**Evaluation of statistical approaches for comparability and similarity studies**

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Statistical comparability studies are an important topic in several scientific fields, including pre-post change assessment, biosimilarity evaluation or scale-down model qualification.

The objective of this talk is to present the performance evaluation of current and alternative comparability methods, based on Operating Characteristics approaches as recommended in EMA Reflection paper. The statistical methods studied are equivalence tests (TOSTs) and statistical intervals (Quality Ranges), both for parametric and non-parametric situations.

The evaluation was done in exhaustive simulations which covered different situations- paired test and reference samples, balanced and unbalanced test and reference sample sizes- for normal- and non-normal data and a set of scenarii regarding differences in mean and variance.

Decision trees have been developed from these simulation results as indicative analysis basis.

To be noted, in the EMA guideline it is recommended to include in the protocol a justification of the choice of the statistical methodology, depending on the similarity condition (for example comparability in means or comparability in ranges of individual values) and Operating Characteristic curves describing the corresponding false positive and false negative probabilities. In addition, complementary topics for future evaluations and amendments are suggested.