Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

Einladung zum

Biometrischen Kolloquium

am Mittwoch, dem 07.11.07, um 15:30 Uhr (s.t.)

im Seminarraum (Raum 88.03.513) der
Besonderen Einrichtung für Medizinische Statistik und Informatik
(MSI) der Medizinischen Universität Wien
Spitalgasse 23, 1090 Wien

Es spricht Herr Dr. Willi Maurer, Novartis Pharma AG, zum Thema:

Sources of Multiplicity in Adaptive Designs

Wir ersuchen um zahlreichen Besuch für diesen sehr interessanten und aktuellen Vortrag.

Werner Brannath   Thomas Lang
Präsident   Sekretär

Sources of Multiplicity in Adaptive Designs

Willi Maurer, Novartis Pharma AG

Sources of multiplicity in adaptive seamless designs and their implications for control of type I errors and decision making will be presented. Repeated testing of the same hypotheses in a group sequential setting with early rejection or acceptance of hypotheses at interim analyses, change of design features (e.g., sample size) and testing of multiple initial hypotheses (e.g. with respect to multiple comparisons), may need to be taken into account simultaneously. For each of these cases methods exist to account for type I error control or estimation. We will discuss some dependences between these sources of multiplicity, in particular sample size re-estimation based on observed effects and early stopping. Dealing with a combination of them within an adaptive trial often can be done in different ways. Options will be compared together with aspects of their performance characteristics and possible operational restrictions as well as their suitability to maintain a confirmatory nature of the trial.

Willi Maurer, PhD, was global Head of Statistical Methodology in the Clinical Development Department of Novartis Pharma AG, Basel, Switzerland until his retirement end of 2006 and is now a senior statistical consultant to the Biostatistics Dept. of Novartis.

He finished his studies of mathematics at the Swiss Federal Institute of Technology in Zürich (SFIT) with a thesis in decision theory in 1972. After postdoctoral studies, research and teaching activities at the Departments of Statistics at Yale University, Iowa State University and the University of Florida and applied work as a statistician he investigated the application of discrete mathematics and algebraic geometry to probability theory and exploratory data analysis during an appointment at the Research Institute for Mathematics at SFIT from 1976 to 78.

From 1976 to 2002 Dr. Maurer lectured applied statistics at the Department of Pharmacy and other Departments of SFIT. He joined the Medical Research Department of Sandoz in 1978 where he worked primarily on clinical projects in the CNS and immunology area before becoming head of Biostatistics in 1983. In 2000 he became head of the newly founded statistical methodology group in Novartis. He is especially interested in the development and application of novel statistical methodology related to multiplicity and adaptive designs that takes into consideration the interdisciplinary, ethical, economical and regulatory challenges to be faced in the design, analysis and interpretation of clinical trials.