Multi-stage gatekeeping procedures with clinical trial applications

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This talk introduces a general approach to constructing gatekeeping procedures for multiple testing problems arising in clinical trials with hierarchically ordered objectives (primary/secondary endpoints, dose-control comparisons, etc). The approach is applied to set up gatekeeping procedures based on popular multiple tests (Holm, fallback and Hochberg tests) and parametric tests. The resulting procedures have a straightforward multi-stage structure that facilitates the implementation of gatekeeping procedures and communication of the results to non-statisticians. The approach can be further extended to account for logical restrictions among multiple analyses. The general approach is illustrated using clinical trial examples.

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