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TITLE: Statistical approaches for comparability of stability data

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

A particular challenge in this context is the comparability of stability data, ie. showing that batches from different sources or before and after a manufacturing change show the same kinetic profile when put on stability. Even though comparability of stability is far less straight forward that comparability of release, we aimed to harmonize as much as possible, proposing a decision tree under consideration of different situations with regards to number of batches, temperatures and time points.

In case of a single storage condition this includes regression control charts and an Analysis of Covariance as described in the ICH Q1, including an additional factor.

If there are at least 3 temperatures (usually long-term, accelerated and stress) available for the reference condition, we propose advanced kinetic modelling to build a temperature dependent kinetic model and compare the individual stability measurements from the test batches with this model. Different experimental situations are used to illustrate the capability of this approach.

BRIEF SPEAKER BIO: A physicist by education, Birgit Niederhaus worked on statistical topics for a few years at the Psychology Department of the University Marburg, the Biology Department of the University Bochum and at Biofrontera, a small biotech company. In 2005 she joined Sanofi as a biostatistician, where she worked for different areas of Nonclinical Statistics. During the first years this also included research and toxicology, since 2010 she is focusing on CMC topics. 2023 she moved from R&D to MSAT, where she works in the statistical team in the global Data Science organization. In this role her main expertise includes standardization and harmonization of practices and advice for statisticians in other part of the organization for example regarding bioassays, method validation, statistical process control and comparability topics.