



Success Story: Clinical Trials Management Tools for Cancer Centers

Summary:

TerpSys supplies systems, application and business support to cancer research centers using clinical trials management tools and standards hosted by a large medical research agency.

Client: National Cancer Institute Center for Bioinformatics (NCICB)

The client is a division of a major federal research organization providing clinical trials software tools to cancer centers nationwide.



Objectives:

- Implement a robust, secure, state-of-the-art clinical trials management system
- Enable real-time electronic data collection and discrepancy management
- Integrate research efforts of participating centers and scientific community at large
- Promote system and standards adoption by cancer centers nationwide
- Improve quality and efficiency of clinical trials at participating cancer centers

Challenge

Outdated legacy systems and non-standardized data management practices impeded the ability of NCICB to collect and share clinical trials research data.

The client's parent agency, The National Cancer Institute (NCI), sought to help by investing in a new data management system and the development of data collection standards for managing clinical trials. A pilot program using the new system was to be field-tested at the Institute, refined, and then shared with cancer research centers across the country.

NCI, a longtime TerpSys client, brought us in to launch, maintain, and enhance the new central clinical trials database system and related tools, supporting first the internal clinical research center, and later expanding to support other cancer research organizations.

Solution

TerpSys designed, implemented, and currently maintains the Oracle Clinical servers and databases that form the IT infrastructure of the clinical trials management solution.

We built electronic Case Report Form templates to facilitate data collection and analysis, and established Standard Operating Procedures for account administration, protocol building, configuration management, and compliance with federal regulations and client standards. TerpSys also programmed template procedures to validate entered data, flag discrepancies, and derive calculable values. We review all studies for technical and standards compliance, and conduct system validation testing for bug fixes and version upgrades.

TerpSys continues to provide application support, reporting assistance, and data entry and discrepancy management training. We mentor remote center programmers, facilitate sharing among the centers, and incorporate user feedback into system and process improvements.

Results

- Implemented system's hardware and software and managed its configuration to ensure maximum availability and continual user-driven enhancements
- Developed reusable form and procedure templates to improve the efficiency and effectiveness of clinical trials data collection and analysis
- Trained and supported a dozen cancer centers and several research consortiums in their adoption of the clinical trials management system via hosted or onsite installation
- Established and promoted standard operating procedures for electronic clinical trials management – including study building, system security, and quality assurance