

## **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***