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Sample size in biosimilar drug product development

Shein-Chung Chow
Center for Drug Evaluation and Research-US FDA, USA

For the approval of biosimilar products, the United States Food and Drug Administration (FDA) recommends a stepwise approach for obtaining the totality-of-the-evidence for assessing biosimilarity between a proposed biosimilar product and its corresponding innovative (reference) biologic product. The stepwise approach starts with the assessment of analytical similarity followed by animal studies for toxicity, pharmacokinetics and pharmacodynamics (PK/PD) for pharmacological activities, immunogenicity and clinical studies for safety and efficacy. At each step, study endpoint and similarity margin for demonstration of biosimilarity are different. In this presentation, we will focus on sample size determination at each step of biosimilar product development. For illustration purpose, we will focus on the discussion of the FDA's proposal (by adjusting similarity margin and variability associated with reference product) for selecting an appropriate sample size for analytical similarity assessment in biosimilar product development.

gerd.kaupp@uni-oldenburg.de