



Global CDx Strategy & Roadmap Guide

Clinical & Regulatory Roadmap for Global CDx Programs

Introduction – Why Your Global CDx Strategy Is Critical

Companion diagnostics (CDx) sit at the intersection of diagnostics and therapeutics, requiring **synchronized drug–test co-development across multiple regulatory systems**. While global regulators share the goal of ensuring patient safety and clinical utility, **CDx requirements are not harmonized**.

Manufacturers must navigate:

- Divergent definitions of companion diagnostics
- Region-specific clinical and analytical evidence thresholds
- Local data expectations and co-review processes
- Limited biomarker-positive populations and assay evolution during development

Failure to anticipate these challenges early can result in **duplicative studies, misaligned submissions, delayed drug launches, or restricted indications**.

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