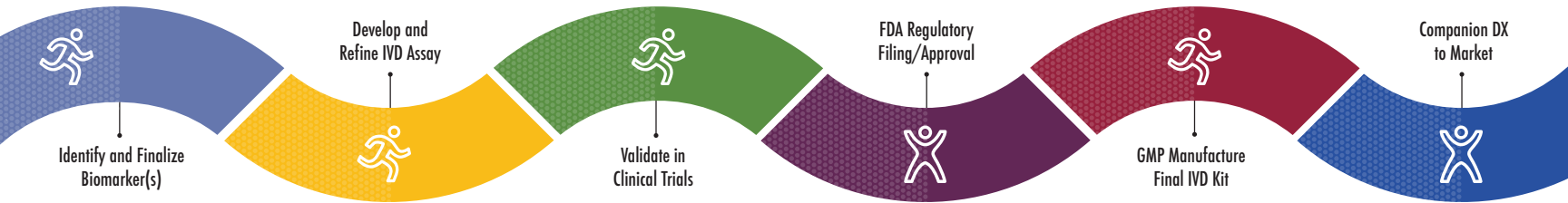


We Build. We Validate. We Deliver.

As your single source partner, we simplify, synchronize and speed the process to ensure delivery of your FDA-approved IVD, at the right time.

It's what we do best.



Built-in Flexibility

As a Contract Diagnostics Organization (CDO), we solve complexities without multi-partner outsourcing. A dedicated project manager will guide you through all phases of your project to ensure your priorities and timelines.

Need flexibility? When your needs or priorities shift, we shift with you.

Pharma and Biotech Support Services

ResearchDx offers complete discovery and *in vitro* diagnostic (IVD) development support services for pharmaceutical and biotechnology industries. This listing highlights frequently utilized services—if you don't see what you need, just ask.

Research & Development

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

Clinical Research

- Complete clinical trial services, program management and support
- Clinical trial strategic 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

- IVD assay manufacture
- ISO 13485 compliance
- Custom reagents, assays, or final kits for research, clinical, final product
- OEM reagents, kit components or assays

Clinical Laboratory

- CLIA, CAP, and state regulatory certifications/accreditation
- High-complexity specialty testing resource
- Broad, multi-platform capability (no bias)
- Pre-inspection auditing/readiness
- Complete consulting resource for new start-ups

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

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