

## ENTERPRISE STANDARDS UNIFORM REPOSITORY FRAMEWORK

CTIS' best practices framework is referred to as Enterprise Standards Uniform Repository (EnSURE™). This framework, which was assessed and certified at CMMI Level 3 in 2007, is the foundation of which CTIS is able to deliver high Earned Value Management (EVM), Return on Investment (ROI), and best outcome management to our clients.



As illustrated above, CTIS has utilized an integrated approach to developing EnSURE, using balanced score card performance measures and best practice standards across all domain service areas to maximize efficiency, productivity, reliability, and effectiveness of the informatics system. This integration allows for highest quality, outcome management, and ROI.

There are five core domains within the EnSURE framework. These include software development, infrastructure, program management, services (customer service), and data (clinical). CTIS has always believed that the key to strengthening these core domains and to delivering a quality product is the adoption of appropriate standards and best practices, which presents a challenge when considering the multiple standards available for various types of services in the IT sector. EnSURE has the ability to bring together, in a structured manner, the various IT governance, service, and software development and project management standards in a single automated process asset library.

### Software Development

At the core of CTIS is our software development service, which enables the delivery of clinical trials research and management solutions to health informatics and networking systems nationwide for both public health and healthcare. CTIS utilizes a number of industry-wide standards and processes to ensure a best practices system for our clients. CTIS is certified at CMMI Level 3 in part because of the standard processes that have been established and continue to be subject to some degree of improvement over time. These standard processes are in place and used to establish consistency of process performance across the organization. In order to ensure our systems are functional a

interoperable services, CTIS utilizes service-oriented architecture methods for systems development and integration. Utilization of the rational unified process framework for software development also contributes to CTIS' overall commitment to best practice and the delivery of quality products to our clients.

### **Infrastructure**

CTIS adopted NIST standards to enhance the IT infrastructure services delivered to our customers. Through the adoption of these infrastructure standards, CTIS achieved FISMA compliance and successfully obtained Certification and Accreditation (C&A) for the systems developed and maintained for our government clients. CTIS plans to begin the process of mapping its internal ITSM processes to Information Technology Infrastructure Library v3 (ITIL v3). ITIL provides organizations with a systematic approach to the provisioning and management of IT services from inception through design, implementation, operation, and continual improvement. We support these services with best practices and guidelines from the ITIL Service Operations and Continuous Improvement guidelines, ASM standards, and C&A Maintenance to ensure security and continuity. In addition, CTIS remains committed to ensuring HIPAA compliance across all relevant systems in order to protect identifiable information that is being used to analyze patient safety events and improve patient safety outcomes.

### **Program Management**

CTIS' commitment to the project management practice has been demonstrated on our various NIH contracts by directly aligning with CMMI, HHS Enterprise Performance Life Cycle, and the PMI Program Management Body Of Knowledge. CTIS brings to the table a team of project managers trained and/or certified in PMP, EVP, and Six Sigma. The CTIS Team uses best practices from its KWF and EnSURE frameworks to support standard reporting formats (e.g., Cost Benefit Analysis Reports, GPRA, OMB 300, Program and Project Status Reports) to enable the analysis, prioritization, selection, monitoring, and evaluation of IT investments. We assist our clients in following CPIC standards of Select, Control, and Evaluate by submitting standard EVM reports based on ANSI/EIA 748-A guidelines. In addition, the completion of cost benefit analysis, prioritization, and selection of the right IT investments that align with our client's mission is also part of the CTIS program management commitment.

### **Services (Customer Service)**

CTIS is committed to not only providing a quality product to our clients, but also with providing on-demand support for any and all client specific needs. This includes the deployment of a help desk, satisfaction surveys and measurements, and proper handling and turnaround of change requests. In order to effectively deliver on this commitment, CTIS uses a Six Sigma and Total Quality Management (TQM) approach to guide the incremental adoption of relevant best practices and standards. This presents optimal value to our customers by delivering quality services and products without adverse impacts to costs or schedules. The TQM framework provides CTIS with a way to manage and apply the standards it has adopted in an incremental and structured manner, whereas the Six Sigma management strategy seeks to identify and remove the causes of defects and errors in manufacturing and business processes by using a set of quality management methods.

### **Data (Clinical)**

CTIS interfaces with the enterprise vocabulary system developed by the NCI, whose purpose is to accelerate information sharing and discovery and facilitate the integration of diverse data systems throughout the cancer research community. This is achieved by providing an electronically-accessible resource for standard terminologies that improves the links between healthcare delivery system and clinical research/trials by increasing

accuracy and speed of data collection, increasing patient safety, and decreasing the approval time for safe and effective treatments. SNOMED is a systematically organized collection of medical terminologies covering most areas of clinical information. It allows a consistent way to index, store, retrieve, and aggregate clinical data across specialties and sites of care. It also helps in organizing the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research. MedDRA is a system of clinically validated international medical terminologies used by regulatory authorities throughout the entire regulatory process for data entry, retrieval, evaluation, and presentation. In addition, it is the adverse event classification dictionary endorsed by the ICH.