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Fall 2016

BIOS 7431 - Statistical Issues in Drug Research and Development

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Georgia Southern University
Jiann-Ping Hsu College of Public Health
BIOS 7431: Statistical Issues in Drug Research and Development

Fall 2016

Instructor:	Karl E. Peace
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E-Mail Address:	Peacekarl@frontier.com, kepeace@georgiasouthern.edu
Office Hours:	Monday – 3:00 PM – 5:00 PM
	Other times by appointment; email contact is encouraged
Class Meets:	Monday – 5:00 PM-to-7:45 PM

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

Secondary Text: Peace, K.E. (Editor and author): Statistical Issues in Pharmaceutical Drug Development; Marcel Dekker, Inc., New York, ISBN 0-8247-8290-9, 1990.

Other Texts: Chen, D, Peace KE: Applied Meta-Analysis using R. Chapman & Hall/CRC, Taylor and Francis Group; 13: 978-1-4665-0599-5; May, 2013.

Chen D, Sun J, Peace KE [Editors and Author contributors] (2012): Interval-Censored Time-to-Event Data: Methods and Applications"; Chapman & Hall/CRC, Taylor and Francis Group; Published July, 2012.

Chen D, Peace KE (2010): Clinical Trial Data Analysis using R; Chapman & Hall/CRC, Taylor and Francis Group; ISBN: 978-1-4398-4020-7

Peace, K. E., Chen, D (2010): Clinical Trial Methodology; Chapman & Hall/CRC, Taylor and Francis Group.

Peace, K. E. [Editor and Author contributor] (2008): <u>Design and Analysis of Clinical Trials with Time to Event Endpoints</u>; Chapman & Hall/CRC Taylor and Francis Group; Boca, ISBN 978-1-4200-6639-5.

Peace, K. E. [Editor and Author contributor] (1992): <u>Biopharmaceutical Sequential Statistical Applications</u>. Marcel Dekker, Inc., New York, ISBN 0-8247-8628-9.

Peace, K.E. [Editor and author] (1988): <u>Biopharmaceutical Statistics in Drug Development</u>. Marcel Dekker, Inc., New York, ISBN 0-8247-7798-0.

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

13. Biostatistical Aspects of the Development of Anti-Anginal Drugs: a Phase II Clinical Trial Incorporating an Equiradial Hexagonal Design with Response Surface Methodology
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
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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

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:

Final Exam	….….……………………	60%
Assignments	………….………………	30%
Class Participation	…………………………	10%
Total Possible		100%

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):

Print Full Name	email address	Pledge to spend enough time to master material? Circle one.		
1. _____	_____	Yes	No	Undecided
2. _____	_____	Yes	No	Undecided
3. _____	_____	Yes	No	Undecided
4. _____	_____	Yes	No	Undecided
5. _____	_____	Yes	No	Undecided
6. _____	_____	Yes	No	Undecided
7. _____	_____	Yes	No	Undecided
8. _____	_____	Yes	No	Undecided
9. _____	_____	Yes	No	Undecided

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