Biostatistics 413
Course Outline

Dr. Martin Lee **Spring, 2016**

Office: CHS 51-239A (hrs: MW 1-1:45pm and 3:15-4pm)
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Text: Class Notes; Buncher CR and Tsay JY. Statistics in the Pharmaceutical Industry, 3rd edition, Chapman and Hall, 2006

Topics	**Reading in Text**	**Approximate number of hours spent on topic**
1. Introduction to drug development a. overview b. FDA and other regulatory agencies c. animals studies	Buncher: Ch. 1, 2, 19, 20	4
2. Bioassay techniques a. parallel line and slope ratio assays b. analysis of variance models c. relative potency and Fieller's theorem d. quantal response assays e. assay validation	Class notes	8
3. Quality control techniques a. control charts b. acceptance sampling c. producer and consumer risk d. OC curves e. AQL and AOQL plans f. Viral safety testing	Class notes	6
4. Pharmacokinetic modeling a. compartmental modeling b. non-compartmental modeling	Class notes; Buncher, Ch. 21	4

c. semi-parametric and non-parametric analyses d. robust estimation techniques e. computer software		
5. Bioequivalence and clinical equivalence studies a. pharmacokinetic studies b. crossover designs c. null and alternative hypotheses d. sample size estimation e. confidence interval approaches f. regulatory requirements	Class notes; Buncher, Ch. 12	2
6. Count data a. virus detection studies b. Poisson modeling and the "rule of threes" c. Clinical studies d. Hypothesis testing	Class notes	2
7. Pharmacoeconomic modeling a. quality of life data b. utility theory c. measuring utilities d. Bayesian and Markov modeling e. QTWIST	Handout	2
8. Pre-clinical studies a. toxicology studies b. efficacy studies c. dose-escalation trials d. analysis of data and design	Buncher, Ch. 2	1
9. Stability testing a. regression models b. accelerated testing	Buncher, Ch. 22	1

Learning Objectives	**MPH Biostatistics Competencies**	**MS Biostatistics Competencies**	**PhD Biostatistics Competencies**
Be able to understand and then use the basic concepts of pharmaceutical drug development as they pertain to statistical evaluations in situations involving actual drug development studies	A5, A6, A7	A2, B5, C1	A1, A2, A4, A5, A8, B1, B2
Be able to employ the principles of statistical bioassay design and analysis in a commercial or academic assay setting	A5, A6, A7, A9	A4, A5, A6, A7, B5, C1	A1, A2, A4, A5, A8, B1, B2
Be able to employ the principles of statistical quality control where necessary in a drug development environment	A5, A6, A7, A9	A4, A5, A6, A7, B5, C1	A1, A2, A4, A5, A8, B1, B2
Understand the statistical issues underlying important drug development concepts such as pre-clinical and stability studies **in order to use** these concepts to design and analyze those types of studies	A5, A6, A7, A9	A4, A5, A6, A7, B5, C1	A1, A2, A4, A5, A8, B1, B2
Be able to employ the basic principles of pharmacoeconomics in the understanding of research in this area and its application to drug development	A7	A5, A6, B5, C1	A1, A5, B1, B2

Note: the text of the competencies will be posted on Moodle for the class in order that students understand how the course learning objectives are related to the specific degree competencies.

Grading: based on midterm (25%), paper(s) (25%), and final (50%)

Midterm will be week of April 25th. It will cover material through the first 4 weeks of class.

Term paper will be assigned mid-quarter and will require some research and a brief write-up, similar to a scientific paper. Also, may be occasional small assignments during the quarter.

Final will be comprehensive (possibly take-home)

Grades assigned on a straight scale: ≥90%=A; ≥70%=B.