



CASE STUDY: Fortune 100 Medical Device Company

Client:

Medtronic, founded in 1949, is a leader in the medical device industry. The company's primary focus is in the development, manufacturing, and sales of devices that address diabetes, heart disease, neurological disorders, and vascular illnesses. Medtronic reported 2007 sales of \$13.5B.

Challenges:

The data collection and analysis for a key trial was in doubt because the study was setup in Oracle Clinical (OC) using generic methodology that failed to account for client and product / industry specifics. There was a need to establish common standards, create custom solutions and re-engineer existing processes in order to increase overall effectiveness in the product development, clinical trial, and post marketing life cycle of products.

How We Helped:

- Analyzed and re-engineered existing clinical processes: Data entry, TMS coding, Discrepancy management, and CRF tracking
- Recommended and developed customized tools
 - A procedure validation tool that reduced testing time and increased accuracy of procedure creation, a key piece in successful study design and conduct
 - A customized application designed around Oracle Clinical to support trial monitoring activities
 - A CRF scanning and tracking application integrated with OC
- Implemented a CTMS system that integrates data from various data sources (OC, SAP, CareLink) into critical reports
- Supported and reported to FDA on the product safety platform for post-market issues
- Conducted interviews to hire key personnel to completely re-structure the clinical department
- Integrated CDISC standards with study set up