

**University of Washington Department of Biostatistics**  
**7<sup>th</sup> Summer Institute in Statistics for Clinical and Epidemiological Research**

**Module 6: Survival Analysis with Emphasis on Applications to Clinical Trials**

**July 22 – 24, 2020**

- Instructors:  
Ying Qing Chen, PhD (Instructor), email: yqchen@uw.edu  
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- Instruction hours via Zoom:  
Lectures/Labs: 8:30am – 10:00am, 10:30am – 12:00noon  
Break: 10:00am – 10:30am
  
- Course description:  
Censored time-to-event data, where not all subjects experience the event of interest, are common in biomedical research. This module introduces some essential statistical tools for analyzing censored time-to-event data and emphasizes methods for clinical trials. The module will:
  - Introduce important functions, including survival curves, the hazard function, and the median survival time, in analyses of time-to-event data;
  - Review life-table analysis, and introduce one-sample Kaplan-Meier estimation of survival curves;
  - Introduce the two-sample log-rank test, and alternative testing procedures that weight group comparisons differently over the follow-up time interval;
  - Introduce the Cox proportional hazards model for regression analysis of the association between an explanatory variable and a censored event-data outcome;
  - Describe how information is accrued when there is group-sequential monitoring of a clinical trial, and
  - Describe power and sample size calculation for a clinical trial with censored time-to-event outcomes;
  - Discuss other topics, such as competing risks and biased sampling, arising from observational studies, if time permits.

The course will focus on application and understanding the concepts with examples from the literature; mathematical details will be kept to a minimum. Working knowledge of basic probability and statistical concepts will be assumed.

- Course Evaluation:  
Two problem sets, four in-class quizzes, and answer keys will be handed out for practice and self-evaluation.

- Recommended textbooks:  
Kleinbaum, DG (1996) *Survival Analysis: A Self Learning Text*. Springer.  
Hosmer, DW & Lemeshow, S (1998) *Applied Survival Analysis*. Wiley.
  
- Course Calendar:
  - July 22: Problem Set 1 assigned; Quiz 1
  - July 23: Problem Set 2 assigned; Quizzes 2 and 3
  - July 24: Quiz 4
  
- Course Outline:
  - Background
    - Brief history of survival analysis
    - Time-to-event and censoring
    - Life tables
  - Parametric Methods
    - Parameter distributions
    - Likelihood functions and maximum likelihood
  - Kaplan-Meier Curves
  - Log-Rank Tests
  - Cox Proportional Hazards Model
  - Additional Topics