



NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

CHALLENGE/SITUATION

The Division of Intramural Research (DIR) and the Office of Biostatistics Research (OBR), of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), has had trouble accessing, disseminating, and sharing clinical data across their clinical, financial, and administrative systems in operations related to heart, lung, and blood research. NHLBI needed an effective and reliable management system to control clinical trials data, patient data, and research outcome data. NHLBI lacked a system architecture and data model that was flexible and scalable and would address various needs, including wide differences in reporting requirements and idiosyncrasies in dealing with internal trials in diverse clinical areas. The Applications Development and Support Branch (ADSB), under the Center for Biomedical Informatics (CBI), Office of the Director (OD) at NHLBI, supports and provides leadership for the Institute in all aspects of biocomputing. There was a lot of fragmented data, lack of standardization process, and disparate “silo” applications. An integrated information and knowledge environment that supports the full span of the NHLBI mission was needed to be built.

APPROACH

CTIS needed to build a web-based system that would assist in data management and coordinate NHLBI clinical studies. CTIS’ approach was to develop a custom application that would allow NHLBI to build in its specific workflow and functional requirements. Our approach needed to provide the best of both “build” and “buy” decisions by starting with an existing product and architecture and building in the desired features and functionality. It would result in significant savings in time, cost, and manpower for NHLBI in comparison to a custom-developed solution; it would also deliver complete functionality in comparison to an “off-the-shelf” product solution.

SOLUTION

CTIS developed a web-based clinical database system to assist the Intramural program in managing data and coordinating clinical studies for four of its branches: Hematology, Cardiology, Pulmonary and Critical Care. The system is built upon a highly scalable, standards-based, cross-language environment and has remote access capability. It provides statistical analysis of trials data; assists in developing interim and final reports for clinical trials; and is designed, implemented, and operated to have a complex relational database that effectively provides timely data and safety monitoring and evaluation of study progress and logistics.

We provide continued support and enhancements to the existing software applications at the CBI branch. A majority of these applications are web-based systems that can access large, high volume internal relational databases of scientific, medical, and administrative data. We also provide software engineering services in the areas of clinical research, clinical trials management, grants management, bioinformatics, and other general business administrative activities. This custom application developed for CBI bridges the gap between research and practice through knowledge networks; develops and retains human capital; supports development of multidisciplinary teams; establishes and expands collaborative resources for clinical research; and develops new technologies, tools and resources that facilitate access to scientific research resources.

BENEFITS

- Reduce the actual development time for new case report forms and medical record reports by 15% through its generic reusable data-driven components for the case report form generator
- Provides access to multiple sources of data that are derived from more than 100 NHLBI-sponsored clinical trials
- Reduces costs and workload; Accelerates study timeline
- Improves the process of intramural clinical research
- Automates and streamlines data collection, monitoring, analyses, and reporting
- Improves clinical trials workflow, data sharing, and interoperability while providing integration with other NIH hospital information systems
- Enhances patient management and data quality by delivering quality and reliable study results
- Provides stronger security and privacy and is compliant with industry standards, such as Medical Dictionary for Regulatory Activities (MedDRA) and 21 Code of Federal Regulations (CFR) Part 11