



## **BUILT TO LEAD**

During the 1980s, the health research community faced a problem: how could new drugs and treatments be brought to market quickly and safely in one of the most heavily regulated industries? It was at this critical time that CTIS was established. The founder, Mr. Raj Shah, brought two decades of experience in increasing Return on Investment (ROI) for Fortune 50 companies utilizing Business Process Reengineering, Total Quality Management, and IT, coupled with a personal desire to make a difference in the healthcare industry. Mr. Shah positioned CTIS ideally to become one of the first change agents in HIT.

CTIS first entered the industry through engaging the National Cancer Institute (NCI) of the National Institutes of Health (NIH) to build IT solutions for the Clinical Trials Research and Management (CTRM) process. The key insight that led to success at the Cancer Therapy Evaluation Program (CTEP) was recognizing that there were no one-size-fits-all solutions for the diverse needs of NCI. Rather than offering a product for a set of problems, CTIS developed an approach for managing the ongoing dilemmas and complexities associated with clinical research.

The resulting system effectively administered clinical trials by facilitating protocol development, inventory management, auditing, and several other functions. To support clinical research with academic medical centers, CTIS built the Protocol Authorization and Tracking System (PATS) as a proof of concept for CTEP. The success of the PATS system paved the way for a suite of CTRM applications that would streamline the clinical research process, connect stakeholders, and build seamless information flow, leading to better regulatory compliance, quality, efficiency, and productivity.

NCI was the ideal place for CTIS to grow because it represented 15% of the total NIH budget and because of the national importance placed on driving new cures for cancer in the general population. CTEP's suite of applications has achieved 250% ROI and was ranked as the #1 IT investment within the NIH, and the #3 IT investment within the Department of Health and Human Services (HHS).



The approach developed by CTIS for NCI began to appeal to a broader segment of health-focused clients in both the public and commercial health markets. Like NCI, they faced burdens associated with a fluid regulatory environment and inefficient processes. In the public market, the National Institute of Allergy and Infectious Diseases (NIAID) and the National Heart, Lung and Blood Institute (NHLBI) both entered engagements with CTIS. A \$300 million dollar total investment in CTIS solutions served as the catalyst for over \$9 billion in research projects across the NIH.

CTIS also began customizing solutions for clients in the biotechnology industry, such as Novartis and Bristol-Myers Squibb, as well as Academic Medical Institutes (AMIs), including Georgetown University and the University of Colorado Cancer Center. Ten years after entering NCI, our solutions were also being implemented by the Johns Hopkins University, Moffitt Cancer Center, GlaxoSmithKline, and Serono. CTIS solutions have been used in over 10,000 sites, 15,000 protocols, 500 Investigational New Drugs (INDs), 1 million patients, and over 20,000 investigators, resulting in redundancy reductions of 20%, and process efficiency improvement of 25%.

With each of these clients, CTIS did not simply apply a turnkey solution. Instead, CTIS leveraged its approach as a systems integrator, custom solution developer, and program manager to oversee the implementation of solutions that maintained high ROI. In response to growing dilemmas within the health sector, CTIS continues to serve clients across the health spectrum including healthcare, public health, health research, health education, and global health initiatives.