LANDRICH GROUP

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.**

Addressing Global Co-Development Complexity Early

Early feasibility decisions determine whether a CDx program can realistically support **parallel or near-parallel global drug approvals.**

Discovery & Feasibility Strategic Considerations

□ Is the **biomarker biologically and clinically justified** for the intended therapeutic indication?

□ Is the intended CDx role clearly defined (companion vs complementary vs stratification)?

□ Has the **drug–diagnostic co-development model** been formally agreed (single sponsor vs partnered)?

□ Are differences in CDx definitions across major regional regulatory bodies like the FDA, IVDR, NMPA, and PMDA understood?

□ Has feasibility been assessed for **rare or heterogeneous biomarker-positive populations**?

□ Is there a strategy for managing **assay evolution** from clinical trial assay to commercial kit?

□ Are early regulatory interactions planned to confirm CDx classification and evidence expectations?

Why this matters: Many CDx programs fail in achieving a global strategy because feasibility was assessed only for one region or with limited sample types, without accounting for global evidence divergence.

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 it intended use?

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