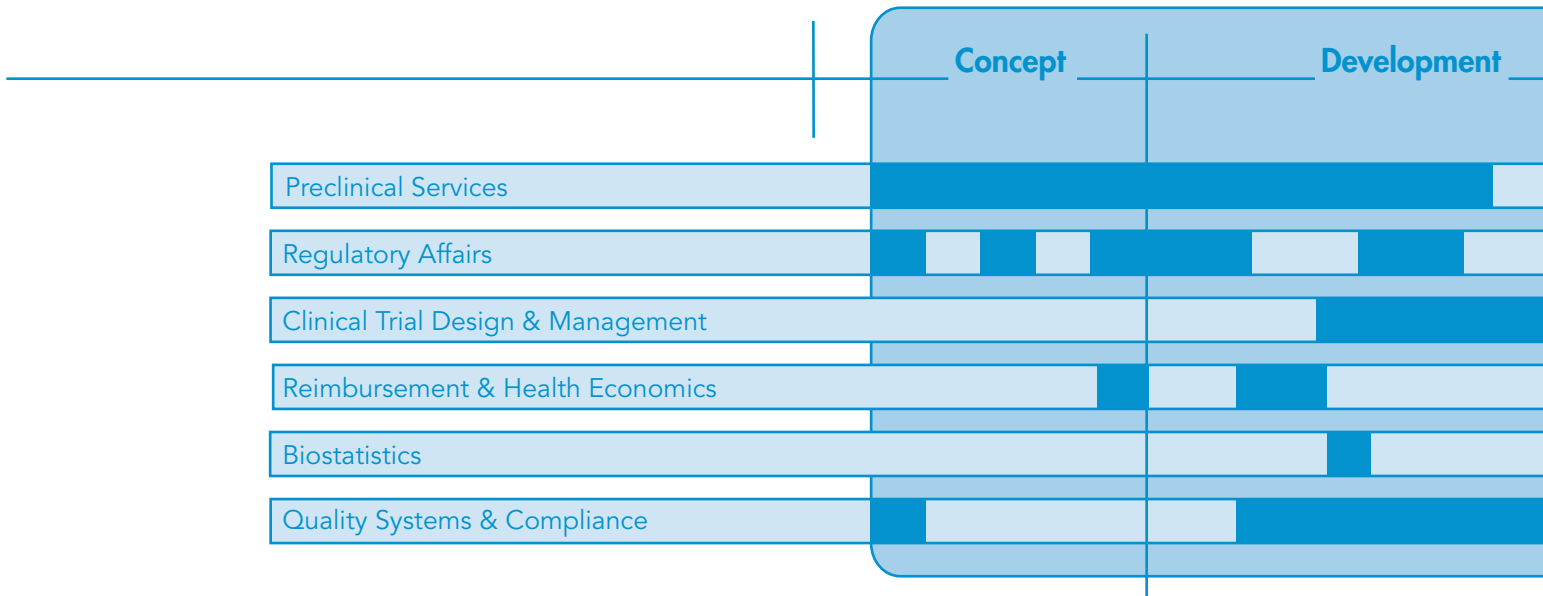




## Providing a Full Array of Services from Concept to Market



### 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, biologics, and combination products industries.

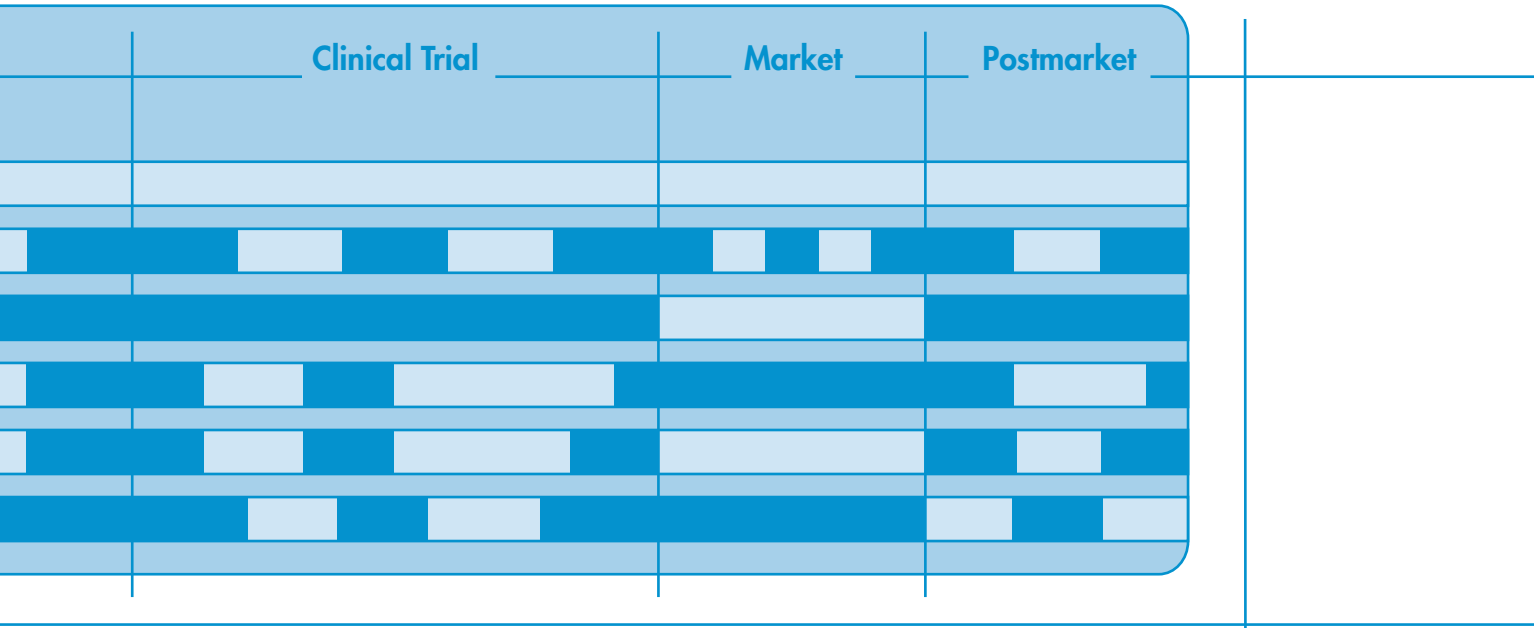
RCRI is ISO 9001:2008 certified.

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.

RCRI has the knowledge and experience required to take on the challenges of even the most innovative of products including those that combine drugs, devices, and biologics.

Whether it's a regulatory submission, clinical research, reimbursement, or the multitude of other tasks required to take a product from concept to market, you can count on our highly qualified professionals to work with you as a team.

We are always working on better and more creative ways to help companies get their products to market approval.



