

Design Stability Studies to Reduce Costs: Matrixing and Bracketing

Stability studies are expensive and time consuming. Recent ICH Stability Guidelines allow matrixing and bracketing concepts to reduce the overall cost of stability program. Most examples are for long-term studies, the concepts could also be applied to short term accelerated studies and/or formulation development in early drug development phases. Discussions are also focused on possible applications to marketed product stability program and new drug product application.

- Define bracketing and matrixing
- Examine possible matrixing designs for stability studies
- Review Q1D for ICH requirements for bracketing and matrixing
- Identify the benefits and drawbacks of bracketing and matrixing
- Discuss matrixing applications for stability submission

Exercise: Propose a Sample Matrix for a New Drug Based on ICH Q1D

Exercise: Discuss Matrixing Strategies for Stability Submission