ZÜRCHER KOLLOQUIUM ÜBER ANWENDUNGSORIENTIERTE STATISTIK

Invitation to a talk

Title **Sensitivity Analysis for Longitudinal Clinical Trials**

Speaker **Herbert Thijs**
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Date, Time Thursday, June, 19, 2003, 16.15 – ca. 17.30

Room Zentrumsgebäude der Universität, **KOL E 18**

Abstract

In longitudinal studies, dropouts are frequent, i.e. subjects who terminate the study early. This has to be considered in the modelling process. A dropout process is said to be completely random (MCAR) if the dropout is independent of both unobserved and observed data and random (MAR) if, conditional on the observed data, the dropout is independent of the unobserved measurements; otherwiese the dropout process is termed non-random (MNAR). In clinical trials the MCAR assumption is made frequently and standard methodology includes Last Observation Carried Forward (LOCF), Complete Case (CC) analysis, etc. Likelihood-based methods are available for the case MAR.
For a non-random dropout, a wholly satisfactory analysis is not possible. One approach is to postulate a model for the non-random dropout mechanism, and there exists a considerable literature in this direction. Subsequently, there was a growing awareness that these models often rest on strong assumptions and relative little empirical evidence. Thus methods have been developed to study the sensitivity of the results with respect to model assumptions. Based on a case study, we will stress the major drawbacks of simple LOCF or CC analysis, and make a comparison with a stronger MAR analysis. Further, we will treat sensitivity issues towards MAR and MNAR models and introduce some recent sensitivity tools.

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