CDO

ResearchDX
Your Companion in Diagnostics®

Partnering to Bridge Gaps

As a Contract Diagnostics Organization (CDO), we solve gaps in resources and expertise for biopharmaceutical and diagnostics industries.

By offering a comprehensive range of *in vitro* diagnostic services, we augment or integrate your project needs through outsourcing to a single partner.

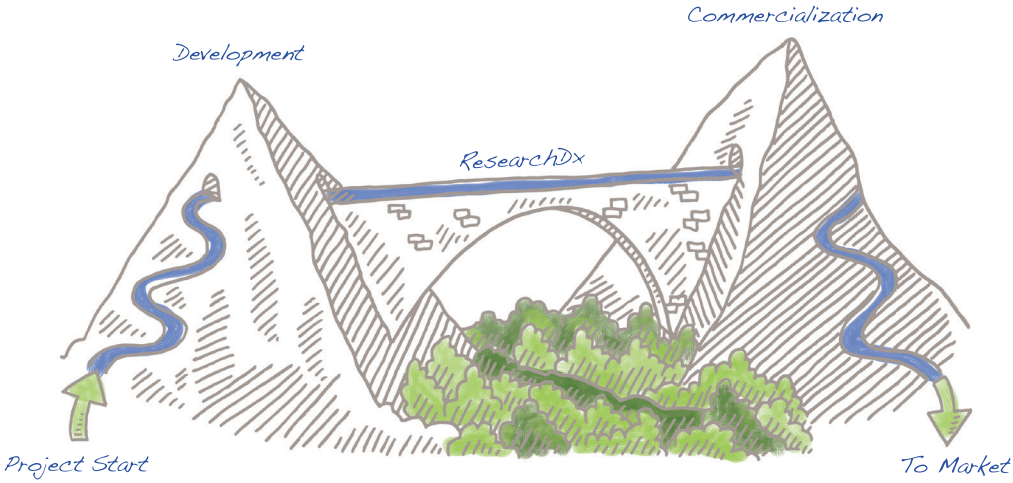
- Integrated development from discovery through regulatory approval
- Discrete development projects in clinical, regulatory and laboratory services
- GMP manufacturing

As your complete diagnostics partner, we tailor to your project needs. Communication and speed efficiency are benefits gained through dedicated project management in a quality-compliant program and environment.

Your project is in capable hands.

We have scientific and medical expertise in all areas of IVD diagnostics to ensure your project is designed, implemented and stays on target with your goals and schedules.

When your project timelines or priorities shift—we shift to meet your needs.



Service Divisions

ResearchDx offers complete diagnostic development support. This listing highlights frequently utilized services; however, if you don't see what you need, just ask.

Research & Development

- Biomarker discovery (molecular, protein, other)
- Assay/kit development and validation
- Platform evaluation and automation
- Studies to establish biological baseline
- Broad, multi-platform technology capability (no bias)
- LDT/custom development/clinical validation

Clinical Research

- Complete clinical trial services, program management and support
- Clinical trial strategic consulting
- Reference trial testing services
- Clinical primary site testing
- Analytical and clinical testing
- Complete data management program support

Regulatory & Compliance

- Strategy and FDA interactions
- IVD PRE-IDE, PMA and 510(k) filings
- International regulatory filings
- Compliance auditing and consulting
- Compliant labeling
- Software documentation
- Third party review by Accredited Persons (AP)

GMP Contract Manufacturing

- Custom reagents, assays, or final kits for research, clinical, final product
- Molecular/non-molecular IVD development
- OEM reagents, kit components or assays
- Certificates of Analysis (COA)
- Sample collection kits

Clinical Laboratory

- CLIA, CAP, ISO, GLP, 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-up
- Mock inspections (CLIA, CAP, ISO)
- Inspection audit responses (CLIA, CAP, ISO)
- Provision of standard laboratory documentation (CLIA, CAP, ISO compliant)

GLP Diagnostic Services

- Non-clinical testing
- Pre-clinical testing
- GLP compliance consulting

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

ResearchDx

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