Multivariate and multiple testing of hypotheses - what is preferred in the analysis of clinical trial data and why?

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While traditionally, confirmatory clinical trials often had a single univariate clinical endpoint, recent trends show a growing number of such trials with multiple endpoints. The reasons for this are an increased interest in safety parameters, improved biomarker assessment technology and an increased number of trials with active comparators as the control group, where the improvement over the existing standard-of-care is not easily characterized by a single measurement.

Regarding the confirmatory analysis of the treatment effects, we have to make a choice between multivariate and multiple hypothesis testing. This talk will review similarities and differences between the two approaches. In lower-dimensional situations, there often is an interest in the individual endpoints. Hence multiple methods that easily facilitate confirmatory statements about the individual endpoints with strong familywise error rate control (Maurer et al., 2011) are often preferred.

In higher-dimensional situations, multiple methods turn out to be too conservative. Additionally, there is usually less interest in the individual endpoints, such that the multiple testing concept of *consonance* (Gabriel, 1969) is less relevant. In this situation, the advantages of multivariate methods (Srivastava, 2002, 2009) may carry more weight.

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