

# Integrated Medical Device and Diagnostic Development Solutions

Whether you're developing a medical device or an in vitro diagnostic product, Labcorp brings you an innovative approach that integrates your development journey from concept through post-market support. This cohesive model enables you to obtain the answers you need to satisfy all your stakeholders – investors, regulators, payers, providers and patients.

## Integrated Insights for the Life Cycle of Your Product:

### Regulatory & Consulting

- Regulatory Affairs
- Clinical Strategy
- Health Economics & Reimbursement
- Medical Writing
- Registration & Submission (i.e. IDE, PMA, HDE, BLA, 510(k), de Novo, CLIA Waiver, Q-sub)

### Preclinical & Surgical

- Biocompatibility Testing
- Non-GLP & GLP (Acute & Chronic) Experimental Surgery & Model Development
- Cadaver Studies

### Clinical & Market Approval

- Protocol development
- Global Trial Support (Feasibility/Pilot & Pivotal)
- Statistical Design & Analysis
- Data Management
- Site Recruitment & Qualification
- Patient Recruitment & Retention
- Central Laboratory Services
- Laboratory Testing Sites
- Analytical Validation Studies

### Commercialization & Post-Market

- Real-world Evidence Development
- Physician and Sales Training
- Post-market Surveillance
- Follow-up Studies
- Audits, Recalls & Obsolescence Support

## Medical Devices, In Vitro Diagnostics, Companion Diagnostics and Combination Products

Programs to get your medical device, in vitro diagnostic, companion diagnostic or combination product to market are made easier by our team of experienced, integrated healthcare product development specialists, synchronizing the development of combination device, in vitro diagnostic and therapeutic compound under one program.

## 30 years of experience across a wide range of critical therapy areas

- Cardiovascular
- Dermatology & Wound Care
- Endocrinology and Diabetes
- Gastrointestinal
- Hematology
- Infectious Disease
- Neuroscience
- Oncology
- Ophthalmology
- Orthopedics
- Radiology/Nuclear Science
- Urogenital
- Vascular
- Women's Health





### Global Clinical Trials

Labcorp brings you the benefit of a sophisticated patient recruitment and site selection solution, helping you match high-performing investigators with optimal patient pools for a successful trial.

**>150M**  
patients

**5**  
central global testing labs

**30**  
diagnostic & specialty testing labs

**>100**  
countries

**>30B**  
test results

### Surgical Facilities and Equipment to Expedite Your Prototype

Our AAALAC-accredited research facility is designed with experimental surgery and you in mind. The facility is outfitted with surgical suites, an expert surgical support team, imaging equipment and product training accommodations for sales staff and physicians.

- Cath Lab
- Endoscopy
- Fluoroscopy
- Laparoscopy
- Ultrasound



### 30 Years of Experience – That Matters

The life cycle approach is made possible by collaborating with a deeply experienced team that has been conducting medical device trials and diagnostic validation for more than 3 decades – since 1985. Our team is as passionate about bringing your new product to market as you are.

**>500\***  
Clinical Studies

**>3,000\***  
Investigator Sites

**>110,000\***  
Patients Worldwide

*\*5-year experience (2015-2019)*

Learn more at [www.labcorp.com/device-cro](http://www.labcorp.com/device-cro)

