

Keck School of Medicine of USC

PM 523: Design of Clinical Trials

Units: 3 units

Term–Day–Time: Spring 2021, Wed 9:00 AM-12:00 PM

Location: virtual

Course Coordinator(s):

Name: Todd Alonzo Contact:

talonzo@childrensoncologygroup.org

Office: Office Hours: By Appointment

Name: Cecilia Patino Sutton Contact: patinosu@usc.edu

Office: Office Hours: By Appointment

Course Instructor(s):

Teaching Assistant(s):

Course Description

This course provides an introduction to the fundamentals of clinical trials, including the design, conduct, analysis, interpretation, and reporting of trial results. Topics include brief introduction of Phase I & II clinical trials, commonly used Phase III clinical trials, protocol writing, hypothesis, methods of randomization, blinding, sample size determination, ethics, subject recruitment, data collection, quality control, monitoring outcomes and adverse events, interim analysis, data analysis, issues with data analysis, missing data, meta-analysis, and current advances in clinical trials.

Learning Objectives

This course is intended to provide a basic grounding in all aspects of the conduct and evaluation of clinical trials from the perspective of a research investigator/collaborator/applied biostatistician.

1. Identify key operational requirements and documents needed for a clinical trial before initiating it
2. Effectively design a clinical trial and produce a clinical trial proposal through a protocol and manual of procedures.
3. Identify key operational requirements needed to monitor a trial
4. Produce a sample size estimation of a trial
5. Design and evaluate a safety and outcome monitoring plan
6. Produce and evaluate the statistical section of a clinical protocol
7. Critically appraise clinical trial articles in medical literature
8. Identify strengths and weaknesses in the design of a clinical trial from a study proposal
9. Present the protocol of a clinical trial as a team through an oral presentation

Prerequisite(s): PM510 and PM512

Co-Requisite(s): PM510 and PM512

Concurrent Enrollment:

Recommended Preparation: SAS, STATA, or R background

Teaching & Assessment Methods

Teaching Methods

- Assigned reading/writing (texts)
- Assigned reading (journal or papers)
- Classroom lecture
- Small group discussion
- Group activity
- Student presentation
- Polling questions
- Recorded lecture
- Group project

Assessment Methods

- Short answer
- Oral presentation
- Group assignment

Course Notes

Copies of lecture slides and other class information are posted on Blackboard weekly.

Communication

Technological Proficiency and Hardware/Software Required

Required Materials

Optional Materials

- [Fundamentals of Clinical Trials](#); Fourth Edition, Friedman, Furberg, and Demets. Available online at [Available online at Book Link](#).

Description and Assessment of Assignments

- In class participation: students are expected to participate in lecture and homework discussions individually and in group activities.
- Final exam: a 3-hour, open book, test will be administered near the end of the course. It will include a series of short answer questions and statistical computations.
- Protocol Drafts: all draft versions of the protocol must be submitted through blackboard on the due date before the lecture.
- Final Written Protocol: A written protocol with size 12 font must be uploaded to Blackboard by 9:00 am on April 28, 2021, no exceptions.
- Protocol Presentation: 20 minute PowerPoint presentation. Powerpoint presentation must be uploaded to Blackboard by 7:00 am on April 28, 2021.

Grading Breakdown

Assignment	% of Grade
Final Exam	35
Written Protocol	35
Protocol Presentation	15
Class Participation	15
Total	100

Grading Scale

Course final grades will be determined using the following scale.

A	95-100
A-	90-94
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	59 and below

Course-specific Policies

Assignment Submission

All assignments are to be submitted through Blackboard.

Grading Timeline

Late work

Technology in the classroom

Academic integrity

A grade of zero will be applied to submitted work that does not comply with the USC standards of academic conduct. Such work may not be resubmitted for a new grade. Academic integrity is included at the end of the syllabus.

Attendance

Classroom norms

Expectations on Student Engagement

Students are expected to participate in class discussions.

Course evaluation

Policy on Learning & Assessment Feedback (LAF)

Feedback on examinations will be provided using the following methods. Please indicate which method(s) you will use in the course.

