



Good Clinical Practice

BUILDING GOOD CLINICAL PRACTICE

The cost of getting a drug to market has doubled to an average of \$1.7 billion from 10 years ago. What has contributed to the dramatic increase? A 30 to 60 percent delay from planned deadlines experienced at each phase in the clinical trials life cycle. Poor clinical trial execution cost companies as much as \$5 million in fore-gone sales each day. With this much at stake, accelerating clinical trials is the highest priority for both government and industry sponsors. Therefore, developing solutions to reduce the time and cost in bringing new treatments to market, without compromising safety or efficacy, is imperative.

For 20 years, CTIS, Inc. (CTIS) has developed and implemented a proven framework of methodology and technologies to address these very issues. The CTIS approach and philosophy to delivering services and developing solutions is derived from Good Clinical Practice (GCP). GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Organizations, involved in clinical trials that comply with this standard provide strong public assurances that the rights, safety, and well-being of trial subjects are protected and are consistent with internationally accepted ethical principles, treaties, and declarations.

CTIS's proprietary framework is an extension to the GCP standards to address the ethical and safety obligations inherent in the use of informatics. Our approach and tools, collectively referred to as Good Clinical Informatics™ (GCI), have been used to reduce trial time, at a number of stages, by over 25% and have provided an overall annual return on investment of over 250% for our clients. GCI™ provides this exceptional return on investment by building a threaded communication channel from beginning to end of the clinical trials processes that assists stakeholders in maximizing connectivity, coordination, and collaboration.

The proven benefits of GCI™ are:

1. More efficient trial planning
2. Better qualified clinicians and practitioners through timely and effective training
3. Optimized management of trial assets
4. Streamlined trial processes
5. Faster recruitment processes of physicians, sites, and patients
6. Better information intelligence, data management, and document management
7. Continuous monitoring, evaluation, and alignment of the study stages
8. Performance measurement of the trial endpoints

CTIS delivers the GCI™ framework through its Trial Bridge™ intellectual property technology framework. GCI™ provides a robust research environment that delivers information through the support of infrastructure requirements, seamless integration with existing systems, and appropriate certifications and accreditations. Also including libraries complete with reusable components, business intelligence capabilities, standardized processes, and a communications framework that enables the building of highly effective coalitions among stakeholders, on-demand target training, and facilitation of continuous information sharing.

GCI™ COMPONENT 1: A GOOD CLINICAL ENVIRONMENT PROVIDES:

- Management of critical cost elements within the clinical environment such as patient and site recruitment, as well as the leveraging of new technology and trial management strategies to improve trial performance and expand trial participation to include untapped patient populations from across the world

- Implementation of a robust information technology platform and infrastructure to meet proper certification and accreditation requirements delivering data assurance and protection, ensuring emergency management and disaster recovery capabilities, and securing the privacy and confidentiality of study participant information
- Facilitation of efficient electronic data capture, management, interchange, and reporting for all transactions that take place at each stage of the clinical trials life cycle
- Integration of data warehousing capabilities and enterprise applications to promote stringent information quality, reliability, predictability, scalability, interoperability, and harmonization across the clinical trials management system

GCI™ COMPONENT 2: A GOOD CLINICAL LIBRARY PROVIDES:

- A global library of trial core contents, configurable components, regulatory and service standards, data coding, and development methodologies
- Standardized, proven development, and management processes, together with domain and thought leadership expertise to maximize the client’s return on investment throughout the clinical trials process
- Comprehensive business intelligence and knowledge management applications that deliver strategic decision support, digital dashboards, data visualization to facilitate study alignment, evaluation of process compliance, and trial outcome analysis
- Content and workflow mechanisms that deliver easy-to-use information customization, trial requirement configurations, threading of trial stages, and the facilitation of best practices throughout the trial life-cycle

GCI™ COMPONENT 3: GOOD CLINICAL COMMUNICATION THAT PROVIDES:

- Continuous stakeholder connectivity, communication and collaboration through the use of the internet, networks, grids, and portals for document, data, and trial event management across the planning, activation, conduct, closing, and completion stages of clinical trials.

- On-demand training on clinical research processes, trial practices, regulatory requirements and study endpoint requirements for trial stakeholders with the goal of increasing trial assets and resource capacity.
- Facilitation of and support for the formation of collaborative groups and networks to bring together diverse stakeholders, industry experts and practitioners to share ideas and discoveries across the clinical research community.

ABOUT CTIS, INC.

CTIS, based in Rockville, Maryland and founded in 1988, is a leading provider of award-winning clinical trial research and management solutions that combine industry best practices, advanced technology and regulatory compliance standards to address the unique needs of healthcare stakeholders worldwide. CTIS has developed a long-standing reputation helping federal regulatory agencies, academic medical institutions, pharmaceutical companies, and Contract Research Organizations (CROs) conduct studies across a broad spectrum of therapeutic areas and at all phases. CTIS offers proven solutions that enable clinical researchers to accurately capture and report data, boost productivity, and maintain fiscal responsibility in order to advance new treatments to market.

