Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz
http://www.meduniwien.ac.at/wbs/

Einladung zum

Biometrischen Kolloquium

am **Donnerstag, 24. Jänner 2013** um **16:30 Uhr** (s.t.)

im Seminarraum (Ebene 3, Raum 88.03.513) des
Zentrums für Medizinische Statistik, Informatik und Intelligente Systeme (CeMSIIS)
der Medizinischen Universität Wien, Spitalgasse 23, 1090 Wien
(Plan siehe http://www.muw.ac.at/cemsiis/allgemeines/anschrift/)

Vortragender:

Frank Miller
Stockholm University

Sample size Re-estimation and Bias

Wir freuen uns auf zahlreichen Besuch.

Gerhard Svolba
Präsident

Franz König
Sekretär

Sample size Re-estimation and Bias

Frank Miller
Stockholm University

Abstract:

Sample size calculations for clinical studies are often subject to substantial uncertainty due to limited prior information on the size of nuisance parameters such as variances or event rates. A possibility to deal with this uncertainty is to estimate the nuisance parameter during the study. Then it is possible to re-estimate the sample size based on this interim information.
In this presentation we consider sample size re-estimation both based on a single interim analysis and based on continuously monitoring the variance. We describe the bias of the variance estimator and the significance test at the end of the study that occurs after this re-estimation. We explain why the bias occurs.

In a randomized, double-blind study, we distinguish between unblinded and blinded sample size re-estimation. Blinded sample size re-estimation does not require breaking the treatment code during the ongoing study. We show that the blinded procedures do not suffer from the same bias for the significance test observed after unblinded sample size re-estimation. However, the variance estimator at the end of the study is still biased. We discuss consequences and open research problems in this context.

Parts of this presentation are joint work with Tim Friede, Dept. of Medical Statistics, University Medical Center Göttingen, Germany.

References:

Friede, T., Miller, F. (2012): Blinded continuous monitoring of the nuisance parameter in clinical trials. J. Royal Stat. Soc. – Series C, 61, 601-618.

Miller, F. (2005): Variance estimation in clinical studies with interim sample size re-estimation. Biometrics, 61, 355-361.