Other Services include:

Biostatistics

- Protocol development
- Sample size determination
- Statistical Analysis Plan
- Randomization
- Statistical Analysis
- Data Safety Committees
- Report ready analysis tables

Data Management

- Case Report Form Design
- Database design and validation
- Data entry
- Programmed edit checks
- Adverse event coding
- Medication coding

Clinical Operations

- Clinical trial tracking and monitoring
- SOP writing
- Vendor contract negotiations
- Resource Planning

Regulatory Operations

- Coordination of NDA Submissions
- Preparation of ISS/ISE and other clinical sections
- Compilation of NDA sections
- Quality assurance

Prosoft Clinical and Adaptive Designs

Prosoft's statisticians have been on the forefront of research and implementation of adaptive designs in various areas of clinical research. Partnering with DANA Pharmaceuticals and Stanford University, Prosoft received an NIH grant for the commercialization of an adaptive design software for cancer research. While not every study is suitable for adaptive design, consultation with PSI can help you better assess the multiple factors affecting the conduct of your study, leading to a better chance of a successful conclusion of your trial.

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www.prosoftclinical.com

PROSOFT Clinical

The POWER of EXPERIENCE

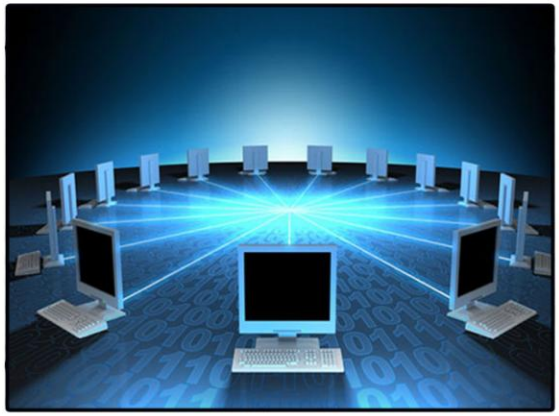
PROSOFT CLINICAL eDC

Established in 1995, Prosoft Clinical is a CRO with experience in all areas of pharmaceutical development. At Prosoft, our mission is to support our clients with world class data services and cutting edge technology. We specialize in clinical data services and software solutions for all of your clinical trial needs.

Our state-of-the-art web-based platforms allow us to launch and manage studies efficiently with a quick start-up and database lock, providing you results as soon as last patient completes last visit. Our systems include Electronic Data Capture (eDC), a multi-function data capture system featuring eCRF data entry, real-time data validation, and real-time reports, including study metrics and coding. Prosoft eDC is designed to expedite data capture in clinical studies in an accurate, efficient and user-friendly manner.

ABOUT PROSOFT CLINICAL's eDC

Prosoft Clinical's eDC provides you with the tools necessary to successfully complete any size clinical study. Our system includes advanced tools and cutting-edge features in a user-friendly interface. Our software offers an Oracle SQL, CDISC-compliant database, advanced security including data encryption, and full CRF 21 Part 11 compliance. Sponsors and CROs will appreciate features found only in leading software systems, including real-time edit checks, auto-coding, one-click study metric reports, full audit and query systems, CRF data book and annotated CRF generation, and much more. Sites and CRAs simply appreciate the easy-to-use, fast and efficient data entry, monitoring, query system and reports.



WHY PROSOFT'S eDC?

Prosoft Clinical's eDC system is among the most advanced and cost-effective systems today. Prosoft offers flexibility in customizing features such as reports and eCRF design. Prosoft's eDC is fully integrated with real-time IVR/IWR for study enrollment and statistical software for interim analyses. Prosoft stands behind its products and services with continual improvements and full technical support.

OTHER eTECHNOLOGIES

eNroll: IWRS/IVRS

- Rapid enrollment and randomization of subjects by phone or internet
- User friendly, logical call flow a
- Complete IP management with automated triggers and email/fax requests and alerts
- Advanced security features

eDSMB

- Set up your Safety Monitoring Board
- Write charters
- Manage meetings
- Produce dynamic real-time drill-down data summaries for review

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