STATISTICAL METHODS FOR ASSESSMENT OF
INDIVIDUAL/POPULATION BIOEQUIVALENCE

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Abstract
In recent years, as more generic drug products become available, it is a concern whether
generic drug products approved based on the current regulation of average bioequivalence
will have the same quality, safety and efficacy as that of the brand-name drug product. In
addition, it is also a great concern whether the approved generic drug products of the same
brand-name drug product can be used interchangeably. In practice, drug interchangeability
can be classified as either drug prescribability or drug switchability. In its recent draft
guidance, the US FDA recommends that population bioequivalence (PBE) and individual
bioequivalence (IBE) be assessed using the method proposed by Hyslop, Hsuan, and Holder
(2000) to address drug prescribability and drug switchability, respectively. The US FDA
suggests that a 2x4 crossover design be considered for assessment of PBE and IBE, while a
2x3 crossover design may be used as an alternative design. In this talk, a brief introduction of
the idea, concept and background of PBE and IBE will be provided. A comprehensive review
of the FDA draft guidances will also be discussed. In addition, detailed statistical procedures
for assessment of IBE/PBE under various crossover designs will be provided.