Prerequisites: CTR

F. Study population, inclusion/exclusion criteria, screen failures, strategies for recruitment and retention, and participant discontinuation/withdrawal
G. Description of study intervention including dosing and administration procedures
H. Measures to minimize bias, including randomization and blinding
I. Study assessments and procedures, including efficacy assessments, safety and other assessments, and definition of adverse events and serious adverse events
J. General statistical considerations
K. Monitoring and quality considerations, including safety oversight, clinical monitoring, quality assurance and control, protocol deviations, data handling and record keeping, study discontinuation and closure
L. Regulatory, ethical and study oversight considerl3 (d)-0.8 (BDC 5)-0 (r)c,rl3 (d)-02 (n)-0.8(d(u)10.2 g8(/LBody <

A. Evaluate the strengths and weaknesses of each type of study design in addressing specific research questions and hypotheses
B. Analyze case studies to illustrate the application of different trial designs in clinical research
C. Compare practical considerations, such as cost, time, and resource constraints associated with prospective, retrospective, and combination types of clinical trials

The textbook and other instructional material will be determined by the instructor.