University of Washington Department of Biostatistics 9th Annual Summer Institute in Statistics for Clinical & Epidemiological Research

Module 12: Survival Analysis with Emphasis on Applications to Clinical Trials

July 20 – 22, 2022

• Instructors

Ying Qing Chen, PhD (Instructor), email: yqchensu@stanford.edu Eric R. Morenz (TA), email: emorenz@uw.edu

• Instruction Hours

Lectures: 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 timeto-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 & Klein, M (2012) Survival Analysis: A Self Learning Text, 3rd Ed. Springer.

Hosmer, DW, Lemeshow, S & May, S (2008) *Applied Survival Analysis: Regression Modeling of Time-to-Event Data, 2nd Ed.* Wiley.

• Course Calendar

- July 20: Problem Set 1 assigned; Quiz 1
- July 21: Problem Set 2 assigned; Quizzes 2 and 3
- July 22: Quiz 4

• Course Outline

- Background
 - o Brief history of survival analysis
 - Time-to-event and censoring
 - o Life tables
- Parametric Methods
 - Parameter distributions
 - Likelihood functions and maximum likelihood
- Kaplan-Meier Curves
- Log-Rank Tests
- Cox Proportional Hazards Model
- Additional Topics

• Zoom Meeting Information

Topic: SISCER 2022 Survival Analysis (Chen) Time: July 20 – 22, 2022 08:30 AM Pacific Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android:

https://stanford.zoom.us/j/93899558605?pwd=eCtNZ1Nic05aeUJ3WHREYzdCYXM0Z z09

Password: 855001

Or iPhone one-tap (US Toll): +18333021536,,93899558605# or +16507249799,,93899558605#

Or Telephone: Dial: +1 650 724 9799 (US, Canada, Caribbean Toll) or +1 833 302 1536 (US, Canada, Caribbean Toll Free) Meeting ID: 938 9955 8605 Password: 855001 International numbers available: https://stanford.zoom.us/u/acHmorGxOj

Meeting ID: 938 9955 8605 Password: 855001 SIP: 93899558605@zoomcrc.com Password: 855001

• Slack Channel

https://app.slack.com/client/T015XK8KHEF/C03L3H9NXRA