



**Regulatory and  
Clinical Research  
Institute, Inc.**  
overview

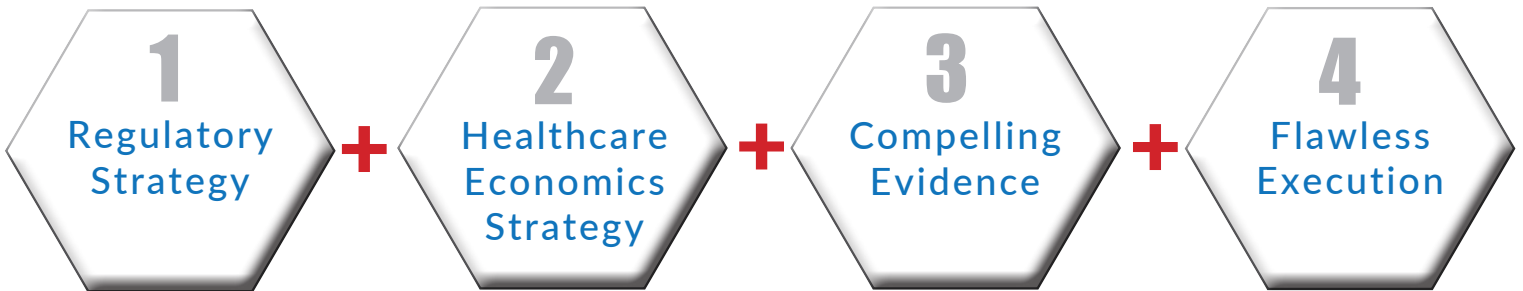
 **RCRI**<sup>®</sup>

Expert advisors. Exact practices.

---

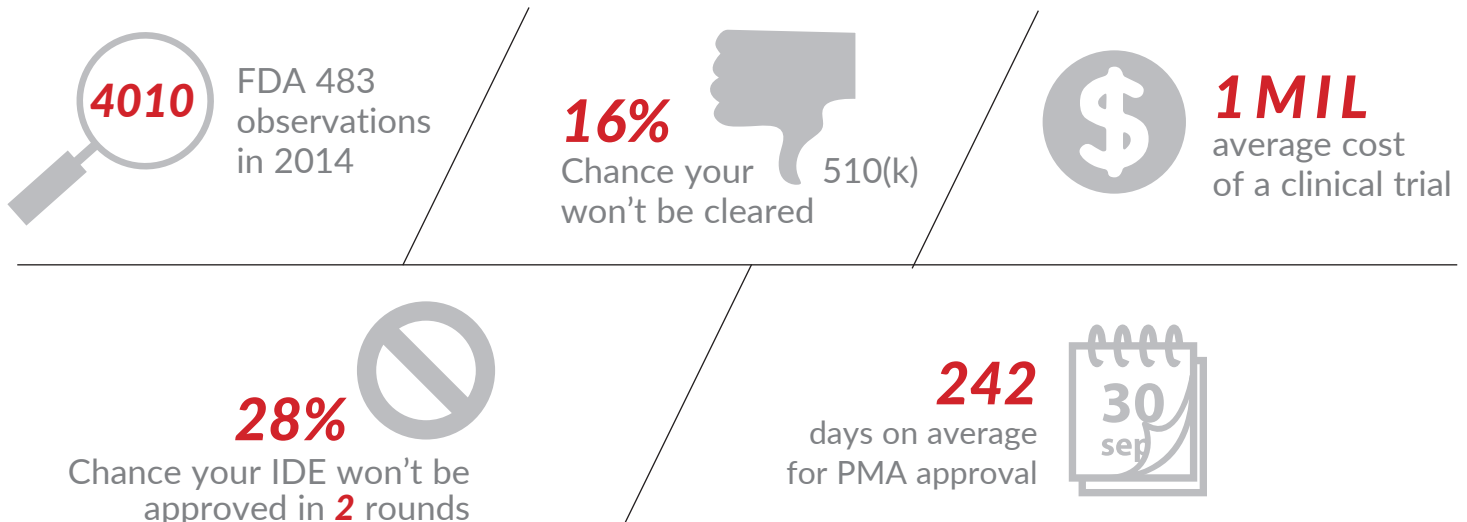
strategic consulting throughout the product lifecycle

There are **4** factors to get your product to market



Successfully bringing and keeping a medical device on the market is more difficult today than ever before. Regulatory bodies are demanding more safety and efficacy data for approvals while payers want compelling economic evidence. Patients want confidence that the product will solve their problem. And- it doesn't stop there. You must also have a robust post-commercialization plan to keep your product on the market.

