

## ***Clinical Trial Design and Management***

### ***Working with You to Achieve Your Clinical Goals***

An effective clinical trial involves more than doing the basics well. It also requires a comprehensive plan. RCRI experts will integrate sound clinical, regulatory, reimbursement, and marketing strategies to achieve your short- and long-term business objectives.

RCRI offers comprehensive clinical trial design and management services including data management and database design.

We can assist you with any size study including large-scale trials involving sophisticated designs and long-term follow-up across clinical settings and geographies.

RCRI can manage your entire clinical program or any part of it. You decide what best fits your product, team, and company.

Whether it is the first clinical trial you have initiated or one of many, you can depend on the highly qualified professionals at RCRI to partner with you. We leave no stone unturned when it comes to clinical trial design and management.

### ***Manage Clinical Data Efficiently***

Efficient data management can speed the entire clinical trial process and increase data collection accuracy and consistency while reducing costs.

RCRI has developed rigorous and detailed procedures for entering, validating, and reporting clinical data, including EDC options.

Custom electronic tools for data entry and query management along with a highly trained and experienced staff ensure accuracy as evidenced by impressive data validation results.

Additionally, RCRI's industry-specific knowledge ensures that data management procedures conform to U.S. and international regulations.

All of our data management systems are 21 CFR Part 11 compliant. Because RCRI's data management function is an integral part of the clinical trial management team, it can be tailored to meet the requirements of specific studies as well as differing business requirements.

RCRI can meet all of your clinical data management needs, either at RCRI or at your company. We can also perform project-specific tasks related to a single clinical study.

### ***Developing a Complete Clinical Plan***

RCRI offers comprehensive services to develop a clinical plan to help you meet your business goals including:

- Clinical trial strategy and design development.
- Investigational plan creation.
- Analysis plan development.
- Investigator and site identification, recruitment, and qualification.
- Study document development.
- Site initiation and training.
- Database development, including EDC options.
- Data and query management.
- CEC/DSMB management.
- Study monitoring.
- Site and sponsor auditing.
- Statistical analysis.
- Clinical report generation.
- Presentation and journal article preparation.
- SOP development.
- Comprehensive staff training.

### ***Database Design and Management***

Unexpected twists and turns are typically a part of many clinical trials. You can reduce uncertainty with database design and management tools you can trust to stand up to the rigors of your clinical trial.

RCRI specializes in creating custom databases and reporting tools quickly and cost-effectively. We start from a core technology that can be tailored to meet the specific needs of your study.

The RCRI database design team works closely with RCRI clinical trial experts on case report forms and databases to build them for efficient data entry and analysis.

RCRI develops a database system and then validates it extensively. The database can be based at RCRI, or we can install it at your company and train your data entry staff. The database along with the data belong to you.

Depending on your needs, we can also provide training on how to utilize the database on an ongoing basis for postmarketing purposes.

RCRI will work with you throughout the clinical study or at specific points, either at RCRI or at your company.

Database design and management capabilities include:

- Development of custom 21 CFR Part 11 databases for clinical studies.
- 21 CFR Part 11 database validation services.
- Statistical programming support using SAS® software.
- 21 CFR Part 11 gap analysis.

### *Integrate Functions for Greater Flexibility*

RCRI considers issues such as reimbursement and product positioning when designing a clinical trial. This approach can result in data to support optimal reimbursement and broader product claims.

Integrating your business goals into the clinical trial strategy means that you can reach approval with more than safety and effectiveness data.

The RCRI staff includes highly qualified professionals in a variety of functional areas related to clinical services. Extensive collaboration with colleagues coupled with ongoing communication with clients ensures the smooth integration of services.

### *We are Flexible*

Each company requires a different set of resources. RCRI is committed to developing a package of services to help you meet your clinical goals in an efficient and cost-effective way.

RCRI can:

- Do it all as a “virtual” clinical department for your company or fulfill discrete project needs.
- Provide you with extra resources to match the ebb and flow of clinical initiatives at your company.

RCRI is flexible. In whatever capacity you choose, you can count on the work of highly qualified RCRI professionals.

### *Our Mission is to Serve our Clients with Knowledge, Integrity, and Ingenuity*

At RCRI, we are proud of our record in providing integrated Contract Research Organization (CRO) services to the medical device, IVD, biologics, and combination products industries. 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.

Whether it is a single task or a complex multi-faceted project, you can count on the highly qualified professionals at RCRI.

### *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.