

Overcoming challenges in clinical biomarker development**Xuemei Zhao**

Merck Research Laboratories, USA

The utility of various types of clinical biomarkers is to aid decision-making in drug development. After a pre-clinical candidate is approved for development in clinical studies, biomarker activities are transitioned from discovery to clinical biomarker development and implementation. Clinical biomarker development includes clinical biomarker assay development, fit-for-purpose assay validation, and clinical biomarker qualification in clinical studies. After a clinical biomarker is qualified, it will then be implemented in clinical studies to aid decision-making. Overcoming challenges in clinical biomarker development will be discussed.

xuemei_zhao@merck.com