THE UNIVERSITY OF ARIZONA
Mel & Enid Zuckerman College of Public Health

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University of Arizona

BIOS 680 Biostatistical Methods I: Clinical Trials/Survival Analysis

Catalog Description: Clinical trials and survival analysis are two critical and relevant topics within the broader area of biostatistics and epidemiology. Clinical trials are conducted on human subjects to evaluate the safety and effectiveness of new drugs, medical devices, or other treatments. On the other hand, survival analysis is a statistical method used to analyze data on the time until an event of interest occurs. It is commonly used in medical research to analyze data on patient survival, disease recurrence, or time to other clinical outcomes. This course deals with methods for clinical trials, including trial design and implementation, as well as survival analysis for time-to-event data. It is essential for students interested in pursuing a career in medical research, biostatistics, or clinical trial design and analysis. (3 units)

Course Topics:

- Fundamentals of Clinical Trials, including:
  - Randomization and Stratification
  - Treatment and Control Groups
  - Inclusion and Exclusion Criteria
  - Ethical Considerations
  - Sample Size Estimation
- Conducting a Survival Analysis, including:
  - Nonparametric Methods
  - Hypothesis Testing
  - Proportional Hazards Regression
  - Regression Diagonostics

Course Objectives: During this course, students will:

- Be presented with fundamental methods for planning, conducting, and analyzing clinical trials, as well as necessary methods to perform time-to-event data analysis.

Learning Outcomes (Competencies Obtained): Upon completion of this course students will be able to:

1. Identify the basic characteristics of a clinical trial and describe the advantages and disadvantages of randomized clinical trials as compared to other epidemiological and clinical investigations.
2. Construct randomization schedules and develop procedures for carrying out randomization.
3. Understand considerations in defining control groups for clinical trials, including the use of placebos.
4. Recognize the advantages and disadvantages of different types of trial designs, e.g., crossover and factorial studies.
5. Determine sample sizes for trials of simple designs and understand ingredients in the sample size determination for more complex designs, including clinical outcome trials and non-inferiority studies.
6. Understand the advantages of intent-to-treat analysis and to differentiate it from analyses such as “per protocol” analysis.
7. Know how to estimate a survival curve.
8. Know how to compare two (or more) survival curves.
9. Understand regression analysis for time-to-event data.