Real-Time Prediction in Clinical Trials: A Statistical History of REMATCH

Randomized clinical trials often include one or more planned interim analyses, during which an external monitoring committee reviews the accumulated data and determines whether it is scientifically and ethically appropriate for the study to continue. With survival-time endpoints, it is often desirable to schedule the interim analyses at the times of occurrence of specified landmark events, such as the 50th event, the 100th event, and so on. Because the timing of such events is random, and the interim analyses impose considerable logistical burdens, it is worthwhile to predict the event times as accurately as possible. Prediction methods available prior to 2001 used data only from previous trials, which are often of questionable relevance to the trial for which one wishes to make predictions. With modern data management systems it is often feasible to use data from the trial itself to make these predictions, rendering them far more reliable. This talk will describe work that some colleagues and students and I have done in this area. I will set the methodologic development in the context of the trial that motivated our work: REMATCH, a randomized clinical trial of a heart assist device that ran from 1998 to 2001 and is considered one of the most rigorous device trials ever conducted.