

# CTSC 5720 Clinical Trials: Design and Conduct

**Faculty:** Jeff Sloan, Ph.D.  
**Credits:** 1  
**Quarter:** Winter  
**Prerequisites:** CTSC 5600



*This course is required for the CTS Postdoctoral Master's Degree and Predoctoral programs.*

## **Overview**

This course will focus on the statistical considerations and practical issues involved in the design and analysis of clinical trials. The foundations of and practical considerations involved in drug development in humans will be presented. The Phase I-III paradigm for clinical trials will be discussed, including issues about aims, endpoints, statistical power, early stopping rules, and analytic techniques. There will be a focus on several case studies of clinical trials. Issues about subject selection, study design, masking treatment assignment, outcome measures, goals, and post hoc analyses will be reviewed. The course is delivered through a series of online lectures and in-person discussions

## **Objectives**

- To provide students with knowledge of theoretical and practical considerations that go into the design of a clinical trial.
- To provide students with tools to successfully interpret publications reporting results of clinical trials.
- To provide students with the background to become an effective collaborator with members of a clinical trial study team.

## **Evaluation**

Students will be evaluated on class participation, online quizzes and a group protocol assignment in which students will develop a clinical trial protocol through a series of drafts. At the end of the course each group will present their final protocol to the class.

Students will be expected to spend approximately two to four hours of time per week on this 1-credit course.

Additional online modules related to this topic are available on the [Continuous Professional Development website](#).

For specific dates and times this course is provided, please see the [quarterly detailed course schedule](#).