## Evidence-driven strategies matter





## Expert advisors. Exact practices.

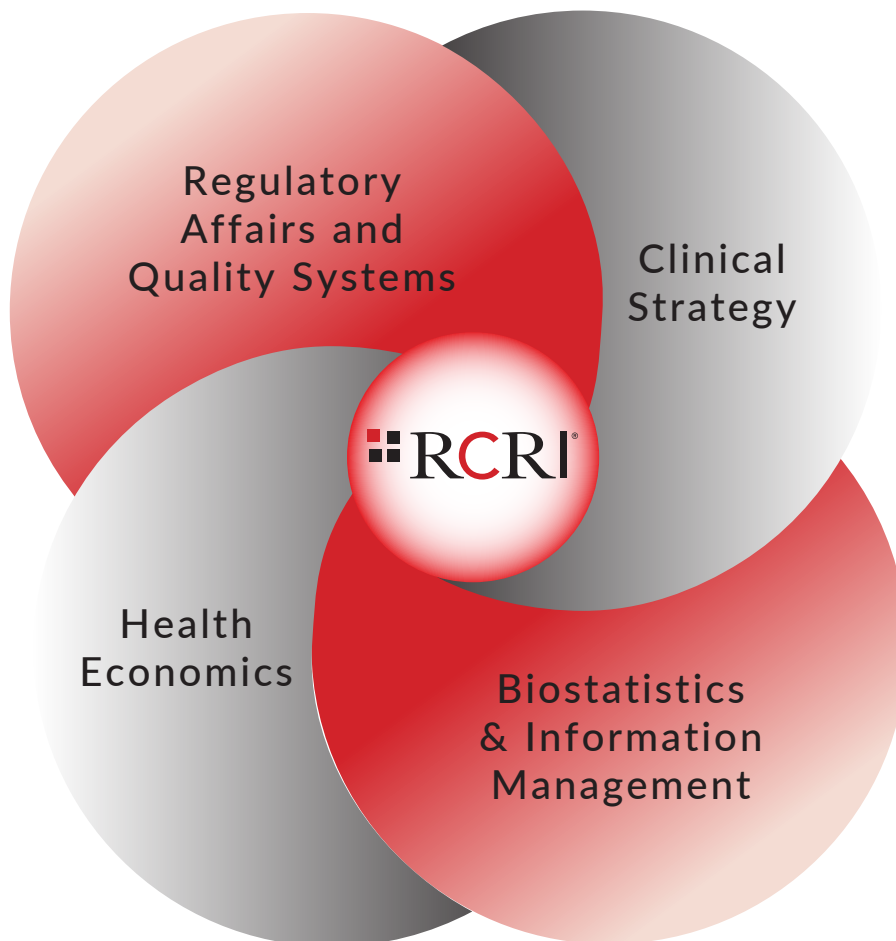
Significant challenges demand strategic thinking from advisors with deep expertise. Combining strategic consulting with operational excellence, RCRI addresses the most formidable challenges in today's global environment.

Our consultants are experienced scientists first. With advisors in a variety of disciplines, we help you achieve your product goals by designing and executing strategies for robust evidence development to meet stakeholder demands for successful commercialization.

## Experts in medical device strategic consulting and CRO services

- Regulatory Strategy
- Regulatory Submissions: preparation and negotiation
- Quality Systems and Compliance
- Quality System Audits
- Risk Management

- Reimbursement Landscape Assessment
- Reimbursement Strategy
- Stakeholder assessment
- Value analysis
- Coding



- Clinical Trial Operations
- Rapid Site Activation
- Clinical Site Audits
- BIMO audit preparation
- Risk based Monitoring
- Clinical Evidence Reports

- Trial Strategy
- Trial Design
- Registries
- Biostatistics
- Technology planning solutions
- Electronic data capture (EDC)
- Data Analysis
- Clinical Data Management
- Medical Writing
- Publications



# Expert advisors. Exact practices.

## technology & product experience

- ablation products
- biologic devices
- combination products
- device delivery systems
- dental implants
- dermal fillers
- imaging technologies
- implantable devices
- IVD
- IVF products
- wound healing: meshes/fabrics
- neurostimulators
- neurovascular devices
- orthopedic/spine implants
- pacing leads
- peripheral vascular devices
- pulmonary products
- stents
- surgical instruments
- surgical technologies
- tissue adhesives & sealants
- urinary incontinence bulking agents

## therapeutic experience

- Cardiology
- Cardiovascular
- CNS/PNS
- Dental
- Dermatology
- Diabetes
- ENT
- Gynecology
- Gastroenterology
- Hematology/Oncology
- Neurology
- Neurosurgery
- Neurovascular
- Ophthalmology
- Orthopedics
- Pain management
- Peripheral vascular
- Pulmonology
- Urology
- Spine
- Wound healing

## expertise

- auditing
- case report design
- CER development
- clinical feasibility
- clinical operations
- clinical strategy
- data flow optimization
- database development
- epidemiology
- medical writing
- protocol development
- publication planning
- quality strategy
- regulatory negotiations
- regulatory strategy
- reimbursement strategy
- statistical strategy
- statistics
- strategic data management planning
- submission preparation