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.
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

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

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

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