Using Contour Plots to Assess the Sensitivity of Clinical Trial Design Assumptions

Sample size calculations are an important part of the design of any clinical trial. These calculations ensure a sufficient number of patients to detect a clinically-meaningful difference between two treatments with high probability. Perhaps less-often discussed, the sample size exercise is important so that resources are not wasted studying too many observations to test a particular hypothesis. Since patients may be randomized to doses of a novel treatment with a limited safety profile, or a placebo which provides no therapeutic benefit, sample size calculations in clinical trials come with an ethical burden not experienced in many subject-matter areas. Unlike many textbooks that perform a single calculation to design an experiment, the sample size of a clinical trial should be determined using as much data as is available, over a range of assumptions, and with input from clinical colleagues. Graphical techniques are often utilized to summarize power and sample size calculations. We propose the use of contour plots to better assess, report and communicate the sensitivity of fixed and adaptive clinical trial design assumptions. Further, contour plots can be used to better enable discussions involving the probability of technical success for a proposed trial. An example clinical trial in plaque psoriasis will be used for motivation, and we will consider various adaptations to a fixed trial design.

Thursday, October 12, 2017
3:30 pm - 4:30 pm
Blue Cross and Blue Shield of North Carolina Foundation Auditorium