Einladung zum virtuellen Biometrischen Kolloquium

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SOME POSSIBLY USEFUL THOUGHTS ON BIOEQUIVALENCE ASSESSMENTS IN THE CASE OF SPARSE SAMPLING

14. Oktober 2020, 9:15h

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HOST: Susanne Strohmaier

ABSTRACT:
In traditional bioequivalence (BE) analysis, the confidence interval inclusion principle is applied on the ratios of geometric means of the area under the concentration-time curves (AUC) and the maximal concentration (Cmax), derived from PK studies with rich sampling using the non-compartmental approach (NCA) to test for equivalence in those PK metrics. This standard approach is not feasible in the case of sparse sampling. This talk will address some challenges regarding establishing bioequivalence in incomplete sampling designs from a technical as well as regulatory point of view.

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