- In-office review (with specific conditions to be defined for each assessment)

Course Schedule: A Weekly Breakdown

Date	Topic	Lecturer
Wed 01/20/21 09:00a - 12:00p	Introduction: Clinical studies vs. clinical trials; Phase I-IV clinical trials, questions (hypothesis); research populations HW #1 and Identify topic for protocol.	Cecilia Patino Sutton
Wed 01/27/21 09:00a - 12:00p	Phase I and II trials; IRB; DSMC; Ethics and Consent; Example of clinical trial protocol HW#2 and Form preliminary hypothesis and specific aims for final project. Lay out primary and secondary hypotheses and primary and secondary outcomes. Propose a study design to test your hypothesis. Submit prior to next lecture.	Todd Alonzo
Wed 02/03/21 09:00a - 12:00p	Basic study design of Phase III clinical trials; randomization, allocation concealment and blinding; Review of Bias HW#3	Cecilia Patino Sutton
Wed 02/10/21 09:00a - 12:00p	Sample size calculations HW#4 and Revise hypothesis, aims, outcomes and designs if needed. Submit revision prior to next lecture.	Todd Alonzo
Wed 02/17/21 09:00a - 12:00p	Systematic Reviews and Meta-Analysis of Clinical Trials HW#5 and Perform sample size calculation for final project and submit the revised protocol prior to next lecture	Cecilia Patino Sutton
Wed 02/24/21 09:00a - 12:00p	Survival Analysis HW#6 and Submit the protocol with revised sample size calculations prior to next lecture	
Wed 03/03/21 09:00a - 12:00p	Baseline assessment, study recruitment, data collection and quality control, form design	Cecilia Patino Sutton

	HW#7 and Produce a draft of Introduction, Background and Preliminary Data sections of your final project.	
Wed 03/10/21 09:00a - 12:00p	Equivalency trials; Non-Inferiority trials, Data analysis. Issues in data analysis: exclusion, withdrawals, covariate adjustment, subgroup analysis. Missing data. HW#8	Todd Alonzo
Wed 03/17/21 09:00a - 12:00p	Monitoring response variables, interim analysis, conditional power HW#9 and Submit a draft of the Research Plan section including data analysis and monitoring plan prior to next lecture	Todd Alonzo
Wed 03/24/21 09:00a - 12:00p	Assessing and reporting adverse events; Participant Compliance; Assessment of health-related quality of life HW#10	Cecilia Patino Sutton
Wed 03/31/21 09:00a - 12:00p	Trials closeout, reporting and interpreting of results; Multi-center trials. HW#11	Cecilia Patino Sutton
Wed 04/14/21 09:00a - 12:00p	Biomarker-driven trials (guest lecturer: Lindsay Renfro)	
Wed 04/21/21 09:00a - 12:00p	Review of recent publication	Todd Alonzo
Wed 04/28/21 09:00a - 12:00p	Student presentations of final team clinical trial protocol Student presentations due, Final written project due	Todd Alonzo
Wed 05/05/21 09:00a - 12:00p	Final Exam	Todd Alonzo Cecilia Patino Sutton

Statement on Academic Conduct and Support Systems

Academic Conduct:

Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in *SCampus* in Part B, Section 11, “Behavior Violating University Standards” policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in *SCampus* and university policies on scientific misconduct, <http://policy.usc.edu/scientific-misconduct>.

Support Systems:

Student Counseling Services (SCS) – (213) 740-7711 – 24/7 on call

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention. engemannshc.usc.edu/counseling

National Suicide Prevention Lifeline – 1 (800) 273-8255

Provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. www.suicidepreventionlifeline.org

Relationship and Sexual Violence Prevention Services (RSVP) – (213) 740-4900 – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender-based harm. engemannshc.usc.edu/rsvp

Sexual Assault Resource Center

For more information about how to get help or help a survivor, rights, reporting options, and additional resources, visit the website: sarc.usc.edu

Office of Equity and Diversity (OED)/Title IX Compliance – (213) 740-5086

Works with faculty, staff, visitors, applicants, and students around issues of protected class. equity.usc.edu

Bias Assessment Response and Support

Incidents of bias, hate crimes and microaggressions need to be reported allowing for appropriate investigation and response. studentaffairs.usc.edu/bias-assessment-response-support

The Office of Disability Services and Programs

Provides certification for students with disabilities and helps arrange relevant accommodations. dsp.usc.edu

Student Support and Advocacy – (213) 821-4710

Assists students and families in resolving complex issues adversely affecting their success as a student EX: personal, financial, and academic. studentaffairs.usc.edu/ssa

Diversity at USC

Information on events, programs and training, the Diversity Task Force (including representatives for each school), chronology, participation, and various resources for students. diversity.usc.edu

USC Emergency Information

Provides safety and other updates, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible. emergency.usc.edu

USC Department of Public Safety – UPC: (213) 740-4321 – HSC: (323) 442-1000 – 24-hour emergency or to report a crime.

Provides overall safety to USC community. dps.usc.edu