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TITLE

THE APPLICATION OF BAYESIAN/ FREQUENTIST ANALYSIS IN BIOEQUIVALENCE/ BIOAVAILABILITY STUDIES

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In spite of the increased application of Bayesian methodology in pharmaceutical industry, frequentist methodology still plays dominant role in bioequivalence (BE) and bioavailability (BA) studies. BE/BA testing is unique in pharmaceutical statistics compared to the usual hypothesis test. The confidence interval approach between test and reference treatments is widely used for decision making with a pre-defined BE/BA boundary. This project takes advantage of Bayesian predictive capability to provide a quantitative solution to one common question in drug development: what is the probability to demonstrate bioequivalence for a hypothetical trial given the observed data in a pilot study? This application can be easily extended to BA, superiority, or non-inferiority cases. The methods compared were the frequentist linear mixed effect model and the Bayesian solution. We hope this work will motivate biopharm statisticians to be more enthusiastic about conducting Bayesian analysis in the near future. In addition, the symmetric and asymmetric precision ranges of estimated clearance to determine the study size in pediatric BA studies using frequentist method were discussed. The symmetric precision in log scale was recommended in sizing pediatric BA studies.