RCRI is a full-service consulting company that provides the right services at the right times in the product development process.\*

### RCRI Services

RCRI offers a wide range of services to help you at any stage along the path to approval and beyond (starting with the earliest prototype to the postmarket study).

Our services include:

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

### RCRI Mission

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

\*(Representative timeline. The exact timing and services involved will vary depending on the specific project.)

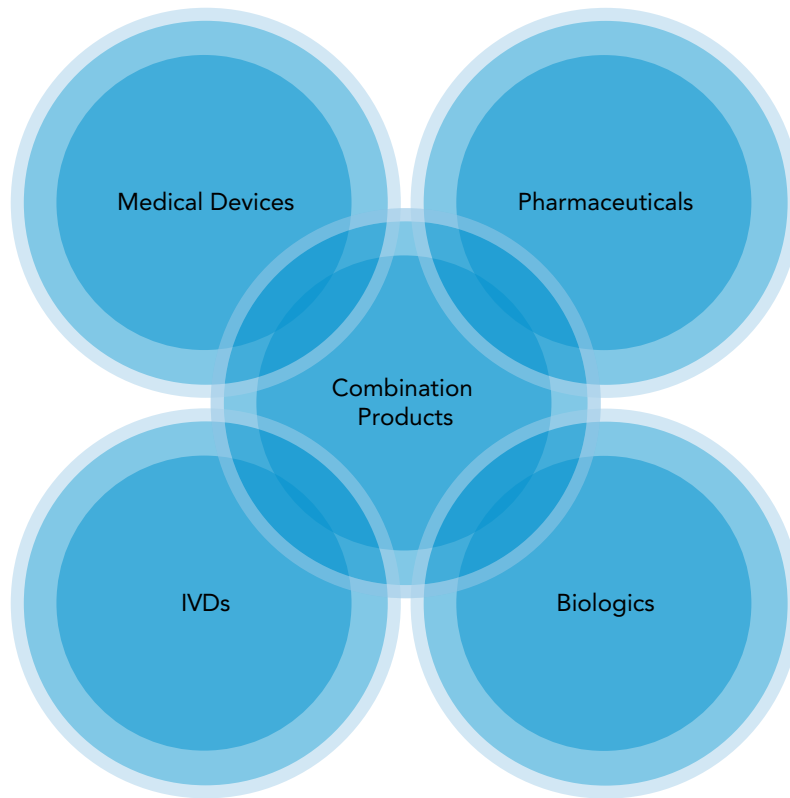
## Wide-ranging Medical Expertise

RCRI has a proven track record in 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



## Comprehensive Product Experience



### Experts in Medical Devices, IVDs, and Biosciences

RCRI knows medical devices, IVDs, and the biosciences.

