Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

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Einladung zum

Biometrischen Kolloquium

am Montag, 20. Oktober 2008, um 16 Uhr (pünktlich)

in der Informatikbibliothek (Ebene 3, Raum 88.03.806) der Besonderen Einrichtung für Medizinische Statistik und Informatik (MSI) der Medizinischen Universität Wien
Spitalgasse 23, 1090 Wien

Es spricht Herr Dr. Zachary Skrivanek (Eli Lilly & Company, IN, USA) zum Thema:

A Seamless 2/3 Design Incorporating a Clinical Utility Index

Wir ersuchen um zahlreichen Besuch.

Thomas Lang
Präsident

Georg Heinze
Sekretär

A Seamless 2/3 Design Incorporating a Clinical Utility Index

Keywords: adaptive design, clinical utility index, dose-finding, seamless phase 2/3 design, Bayesian decision analytic, inferentially seamless

Diabetes is a disease with well understood and validated biomarkers that have been used in clinical trials for decades to assess the safety and efficacy of diabetes therapies. Consequently, adaptive designs are well suited for learning about the dose response of a diabetes drug and providing confirmatory evidence for the safety and efficacy of the optimal dose(s). We will discuss the design of a novel adaptive, inferentially seamless phase 2/3 study for an experimental drug to treat diabetes. The design employs a Bayesian Analytical approach to allocate patients to a set of doses of the experimental drug and to determine if there are 1-2 doses that could be continued to be studied for the purposes of "confirming" safety and efficacy of those doses. The preference for a dose is determined by a Clinical Utility Index, which balances the select efficacy and safety measures. The algorithm is completely pre-specified and the operating characteristics were assessed via simulation. This design was developed through iterative simulations that involved key decision makers who would normally have input as to what doses were to be selected for confirmatory trials. It involved much more apriori planning than would be required for a typical fixed design. We will discuss the differences between this approach of designing a study and the traditional fixed design approach. We will also discuss the mathematical form of the Clinical Utility Index and compare it to alternative derivations.

Dr. Skrivanek graduated with a Ph.D. in biostatistics from Ohio State University and a B.S. in Industrial and Labor Relations from Cornell University. Dr. Skrivanek's research interests started in genetic linkage analysis. He has published several papers and presented at Joint Statistical Meetings in this area. He wrote software in C, Sequential Imputation for Multi Point Linkage Estimation (SIMPLE), to implement the methods that he developed and still consults people on this topic and/or using the software. He joined Eli Lilly in 2002 where he contributed to the development of Endocrine drugs and related biomarkers. He transitioned to a product team where he is the lead statistician for a diabetes drug. He has played a leading role in developing a seamless phase 2/3 study which will contribute to the overall data package for this compound. Dr. Skrivanek is also chair of a lecture series, "Pharmaceutical Statistics", which is taught as part of the doctoral program at IUPUI (Indiana University Purdue University Indianapolis).