

Adaptive Design for Bioequivalence Studies

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SBIA: A Deep Dive: FDA Draft Guidance on Statistical Approaches
to Establishing Bioequivalence
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Outline

- What is an Adaptive Design?
- Advantages of Adaptive Design
- Limitations of Adaptive Design
- How to Design and Conduct an Adaptive Study
- Key Message

What is an Adaptive Design?

Clinical trial design

- prospectively planned modifications to one or more aspects of the design
- based on accumulating data from subjects in the trial

Example: Potvin's methods (Potvin et al 2008)

Advantages of Adaptive Design

When appropriately implemented, it can

- Provide ethical advantages
- Increase statistical efficiency
- Reduce resources used
- Decrease time to study completion
- Increase the chance of study success

Limitations of Adaptive Design

- May need certain statistical methods to avoid
 - increasing the chance of erroneous conclusions
 - introducing bias in estimates
- For complex adaptive designs,
 - such methods may not be readily available.
- The decision to use an adaptive design
 - At the applicant's discretion

How to Design and Conduct an Adaptive Design

- Details – completely pre-specified and documented
- Scientifically justified
 - published literature or simulation results
- Ensure study integrity appropriately maintained
- Refer to “Adaptive Design for Clinical Trials of Drugs and Biologics Guidance for Industry”
- Contact the Agency early - discuss complex adaptive design



Key Message

**Pre-Specify Your Statistical
Analysis Plan**

Be Scientifically Justified!