Our proven track record includes everything from simple modifications of a market released product to novel device/drug combinations and everything in between.

RCRI's growing staff of experts will provide you with the exact services needed to achieve the best results in this dynamic marketplace.

RCRI principals, senior consultants, and specialists all bring a wealth of experience to your product development. During their careers, they 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.

## Building Networks through Leadership

RCRI professionals participate actively in organizational activities furthering their knowledge and building strong connections. Current and past leadership positions include:

- Technical advisor to the FDA on pharmaceutical technology and medical device manufacturing
- ASTM consensus standards author
- Editor-in-chief, Regulatory Affairs Professional Society (RAPS) book, US Fundamentals of Regulatory Affairs
- Statistician, Data Safety Monitoring Boards
- Statistician, Pivotal Study Steering Committee
- Co-chair of the Medical Alley Regulatory Affairs and Clinical Affairs special interest groups
- Advisory Board Member, Research Services Organization, University of Minnesota
- Chairperson, International Harmonization of Medical Device Regulation
- Regulatory affairs technical advisor to the National Institute for Occupational Safety and Health (NIOSH) on medical device manufacturing and pharmaceutical technology
- RAPS Annual Meeting panel member

## We Work as a Team

RCRI 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.

RCRI principals and senior consultants 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



**Steve Norsted, PhD, MPH**

Extensive experience in the design, conduct, and analysis of preclinical and clinical studies since 1980. He has served as an epidemiologist for the Washington State Health Department and held management level positions in clinical research at several medical device companies.



**Jennifer Marrone, MBA**

Experience in preparing submissions, dossiers, and technical files; negotiating with authorities; and interacting with clinicians since 1978. She has also organized and managed the regulatory, clinical, and quality systems/compliance functions at leading medical device companies.



**Terry Norsted, PhD, MPH**

Experience in the design, conduct, and analysis of clinical trials since 1981. She has held clinical and regulatory management positions at medical device companies since 1987 and has been responsible for domestic and international regulatory submissions, and the design, implementation, and analysis of clinical trials.

## **Powered to Perform**

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

We are large enough to assist you with complex large-scale projects, yet small enough to get to know you, your company, and your culture.

Depending on your needs, we will develop a staffing plan powered with the right number of people, experience, and skill sets.

Regardless of the size of your project, you can count on the work of highly qualified RCRI professionals.

