



Biostatistics

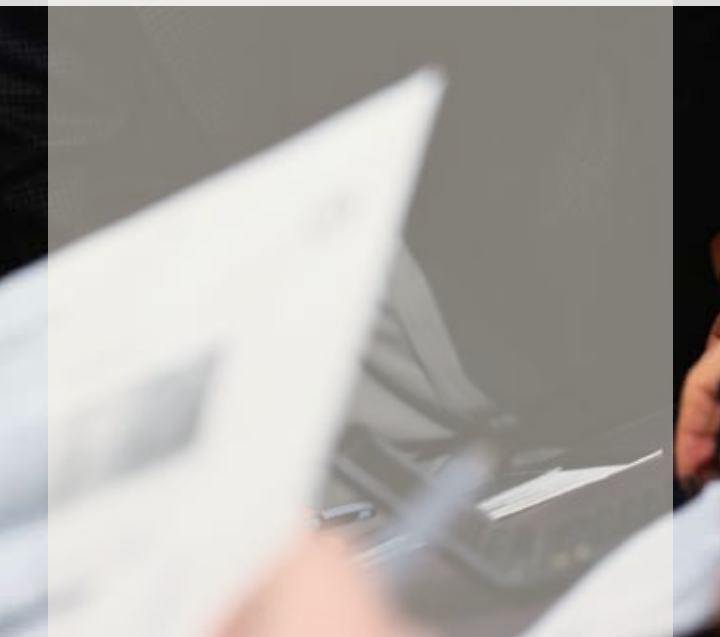


Helping you develop robust conclusions

Biostatistics plays an important role in the process of taking a product from concept to market. It is biostatistical analysis that ultimately demonstrates the safety and effectiveness of a product to regulatory officials and supports reimbursement decisions.

The Regulatory & Clinical Research Institute (RCRI) offers expert biostatistical capabilities. All of our biostatisticians hold graduate degrees in one or more statistical specialities. They have diverse backgrounds including experience in industry, academia, and government.

We pride ourselves on making this complex subject matter easier to understand and will develop a statistical approach in line with your corporate goals.



RCRI can assist with your statistical needs at many stages in the product development process such as:

- Determining the sample size required to power a clinical trial.
- Analyzing the data sets.
- Presenting the results to multiple audiences.

It is our goal to help you develop the most robust conclusions possible. Including RCRI early in the clinical trial design process results in efficient sample sizes and shorter analysis time.



Biostatistics capabilities

RCRI offers a broad spectrum of biostatistical services. We will:

- Determine the optimum approach for your application using either bayesian or frequentist techniques.
- Calculate sample sizes.
- Investigate the benefits of interim analysis for early publication or early trial termination.
- Negotiate with the FDA regarding the proposed sample size, statistical approach, and analysis techniques.
- Develop an analysis plan, perform interim analyses, and analyze the completed clinical study.
- Serve on or as a liaison to the Data Safety Monitoring Board.
- Write the summary report and the statistical analysis section of scientific papers and regulatory applications.

Experts in statistical analysis

RCRI statisticians are well versed in a variety of techniques and tools including:

- Statistical significance and hypothesis testing.
- Survival analysis (e.g., Kaplan Meier, proportional hazard regression, etc.).
- Parametric and non-parametric tests.
- Regression techniques (e.g., linear, logistic, multiple, etc.).
- Simulation modeling (e.g., Markov and Monte Carlo techniques).

Increased efficiency through integrated functions

RCRI biostatisticians work closely with RCRI experts in regulatory affairs and clinical trial design to help ensure sound results and valid conclusions.

Similarly, RCRI databases are designed with the statisticians' needs at the forefront so the data is in optimum form for analysis. If revisions are required, they can be made quickly and efficiently by in-house professionals.

SAS code programming is created and validated at RCRI using in-house experts. We can use our internal standard operating procedures (SOPs) for this process or adopt your procedures. You choose.



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 can:

- Provide complete biostatistical services starting with the earliest preclinical testing.
- Fulfill discrete biostatistical project needs at any point during the clinical trial or thereafter.

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, and biologics 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 multifaceted project, you can count on the highly qualified professionals at RCRI.

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
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