Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

http://www.meduniwien.ac.at/wbs/

Einladung zum

Biometrischen Kolloquium

am Dienstag, dem 5. Mai 2011 um 16:00 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:

Martin Wolfsegger (Baxter Innovations GmbH, Wien):

**Assessing Systemic Drug Exposure in Repeated Dose
Toxicity Studies in the Case of Complete and Incomplete
Sampling**

Wir freuen uns auf zahlreichen Besuch.

Georg Heinze
Präsident

Assessing Systemic Drug Exposure in Repeated Dose Toxicity Studies in the Case of Complete and Incomplete Sampling

Martin Wolfsegger

The presentation will provide an introduction to toxicokinetics, which is a regulatory requirement in the drug development process, with a focus on repeated dose toxicity studies which are performed to characterize the toxicological profile of a test compound following repeated administrations. The findings and interpretations from these systemic exposure studies in animals are essential for designing subsequent studies and evaluating the safety of the test item for humans. Blood samples for assessment of systemic exposure are usually collected on day one and at the end of the study with multiple dosings of the compound in between. Restrictions in blood volume often require an incomplete sampling design, in which each animal contributes sample measurements at some but not all time points. An estimator and a corresponding confidence interval for the ratio of the area under the concentration versus time curves (AUCs) will be presented to quantify the difference in exposure between first and repeated administration that is applicable in such sparse sampling designs as well as in complete data situations. Asymptotic and simulated statistical properties of the proposed estimator, which incorporates the dependencies of measurements between first and repeated dosings as well as the dependency inherent in repeated sampling for each dosing, will be presented.