

# **A Bayesian Approach to Average Bioequivalence**

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## **Abstract:**

In recent years, Bioavailability studies for assessment of bioequivalence between two or more drug formulations have become very popular in drug development. The determination of bioequivalence of two or more competing drugs is very important in the pharmaceutical industries because the regulatory agencies such as Food and Drug Administration allow a generic drug to be marketed only if its manufacturer can demonstrate that the generic product is bioequivalent to the brand-name product. However, the current practice for the assessment of bioequivalence suffers from certain serious drawbacks. In this talk, I will introduce a Bayesian approach to assess average bioequivalence of two drugs. We will discuss several advantages of Bayesian methods. The new procedure is applied and evaluated using real data sets from FDA. Future research problems will also be discussed.