

# STAT 321: Methodology in Clinical Trials

The objective of this course is to learn the concepts and methodology used in the design and conduct of randomized clinical trials. Topics to be covered will include the description of main types of trial designs, principles of randomization and stratification, issues in protocol development (defining objectives and endpoints, blinding, choice of control), recruitment and retention, data collection and quality control issues, monitoring, and analyses of trials reports. Textbook material will be frequently supplemented by material from the literature. Guest lecturers will give lectures on power and sample size calculations, life table analysis, quality of life and cost evaluation. Examples from the cardiovascular, pulmonary, and cancer areas will be used when appropriate. The course is intended for biomedical researchers desiring exposure to the clinical-trial field. In order to run this course, minimum 10 students need to register.

## Learning Objectives

- Acquire a fundamental understanding of methodological principles and concepts in clinical trials
- Describe essential elements of clinical trials and use this knowledge to contribute to the successful conduct of a clinical trial
- Read critically clinical trials literature

**Credits:** 3

**Class Type:** Graduate Course

**Program:** Bioinformatics and Data Science