

Product Safety Monitoring Services

- Comprehensive product safety management / monitoring plan
- **SAEpro™**: Web-based SAE capture, management and reporting system
 - System customization – rapid implementation
 - Intuitive, user-friendly interface for data capture and data review
 - System hosted by SciAn Services Inc. using secure SSL connection (128 bit encryption) over a T1 line
 - FDA 21 CFR Part 11 compliant system
 - User training (central, local, Web-casting)
 - User support / help desk
 - Additional Safety Data Center services:
 - Alternative data capture: data entry from faxed SAE reports
 - Medical reviews – reconciliation with sites & study teams
 - Expedited reporting
 - Status reporting – data extracts – analysis tools
 - Database exports and locks
- Development & maintenance of integrated safety databases (ISD)
 - Development of integrated database structure
 - Data transfers and database maintenance
 - Generate and update reports
- Analysis & Reporting of ISD and SAE databases
 - Periodic Safety Updates for regulatory submission
 - ISS & ISE Reports for regulatory submission
 - Custom analyses & reports for the detection of:
 - Unexpected adverse events / changes in AE profile
 - Changes in incidence and/or severity of AEs
 - New drug-drug interactions
 - New drug-disease/demographics interactions
 - Methodology: multivariate analysis, cluster analysis, pattern recognition, trend analysis, Bayesian methods