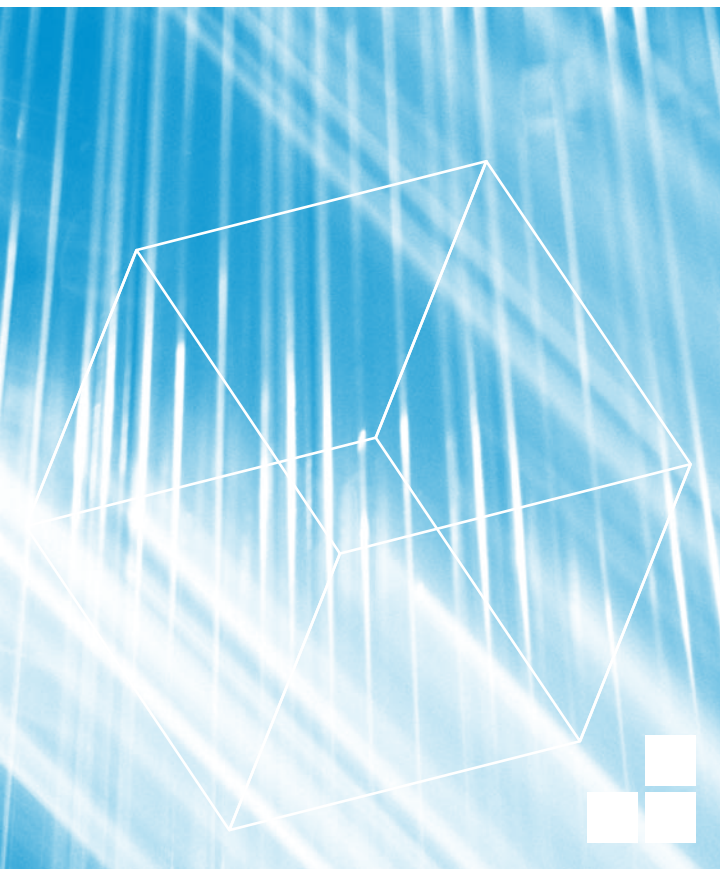




Corporate Capabilities



Who We Are

The Regulatory & Clinical Research Institute, Inc. (RCRI) is a consulting company leading the way in providing integrated Contract Research Organization (CRO) services to the medical device, IVD, and bioscience industries.

RCRI is ISO 9001:2000 certified.

Since our inception in 1999, RCRI has helped more than 400 companies worldwide translate their product plans into successful revenue generating businesses. Our clients range from development stage start-ups to the largest Fortune 500 companies.

Our mission is to provide clients with knowledge, experience and ingenuity, within a suite of integrated services, throughout the product life cycle.

What We Do

RCRI offers a wide range of services including:

- Regulatory affairs
- Clinical trial design & management
- Reimbursement & health economics
- Quality systems & compliance
- Biostatistics
- Preclinical research
- Venture capital due diligence

Experts in Medical Devices, IVDs, and Biosciences

Our proven track record with medical devices, IVDs, and bioscience products includes everything from simple modifications of a market released product to novel device/drug combinations and everything in between.

RCRI will help you at any stage along the path to approval and beyond – from the prototype to the postmarket study.

Wide-ranging Medical Expertise

Our work has involved many medical specialties including:

- Anesthesiology
- OB/GYN
- Biologicals
- Ophthalmology
- Cardiology
- Orthopedics
- Dental
- Radiology
- Gastroenterology
- Respiratory
- Infection control
- Spinal
- In-vitro diagnostics
- Urology
- Microbiology
- Wound healing
- Neurology

How We Work



Whenever RCRI starts a project, we make sure we understand the big picture first. By taking a broader view and learning where the individual pieces fit, we can better develop an integrated action plan.

We take the time to get to know you, your business, and your company culture, so we can develop a customized solution delivered with a personal touch.

Team Powered




RCRI's growing staff of highly qualified professionals work with you as a team.

A project manager is assigned to each project, so you will always have a point person directing the workflow and providing you with up-to-date status information. Depending on the type and size of the project, you may work with one or more RCRI experts.

Senior consultants and RCRI principals collaborate extensively with project teams, either directly or in an advisory capacity, so clients benefit from the collective knowledge of the RCRI staff.

This teamwork coupled with a high level of communication and staff continuity help ensure client satisfaction.



Founding Principals

The three people who founded RCRI bring a wealth of experience to your product development effort.

During their careers, principals Steve Norsted, Jennifer Marrone, and Terry Norsted have held positions in industry, academia, and government. They are well networked with experts and key opinion leaders in clinical practice and at regulatory agencies.



Steve Norsted, PhD, MPH



We Are Flexible




Each company requires a different set of resources. RCRI is committed to tailoring services to help you meet your goals and objectives.

RCRI is flexible. We can work with you in many capacities and can adapt as your business grows and evolves.

RCRI can assist your company at the very beginning of a project by developing a regulatory and clinical plan that your staff members implement.

Or, RCRI can serve as a full member of your company's product development team, providing input at project meetings and even presenting to senior management or the board of directors on specific topics.

Regardless of whether it is a single task or a large-scale project, you can count on the work of highly qualified RCRI professionals.



Getting Started




Getting started is as easy as making a phone call. During an introductory session, we will discuss and evaluate your needs.

RCRI professionals will start a project with a simple work order. Or, we can develop a formal proposal with detailed timelines, milestones, deliverables, and budgets.

RCRI is committed to helping companies get their products to market approval more quickly, efficiently, and effectively.

Please contact us to discuss how we can assist you.



RCRI is a leader in providing integrated CRO services to the medical device, IVD, biologics, and combination products industries.

RCRI is ISO 9001:2008 certified.



ISO 9001:2008
FM 89594



Regulatory & Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416

main: 952.746.8080
fax: 952.884.6518
www.rcri-inc.com

© 2010 Regulatory & Clinical Research Institute, Inc.