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Overcoming challenges of clinical biomarker development

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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 of clinical biomarker development such as preanalytics, assay selectivity, and matrix effect will be discussed.

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