Services Provided

Protocol / CRF

- Develop Clinical Protocol
- Write Clinical SOPs
- Design CRF
- Investigator Selection
- Budget Negotiations
- Contractual Agreements
- Plan, Organize and Conduct Investigators' Meetings

Monitoring

- Pre-Study Visits
- Study Initiation Visits
- Interim Monitoring Visits
- Study Close-Out Visits

Qualified to monitor clinical trials in North America, South America, Europe, and India. Monitoring services include 100% source data verification. A timely, comprehensive monitoring report is provided along with weekly patient status reports to the Sponsor.

Quality Assurance Audits

- Perform 100% verification of data
- Experienced in auditing clinical trials for Neurological Disorders in North America

Compassionate Use

- Coordinate and manage compassionate use protocol for spinal cord injury

Clinical Data Management and Data Analysis

- Provide randomization, full service data entry, QA, reporting and production of analysis data sets, and assistance with statistical analysis
- Windows 2000 secure data server, and Professional workstations used exclusively for data management
- Data base engine is MS SQL server, Applications Development provided by Access 2000, SAS is used for statistical analysis
- Collaborate with reputable statistical groups for complex statistical requirements

Educational

- Provide in-house continuing education programs for CRAs
- Train study personnel at the sites
- Write newsletter for Multicenter Clinical Trials