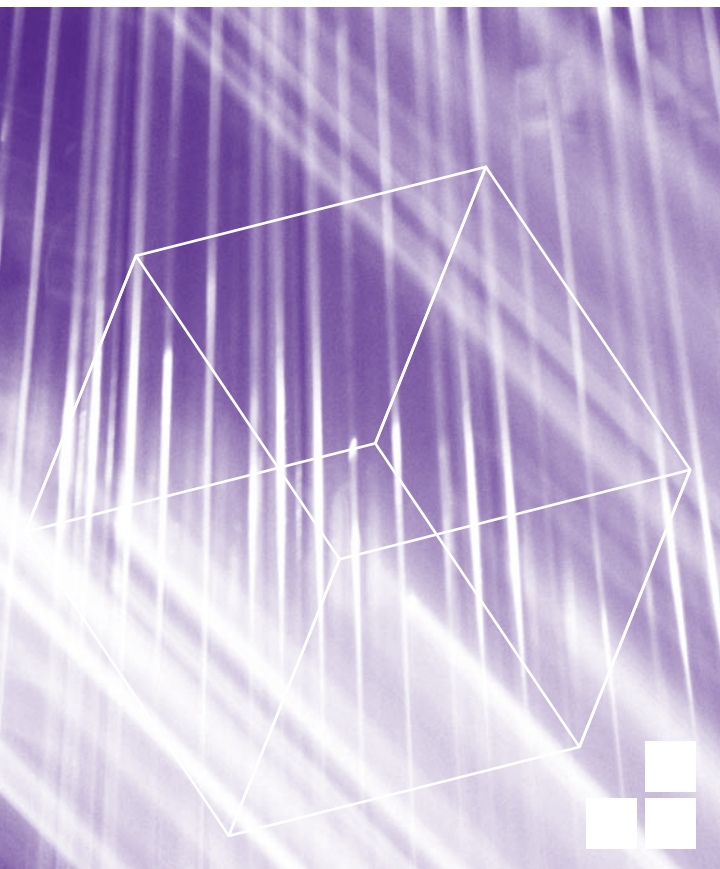




Database Development and Compliance



Database Development

A comprehensive clinical database that has been validated thoroughly is an important tool for monitoring your study and safeguarding the integrity of your results.

RCRI will work with you to develop databases and reporting tools that will stand up to the rigors of your clinical trial and meet regulatory standards.

At each step in the process, we will provide you with options to help meet your specific needs in a timely and cost-effective manner.

With RCRI you have choices

- RCRI can manage your database and data
- You can manage your database and data

Depending on your choice, a database can be installed at RCRI with remote access capabilities, or it can be located at your company. In either case, the data belongs to you.

When you work with RCRI, you choose only the services you need to meet your project goals.

You can manage your database and data

Clindex® services

If you already own Clindex and need additional support, RCRI Clindex experts can help you with a wide range of activities including:

- Data entry form/CRF development
- Edit check logic definition
- Monitoring setup
- "Information Manger" configuration
- Database validation
- Advanced report writing
- Development of site payment rules
- Custom interfaces to existing software/platforms

RCRI can manage your database and data

RCRI can manage your database and data from start to finish using Clindex® Clinical Trial and Data Management software. This premier technical solution can be customized to meet your specific study needs.

You choose only the Clindex features that you need to meet your project needs:

- Onsite study monitoring without an Internet connection
- Over 100 standard reports
- On-line randomization
- Custom study progress reports
- Visit tracking
- Site management and payment
- Device tracking
- Electronic data capture (EDC)
- Export to SAS for analysis purposes
- Remote sponsor access for CRF review and report generation

RCRI specializes in validating databases and auditing quality systems for regulatory compliance.

Validation services include:

- Validation of databases developed by RCRI or you
- Creation of validation SOPs

Auditing services include:

- 21 CFR Part 11 gap analysis
- Creation of SOPs for database development, maintenance, and archiving
- Assistance with software development history files to prepare for GMP and FDA audits.

Data Migration services

- From your clinical database to a solution of your choosing.

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

RCRI is ISO 9001:2008 certified.



ISO 9001:2008
FM 89594



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