouthern.edu

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Prerequisites: First year MS biostatistics courses

Description: Numerous statistical issues attendant to providing biostatistical support to drug research and clinical development programs are identified and discussed. Real examples are used to illustrate and solidify how to address the issues.

Required Textbook: No textbook required. The course is presented using power points developed by the professor and will be provided to students on a flash drive


**Program Goals:** At the completion of this program the student will be able to:

- Distinguish among the different measurement scales and the implications for selection of statistical methods to be used based on these distinctions;
- Apply descriptive techniques commonly used to summarize health related data;
- Apply common statistical methods for inference;
- Describe preferred methodological alternatives to commonly used statistical methods when assumptions are not met;
- Apply descriptive and inferential methodologies according to the type of study design for answering a particular research question;
- Interpret results of statistical analyses found in health related studies;
- Develop written and oral presentations based on statistical analyses for both health professionals and educated lay audiences; and

**Course Objectives:** At the completion of this course the student will have an understanding of:

1. Statistical Issues in Drug Research & Development Background
2. Constructing Statistical Hypotheses to Reflect Study Objectives
3. P-values vs. C.I. for Statistical Inference
4. P-Values: One-Sided or Two-Sided?
5. Sample Size Considerations in Clinical Trials Pre-Market Approval
6. Statistical Analysis Section of a Clinical Trial Protocol
7. The Importance of Numbers (of Patients) in Cancer Clinical Trials
8. The Use of the Global Null Hypothesis in Clinical Trials
9. A. Dual Control Groups in Rodent Carcinogenicity Studies
   B. Some Real Examples of Dual Control Groups in Rodent Carcinogenicity Studies
10. Statistical Methods for a Three-Period Crossover Design in Which High Dose Cannot be Used First
11. Active Controlled Equivalence Studies (ACES) or Non-Inferiority Trials
12. The Use of Placebo in Combination Drug Development
14. Intention-to-Treat in Clinical Trials
15. Interim Analyses: p-Value and Power Computations in Multiple Look Trials
16. The Statistical Analysis of Dose Response Studies
17. Multiple Inferences in Clinical Trials
18. Dosing in the Elderly
19. The Pooling of Data from Multicentre Clinical Trials
20. Monitoring Adverse Experiences in Clinical Drug Development
21. Analysis and Summarization of Safety Data Collected in Clinical Trials
22. Meta-Analysis in Ulcer Disease

**Overview of the Content to be Covered During the Semester:**

1. Background
2. Constructing Statistical Hypotheses to Reflect Study Objectives
3. P-values vs. C.I. for Statistical Inference
4. P-Values: One-Sided or Two-Sided?
5. Sample Size Considerations in Clinical Trials Pre-Market Approval
6. Statistical Analysis Section of a Clinical Trial Protocol
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8. The Use of the Global Null Hypothesis in Clinical Trials
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16. The Statistical Analysis of Dose Response Studies
17. Multiple Inferences in Clinical Trials
18. Dosing in the Elderly
19. The Pooling of Data from Multicentre Clinical Trials
20. Monitoring Adverse Experiences in Clinical Drug Development
21. Analysis and Summarization of Safety Data Collected in Clinical Trials
22. Meta-Analysis in Ulcer Disease

**Instructional Methods:** Class meetings will be a combination of lecture and class discussion. Approximately half of the class meetings will be facilitated via Adobe Connect in real time (blended format) and the remainder physically in the classroom. Homework assignments, class participation and the final examination constitute the basis of student evaluation. Students
are expected to make use of office hours (in my office or via adobe connect) and email contact to discuss concepts or difficulties they may have. In addition, they may seek the assistance of the GA.

**Exam Schedule and Final Examination:**

Final Examination: Week of Finals Spring 2016

**Grading:**

Weighting of assignments for purposes of grading will be as follows:

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<th>Component</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Final Exam</td>
<td>60%</td>
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<tr>
<td>Assignments</td>
<td>30%</td>
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<tr>
<td>Class Participation</td>
<td>10%</td>
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<tr>
<td><strong>Total Possible</strong></td>
<td>100%</td>
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</tbody>
</table>

The following point scale will be utilized in grading:

- 90% - 100% A
- 80% - 90% B
- 70% - 80% C
- 60% - 70% D

There are times when extraordinary circumstances occur (e.g., serious illness, death in the family, etc.). In such circumstances, and/or if you need additional time to satisfactorily complete any course requirement, please consult with the instructor within a reasonable amount of time. *Nota Bene:* Extensions are not guaranteed and will be granted solely at the discretion of the instructor.

**Academic Misconduct:**

As a student registered at this University, it is expected that you will adhere to only the strictest standards of conduct. Your continued enrollment in this course is an implied contract between you and the instructor on this issue; from this point forward, it is assumed that you will conduct yourself appropriately.

Academic integrity relates to the appropriate use of intellectual property. The syllabus, lecture notes, and all materials presented and/or distributed during this course are protected by copyright law. Students are authorized to take notes in class, but that authorization extends only to making one set of notes for personal (and no other) use. As such, students are not authorized to sell, license, commercially publish, distribute, transmit, display, or record notes in or from class without the express written permission of the instructor.
**Attendance Policy:** Federal regulations require attendance be verified prior to distribution of financial aid allotments. Attendance will not be recorded after this initial period.

**One Final Note:** The contents of this syllabus are as complete and accurate as possible. The instructor reserves the right to make any changes necessary to the syllabus and course material. The instructor will make every effort to inform students of changes as they occur. It is the responsibility of the student to know what changes have been made in order to successfully complete the requirements of the course.
Student Information (SIDRD Class):

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<th>Print Full Name</th>
<th>email address</th>
<th>Pledge to spend enough time to master material? Circle one.</th>
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