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

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3:30-4:30pm, New PI 6th Floor Multipurpose Room (6602)
Light refreshments provided

Abstract

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 was considered one of the most rigorous and expensive device trials ever conducted.

Biographical Note

Daniel Heitjan earned his PhD in Statistics in 1985 from the University of Chicago. He has served on the faculties of UCLA (1985–1988), Penn State University (1988–1995), Columbia University (1995–2002), and is now at the University of Pennsylvania, where he is Professor of Biostatistics and Statistics and Director of the Biostatistics Core Facility in the Abramson Cancer

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[1] The PI Biostatistics Seminar Series is held on Tuesdays at New York State Psychiatric Institute. If you are interested in receiving regular announcements for our seminars in the future, or if you need further information, please contact Jina James (jamesji@nyspi.columbia.edu, (212) 543-5589).

Center. Dr. Heitjan is an associate editor of *Statistics in Biopharmaceutical Research*, *Clinical Trials*, and *Communications for Statistical Applications & Methods*, and a statistical editor of *Journal of the National Cancer Institute*. His research interests include clinical trial design, Bayesian methods, the theory of inference with incomplete data, and statistical methods in health economics, pharmacogenomics, and smoking cessation research. He was formerly a member of the AHRQ Health Care Technology & Decision Science study section. He was Program Chair of the 2005 Joint Statistical Meetings in Minneapolis, 2009 Chair of the American Statistical Association's Biometrics Section, and is 2013 President of the Eastern North American Region of the International Biometric Society. He was elected a Fellow of the ASA in 1997 and of the Institute of Mathematical Statistics in 2012.