

**Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz**
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Einladung zum

BIOMETRISCHEN KOLLOQUIUM

am **Montag, 6. Oktober 2014** um **11:00 Uhr** (s.t.)

in der Informatik-Bibliothek (Ebene 3, Raum 88.03.806) 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/>)

Vortragende:

GERALDINE RAUCH

Universitätsklinikum Heidelberg, Medizinische Biometrie

**CHANCES AND CHALLENGES OF COMPOSITE ENDPOINTS -
NEW METHODS TO OVERCOME PLANNING, ANALYSIS AND
INTERPRETATION PROBLEMS**

Wir freuen uns auf zahlreichen Besuch.

Franz König
Präsident

Stephan Lehr
Sekretär

GERALDINE RAUCH

CHANCES AND CHALLENGES OF COMPOSITE ENDPOINTS - NEW METHODS TO OVERCOME PLANNING, ANALYSIS AND INTERPRETATION PROBLEMS

Abstract:

Composite endpoints are often used as primary efficacy endpoints, particularly in the field of oncology and cardiology. These endpoints combine several time-to-event variables of interest within a single time-to-first-event outcome. Thereby, it is intended to enlarge the expected effect size and thus to increase the power of the clinical trial. However, the interpretation of composite endpoints can be difficult, if the effects of the single components are of different magnitude or even point in adverse directions. Therefore, it might not be adequate to judge the efficacy of the new intervention exclusively on the composite effect.

There exist two main approaches to solve this problem: On the one hand, a possible solution might be to use a weighted effect measure and to assign higher weights to the more harmful components.

On the other hand, the most relevant components could also be addressed within an adequate multiple testing strategy. For both approaches, it must be kept in mind, that the individual components usually define competing risks.

Moreover, a particular challenge is that valid parameter assumptions for planning purposes are usually based on a high level of uncertainty, as the number of required parameters increases with the number of components in a composite endpoint.

In this talk, several new strategies to solve the above problems are presented and compared. The new methods are also discussed with respect to the current guidelines.