

CDx DEVELOPMENT SERVICES

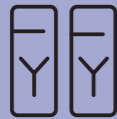
SCALE ACCESS TO
THERAPIES FASTER
WITH OUR BROAD CDx
CAPABILITIES



Partner with a leader in
anatomic pathology, combining
our global clinical installed base
with next-generation AI-powered
precision diagnostics

CDx DEVELOPMENT SERVICES

Scale access to therapies faster with our broad CDx capabilities



Flexible CDx Development

- › Develop fit-for-purpose assays guided by global IVD expertise
- › Accelerate timelines with modular development and streamlined data continuity from translational to clinical stages
- › Customize with recombinant antibody technology



AI-Enabled Portfolio for Precision Dx

- › Access 11,000+ antibodies and multimodal CDx via Danaher's Abcam, Beckman Coulter, and Cepheid
- › Integrate AI-powered precision diagnostics and Indica Labs' image management system
- › Enable complex biomarker strategies with multiplex IHC solutions



Global Clinical & Regulatory Support

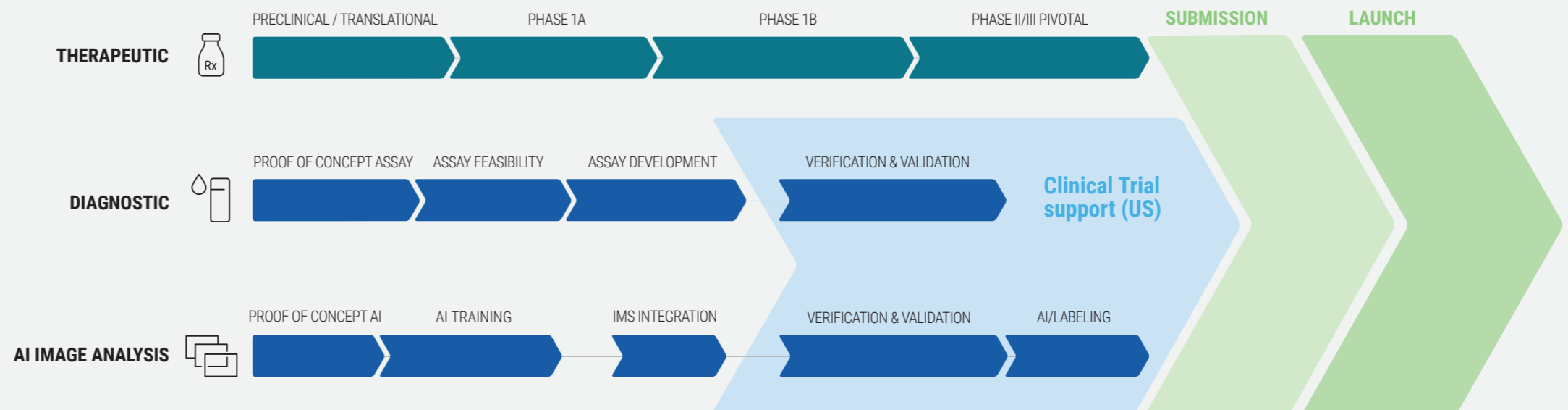
- › Accelerate CDx development with CAP/CLIA-certified labs
- › Seamless integration into CDx development process when clinical trial needs evolve
- › Navigate global submissions with regional regulatory specialists



Fast Commercial Scale-Up

- › Reach patients faster with a leading global installed base of IHC instruments and digital scanners
- › Drive adoption with support from 1,300+ commercial experts
- › Ensure global access through direct and indirect sales to 100+ countries

CDx OPERATING MODEL AND PROCESS



Comprehensive and Seamless Capabilities

AI-Enabled Portfolio for Precision Dx

- ▶ **Computational Pathology for Next-Gen CDx:** Harness AI-powered precision diagnostics through the largest digital pathology scanner installed base
- ▶ **Your Single-Source Digital Pathology Partner:** End-to-end portfolio including scanners, image management, and AI-powered analysis across the full ecosystem
- ▶ **Flexibility to Choose AI Applications:** Deploy partner apps or integrate custom solutions to accelerate assay development and optimize patient selection
- ▶ **Seamless Tech Transfer:** BOND platforms share hardware and reagents to streamline translation from research to clinical

Fast Commercial Scale-Up

- ▶ **Installed Base at Scale:** 8,000+ IHC instruments and the most (3,000+) digital pathology scanners deployed across 109 countries
- ▶ **Clinical Lab Integration:** Easily deploy into existing lab workflows to accelerate CDx adoption
- ▶ **Day 1 Readiness:** Establish CDx from day one by preparing key labs for launch



Flexible CDx Development

- ▶ **Assay Expertise Since 1987:** Decades of experience optimizing assay sensitivity and specificity
- ▶ **Flexible Design Options:** Assays developed across detection technologies and plex levels
- ▶ **Tailored Timelines:** Modular programs to meet your CDx milestones



Global Clinical & Regulatory Support

- ▶ **Streamlined Assay Transition:** Seamlessly move from RUO to IVO without external hand-offs
- ▶ **Local Oversight, Global Reach:** Experienced clinical and regulatory teams across China, Japan, E.U., and U.S.
- ▶ **Proven Regulatory Expertise:** 1,300+ IVDs supported globally and expertise in pre-sub, trial submissions, 510(k), IVDR, and global CDx submissions

Partner with
Leica Biosystems to
accelerate your CDx program



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