



DIVISION OF ACQUIRED IMMUNODEFICIENCY SYNDROME - ENTERPRISE SYSTEM (DAIDS-ES)

CHALLENGE/SITUATION

There are more than 25 million people who have died of Acquired Immunodeficiency Syndrome (AIDS) worldwide; another 33.4 million currently live with Human Immunodeficiency Virus (HIV)/AIDS (HIV/AIDS). HIV/AIDS is a global burden and pandemic; there is a clear requirement for new drugs, discoveries, and prevention and epidemiology studies. With the rise of new HIV/AIDS discoveries, the DAIDS of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), saw a rapid and remarkable rise in the scope, magnitude, and complexity of its research agenda. The number of active clinical studies had nearly doubled, with over 300 new international clinical performance sites in over 30 countries. These trials span across the areas of prevention, microbicides, genetics, and therapeutics. An Information Communication and Technology (ICT)-driven enterprise data warehousing system needed to be developed in support of global operations to improve its data sharing, integration, collaboration and communication, reduce its administrative costs and time to get the drugs to the market while increasing patient safety.

APPROACH

CTIS defined the current DAIDS clinical research environment and existing barriers through its business processes for efficient data entry, access, dissemination, and exchange. The new enterprise system needed to increase the efficiency and effectiveness of clinical research; strengthen safety and pharmacovigilance monitoring; improve data quality, integrity, and stability; strengthen regulatory compliance and development of evidence-based clinical research policy; achieve interoperability and eliminate redundancies; accelerate the ability to capitalize on scientific opportunities; and support reuse across various Divisions.

SOLUTION

CTIS designed and developed the DAIDS-ES ICT solution, which is a scalable, robust, web-based enterprise system. The technologies involved include web portal, mobile interface, relational database, middleware, data interchange, data warehousing, and reporting. It provides simple, unified access to multiple sources of data generated by DAIDS-sponsored clinical trials worldwide. DAIDS-ES supports the full life cycle of critical enterprise activities and objectives, from protocol management and clinical site monitoring to wireless database queries and adverse event reporting.

BENEFITS

DAIDS-ES provides essential knowledge and institutional memory in knowledge libraries and enhances information exchange and collaboration across DAIDS and its global programs. It also reduces infrastructure and development costs; streamlines compliance with federal regulations and data standards; simplifies protocol management and abstraction; allows flexible access to centralized contact information; and supports mobile information access and dissemination. DAIDS-ES strengthens the safety and pharmacovigilance monitoring; improves data quality, integrity and stability; and allows for rapid, secure, and accurate adverse event reporting globally. Without a change in the number of DAIDS staff members, there has been a dramatic increase in productivity and the number of new sites, protocols, protocol study chairs, organizations, and users in DAIDS-ES.

- 50% increase in the number of sites
- 149% increase in new protocols
- 173% increase in new protocol study chairs
- Over 2000 organizations
- Over 3300 users