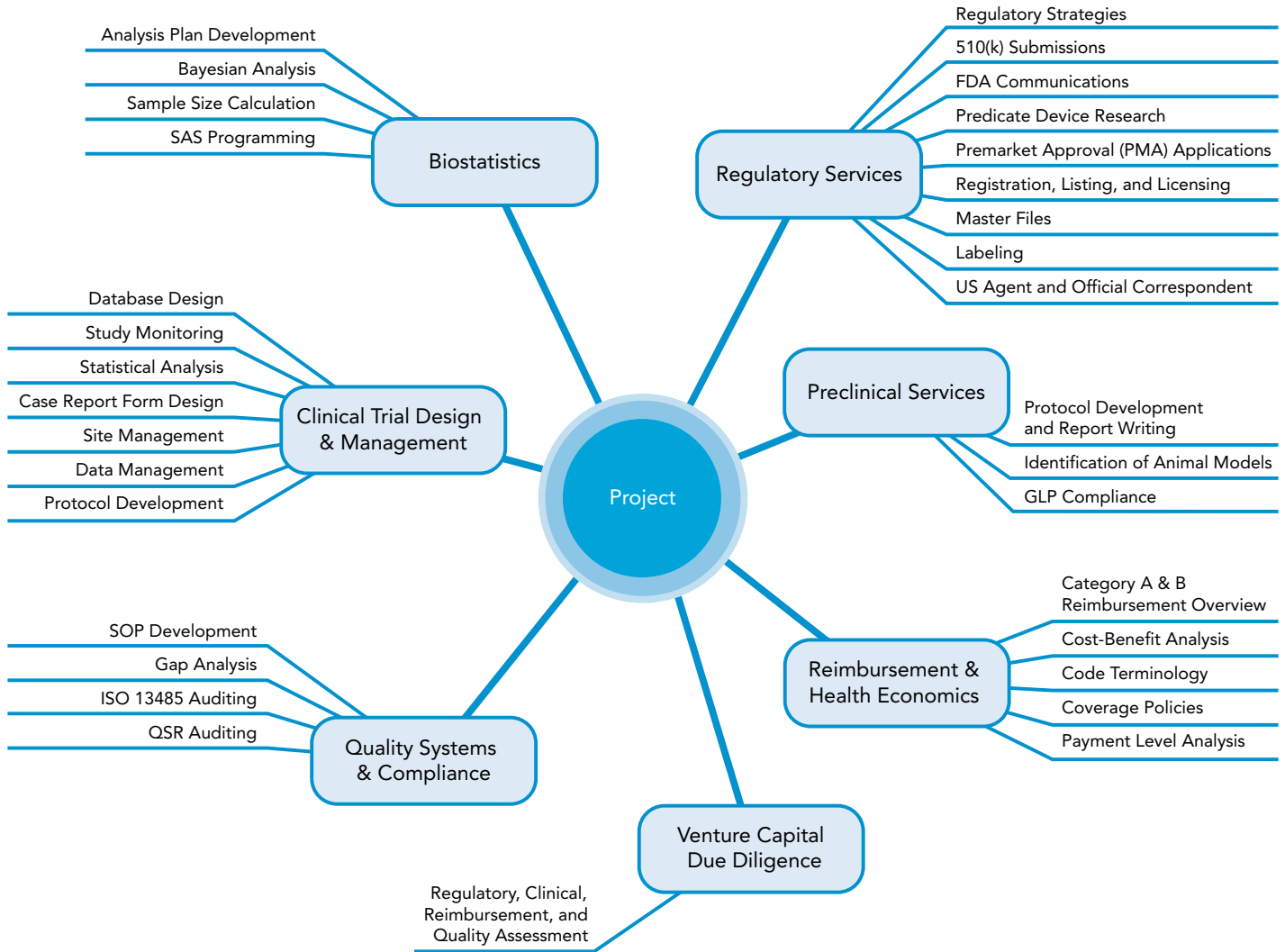
## **Achieve More through Integrated Services**

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.

RCRI considers issues such as reimbursement and marketing goals up front, so that these important targets can be integrated into the clinical trial design.

This approach results in data to support optimal reimbursement and product claims. It can mean the difference between an average and an outstanding product launch.

## Increase Your Product's Value through Integrated Services



RCRI will integrate services and strategies from multiple functional areas to help you achieve your short- and long-term business objectives.

(The types of services listed under each functional area are representative but not inclusive of those offered by RCRI.)

## We Are Flexible

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

We 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.

In whatever capacity you choose, RCRI will go beyond the routine to advocate for your product.

## Case Studies Illustrating Flexibility

---

**Case:** Doing it all-regulatory affairs

**Situation:** A medical device company with no regulatory staff.

**Need:** A regulatory affairs department.

**RCRI Solution:**

- RCRI served as a "virtual" regulatory affairs department for five months.
- Three RCRI employees served in different regulatory roles while working on three different products.
- RCRI helped the company create its own regulatory affairs department by assisting with the recruitment and interviewing process.

---

**Case:** Providing additional resources as needed

**Situation:** A medical device company with a complex implantable system finds that it requires additional resources to handle regulatory projects from time to time.

**Need:** Experts to match the ebb and flow of regulatory work.

**RCRI Solution:**

- RCRI provided regulatory support on an as-needed basis over a two-year period.
- Expertise involved a senior regulatory associate providing hands on product support; a principal advisor to interface with high level regulatory officials; and a project manager.

---

**Case:** Fulfilling a discrete project need

**Situation:** An interventional cardiology company requires support for clinical audits of a Class III implantable device.

**Need:** A professional who understands the auditing process and can work independently and efficiently.

**RCRI Solution:**

- An RCRI principal advisor conducted clinical audits on-site. The audits included reviewing internal records and those at investigational sites as well as conducting data validation.

---

**Case:** Responding to an immediate need

**Situation:** A mid-sized medical device company with a product that was reimbursed by the Centers for Medicare and Medicaid Services (CMS) unexpectedly learns that selected claims are being rejected.

**Need:** Restore reimbursement as quickly as possible.

**RCRI Solution:**

- RCRI started work the same day and found that CMS had posted a reimbursement policy change that the company was not aware of.
- RCRI identified the policy change, notified the company, and assessed the appropriate coding options.
- The company applied the new codes, and reimbursement was restored within three days.



## **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.



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](http://www.rcri-inc.com)

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

RCRI is ISO 9001:2008 certified.



ISO 9001:2008  
FM 89594