



Global CDx Strategy & Roadmap Guide

Clinical Development Strategy

Managing Limited Samples, Assay Bridging, and Global Evidence Needs

Clinical development for companion diagnostics must support **drug labeling claims**, often with **small biomarker-positive cohorts** and evolving assay platforms.

Clinical Development Strategic Considerations

- Is the CDx clinical strategy aligned with the **therapeutic clinical development plan**?
- Are clinical endpoints sufficient to support **PMA-level evidence in the US**?
- Is there a predefined **bridging strategy** from trial assay(s) to the commercial CDx kit?
- Are multiple assays for the same biomarker being used, and if so, is comparability addressed?
- Has statistical power been assessed, given limited biomarker-positive samples?
- Are clinical studies designed to support **multiple regions**, not just a single authority?
- Are sample handling, storage, and traceability globally compliant?
- Is the diagnostic assay or Clinical Trial Assay analytically validated for its intended use?

Why this matters: Regulators increasingly scrutinize assay comparability and clinical relevance when trial assays differ from marketed CDx kits.

This guide is designed to help CDx sponsors develop a comprehensive global CDx strategy across discovery, clinical development, regulatory strategy, quality systems, and commercialization, with explicit consideration of requirements in major regulatory regions including the US, EU, China, and Japan.

Contact us for a free consultation at admin@landrichgroup.com