Continuous Monitoring in a Clinical Trial: A Fully Sequential Approach

Abstract

In this talk we introduce Sequential Patient Recruit Monitoring (SPRM), a new and efficient accrual monitoring method. Built on a sequential probability ratio test using Woodroofe boundaries, SPRM is an evidence-based, decision-support tool that provides opportunity for corrective action in a timely manner. Suitable for the modern, centralized data management environment, it requires minimal effort to maintain. The method can easily accommodate protocol changes involving sample size and/or recruitment period modification.

We also propose Sequential Event Rate Monitoring (SERM), a new continuous monitoring method for the event rate of time-to-event data in a clinical trial. SERM gives an early warning if the target rate is unlikely to be achieved by the end of study. Since SERM is designed to monitor the overall event rate, blindness of the trial is preserved. If necessary, the method could suggest the number of extra recruitments required for the planned number of primary events. It can also be used to estimate an extension of the follow-up time. We illustrate the methods using data from a well-known Phase III clinical trial.

Bio: Dr. Kim is a mathematical statistician at the Office of Biostatistics Research within National Heart, Lung, and Blood Institute (NHLBI), Bethesda, Maryland. She received PhD in Statistics from the University of Michigan, Ann Arbor in 2003. Before joining NIH in 2013, she held a faculty position at Virginia Tech. Her research interests include: sequential methods in clinical trials, change-point inference, statistical genetics and bioinformatics. At NIH, she has been involved in large NHLBI-sponsored clinical trials and intramural projects, provided scientific reviews of protocols and expert opinions for these projects, and developed novel methodologies for applications in clinical trials. Also, Dr. Kim has years of experience in collaborative research in other areas including mobile health, bioengineering, health services, and environmental science.

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