LANDRICH GROUP

Global CDx Strategy & Roadmap Guide

Discovery & Feasibility Strategy

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.

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