

Preface

Continuing the tradition, once every half decade, of hosting a major biostatistical meeting, where thought leaders can gather to address scientific issues of current and compelling importance, the organizing committee and sponsors held the Fourth Seattle Symposium on Biostatistics on November 22 and 23, 2010. The topic area for this successful meeting was clinical trials, with focus on the use of biomarkers, issues in multi-regional clinical trials, and identifying and addressing safety signals. The event was sponsored by Axio Research, Bristol-Myers Squibb, Genentech, Novartis and Onyx and was co-sponsored by the UW School of Public Health and the Division of Public Health Sciences at the Fred Hutchinson Cancer Research Center (FHCRC). The symposium featured keynote lectures by Robert O'Neill, Ross Prentice and Robert Temple, as well as invited talks by Jesse Berlin, Christy Chuang-Stein, David DeMets, Bill DuMouchel, Susan Ellenberg, Thomas Fleming, Laurence Freedman, Margaret Pepe, Steve Self, Richard Simon, Bruce Weir, John Whittaker and Janet Wittes. Invited panelists included Jesse Berlin, Bruce Binkowitz, Christy Chuang-Stein, Bill DuMouchel, Susan Ellenberg, Thomas Fleming, Henry Fuchs, Dominic Labriola, Robert O'Neill, Robert Temple and Janet Wittes. There were 200 attendees at the symposium. In addition, more than 100 people attended short courses delivered on November 20 and 21, 2010. At these short courses, "Statistical Design of Sequential Clinical Trials in R" was taught by Scott Emerson and Dan Gillen, "The Use of Genetic Marker Data in Clinical Trials" was taught by Bruce Weir and Patrick Heagerty, "Data Monitoring Committees: A Practical Approach" was taught by Susan Ellenberg, Thomas Fleming and David DeMets, "Statistical Evaluation of Markers for Classification and Prediction" was taught by Margaret Pepe and "Practice Issues in the Conduct and Reporting of Large-Scale Clinical Trials: The Women's Health Initiative Experience" was taught by Garnet Anderson and Andrea LeCroix.

When the UW School of Public Health was formed in 1970, biostatistics as a discipline was very young. In the subsequent 40 years, both the field and the UW Department of Biostatistics have evolved in many exciting ways. The department had only seven faculty when it moved from the School of Medicine to the new School of Public Health and Community Medicine in 1970. The faculty roster

currently lists 49 regular and research faculty and 34 adjunct and affiliate faculty. Ed Perrin was the Department Chair in 1970, succeeded by Donovan Thompson, Norman Breslow, Thomas Fleming and presently Bruce Weir. The faculty have been actively involved in methodological and collaborative research in addition to graduate teaching. The choice of *Clinical Trials* as the theme for the *Fourth Seattle Symposium in Biostatistics* was a tribute to the significant contributions made by the UW and FHCRC faculty to this important area of statistical science.

The Symposium Organizing Committee consisted of Susan Ellenberg, Scott Emerson, Nathalie Ezzet, Thomas Fleming (Chair), Henry Fuchs, Lee Hooks, Dominic Labriola, Michael Ostland, Ross Prentice and Bruce Weir. The staff of the Department of Biostatistics, especially Sandra Coke, provided great administrative support to the symposium. The UW School of Public Health Dean Howard Frumkin, the Department Chair Bruce Weir and the Organizing Committee Chair Thomas Fleming delivered the opening remarks. The scientific sessions were chaired by Bruce Weir, Scott Emerson, Thomas Fleming, Lee Hooks, Henry Fuchs, Michael Ostland, Susan Ellenberg, Nathalie Ezzet and Dominic Labriola. We are grateful to the aforementioned people as well as all the speakers and participants for making the symposium a great success.

This volume contains most of the papers presented at the symposium, as well as some of the science presented at the short courses. These papers encompass recent methodological advances on several important topics, summaries of the state of the art of methodology in key areas of clinical trials, as well as innovative applications of the existing theory and methods. This collection serves as a reference for those working in several key areas of clinical trials.

Each of the 12 papers in this volume was referred by two or three peer reviewers, and their comments were incorporated by the authors into the final versions of the papers. The referees are listed at the end of this book. We are indebted to them for their time and efforts. We also appreciate the guidance and assistance by Marc Springer of Springer-Verlag.

<http://www.springer.com/978-1-4614-5244-7>

Proceedings of the Fourth Seattle Symposium in

Biostatistics: Clinical Trials

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2013, VIII, 249 p. 29 illus., 13 illus. in color., Softcover

ISBN: 978-1-4614-5244-7