



Partnering for Therapeutic & Companion Diagnostic Co-Development

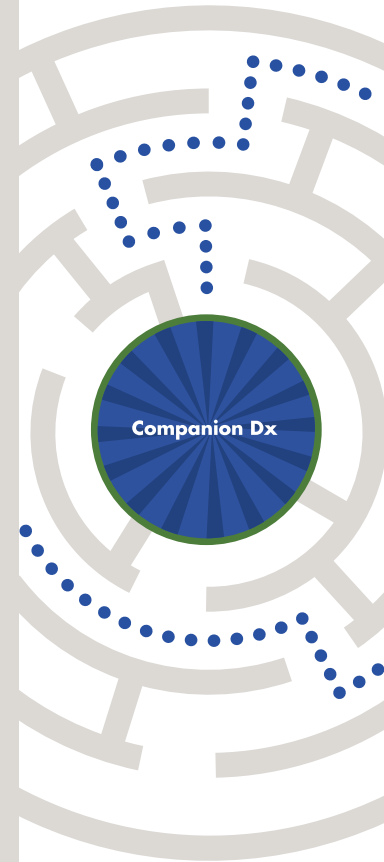
Navigating through the IVD development maze doesn't have to be complex—it just requires the right partner who knows the way.

As a Contract Diagnostics Organization (CDO), we solve logistical complexities associated with multi-partner outsourcing for companion diagnostics. By integrating and synchronizing all IVD and pharmaceutical development activities, a single 'start-to-finish' partner simplifies and speeds the process to complete your FDA-approved companion diagnostic at the right time.

Built-in flexibility

Unlike multi-partner outsourcing, your dedicated project manager at ResearchDx serves as your point person to guide you through all phases of your project. And, when you need to shift — we shift, adapting to your evolving needs and priorities.

CDO



Service Divisions

Research & Development

- Biomarker discovery (molecular, protein, other)
- Assay development and validation
- Platform evaluation and automation

Clinical Research

- Complete clinical trial services, management, support
- Clinical trial consulting
- Reference trial testing services

Regulatory & Compliance

- Regulatory strategy
- IVD PRE-IDE, PMA, 510(k) filings and FDA interactions
- International regulatory filings
- Compliance auditing and consulting

ResearchDx maintains licensure, accreditation, certification and/or compliance where applicable to pertinent regulatory bodies and to local, state and federal laws.

ResearchDx

Email: info@researchdx.com

Online: Researchdx.com

Ph: 866 225 9195 or 949 812 6902

Fax: 949 297 3983

GMP Contract Manufacturing

- Molecular/non-molecular IVD development
- Custom reagents, assays, or final kits for research, clinical, final product
- OEM reagents, kit components or assays

Clinical Laboratory

- CLIA, CAP, ISO, state and regulatory certification, accreditation and compliance
- High-Complexity specialty testing resource (molecular/non-molecular)
- Broad, multi-platform capability (no bias)
- Pre-inspection auditing/readiness
- Complete resource and consulting for new start-ups

Your Companion in Diagnostics® is a registered trademark of ResearchDx in the USA. All other trademarks, brands and names contained herein are the property of their respective owners.

MKT001 Rev 1, © 2017 ResearchDx USA