BSTA 661 Fall 2019

BSTA 661: DESIGN OF INTERVENTIONAL STUDIES
INSTRUCTOR: ALISA J. STEPHENS-SHIELDS, PHD, FALL SEMESTER 2020
TUESDAYS AND THURSDAYS, 1:30-2:50 PM
MEETING: https://bluejeans.com/5105079847

SYLLABUS:

Description: This course is designed for graduate students in statistics or biostatistics interested in the issues underlying the design of interventional studies. General topics include designs for various types of clinical trials (Phase I, II, III), endpoints and control groups, statistical inference in interventional studies, sample size determination, and design considerations for adaptive designs and interventions. Regulatory and ethical issues will also be covered. Students should have a working knowledge of basic biostatistical principles and familiarity with a statistical programming language (e.g. R, SAS). (0.5 course unit, second half of fall semester)

Prerequisites: Permission of instructor

Recommended Text: *Piantadosi S. Clinical Trials: A Methodologic Perspective. Second edition. Wiley, 2005.* Additional readings will be taken from the classic and current literature, including textbooks and journal articles

Supplementary Texts: See next page (optional, students may find helpful for additional reading)

Grading: There will be two homework assignments and a final project. Grading will be based on the homework (50%), final project (35%), and class participation (15%).

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<td>Introduction to Interventional Studies</td>
<td>6.1-6.3,3.1-3.4</td>
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<td>September 3</td>
<td>Lecture 2</td>
<td>Phase I and Phase II Clinical Trials</td>
<td>10.2,10.3.1-2</td>
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<td>SMARTs for Adaptive Interventions</td>
<td>Almirall et al. (2011)</td>
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Texts Recommended for Further Reading on Clinical Trials

Highly-recommended:

Other Texts on Clinical Trials in General:

Specialized Trial Designs:

Sequential/Adaptive Methods and Monitoring:

Related Topics: