



CTIS | A HEALTH
INFORMATICS
COMPANY
Proven Solutions. Improved Results.



Clinical Trials Research Management

Accelerating Drug Delivery From Bench-to-Bedside



IT'S ABOUT.....

Collaboration
Interoperability
Regulatory Compliance
Organization Realignment
Process Efficiency

Innovation
Best Practices & Standards
Patient Safety
Drug Efficacy
Treatment Outcome

Quality of Care
Chronic Disease
Individualized Medicine
Translational Research
Data Interfaces

Today, as the development of a single drug can take over 15 years and cost over \$1billion, there is an urgent need to expedite drugs benefits to patients in a safe and cost effective manner. The current process to take a drug from “bench-to-bedside” is extensive as it is driven by paper-based processes causing redundant efforts, disconnected stakeholders, and regulatory burdens. Information Technology can shorten the time span; streamline processes and collaboration and lower the overall cost of the clinical drug development lifecycle.



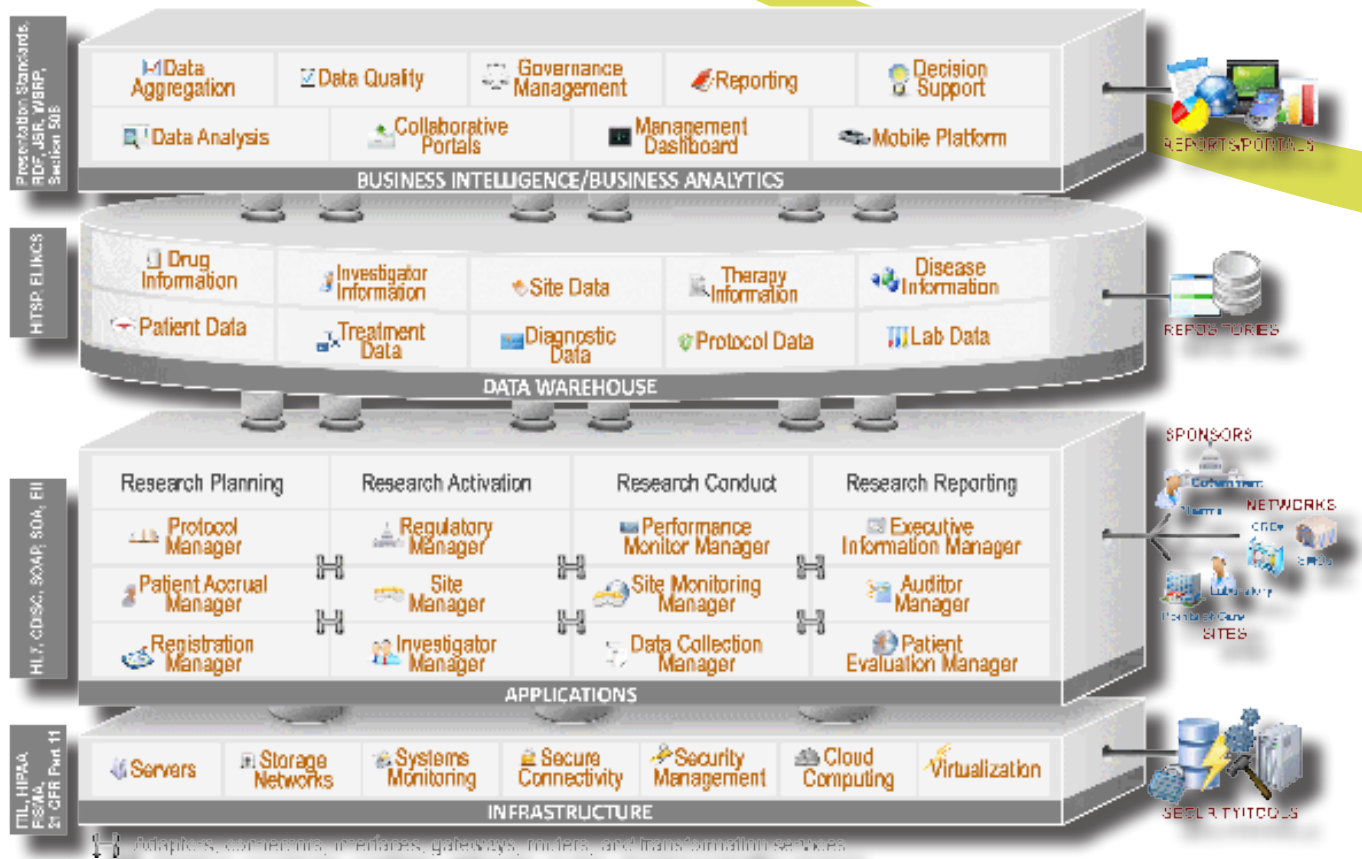
The CTRM ecosystem broadly consists of three mutually dependent stakeholders, each requiring specific information during various stages of the clinical trial process.

- **Sponsors:** Organizations that are responsible for conducting research and drug development such as Pharmaceutical/Biopharmaceutical and government agencies such as the NIH, and DOD/VA.
- **Networks/Facilitators:** Organizations, such as Contract Research Organizations (CROs), Site Management Organizations (SMOs), and co-operative groups and networks, who oversee, coordinate, facilitate, and implement research activities involved with the clinical trials.
- **Sites:** Organizations where physician-patient interaction takes place, such as hospitals, clinics, labs, and other diagnostic/clinical centers.

The ability for stakeholders to acquire timely, accurate and relevant clinical trial information is critical to the success of their trial, but obtaining such information is a challenge due to a general lack of connectivity and inefficient processes in place that affects the overall performance, length, and cost of the trial. Our solutions will facilitate collaboration, increase efficacy, and shorten the bench-to-beside timeframes and costs. Driven by the power of IT, process efficiency and increased productivity will be achieved through the connectivity and collaboration among CTRM stakeholders and their ability to access the right information at the right time.

“As we continue our successful relationship with CTIS Inc. and continue the development of the National Cancer Institute’s Cancer Therapy Evaluation Program - Enterprise System (CTEP-ESYS) into an enterprise-wide biomedical informatics program, I would like to take this opportunity to express how pleased I am that CTIS is my partner. As an organization CTIS performs critical work in the national interest as part of the National Cancer Institute’s ongoing expansion of clinical informatics solutions to enhance cancer therapy and treatment.” – Program Officer, NCI

CTIS' CTRM Four-Layer Solution Architecture



With over 20 years of experience working with various stakeholders, we have developed a deep understanding of the processes and requirements. We have applied this knowledge by defining, designing, developing, and deploying proven solutions which focus on the delivery of information to CTRM stakeholders through our solution architecture, as shown above. We have simplified the processes and our solution stack to address the clinical research lifecycle into four stages across the three types of stakeholders. The core tenets of our solution are the stakeholder-focused applications layer and the business intelligence/business analytics layer. Providing foundation support are the data warehouse and infrastructure layers, the latter of which offers a scalable, dynamic and interoperable approach to providing standards-compliant infrastructure services.

Layer 1 – Infrastructure Layer

At the foundation of the five-layer solution architecture is the Infrastructure layer and our ability to provide:

- Robust, scalable, and completely interoperable infrastructure services
- Dynamic provisioning of servers, storage, and network connectivity
- Best of breed solutions supplemented by proactive systems monitoring, secure connectivity, and security management
- Compliance with regulatory standards such as ITIL, HIPAA, FISMA, and 21 CFR Part 11

Layer 2 – Application Layer

The application layer consists of components that can function both independently and in an enterprise setting assisted by common infrastructure platform and gateways. This layer addresses process deficiencies, rate-limiting factors, and the specific needs of all CTRM stakeholders. Whether a sponsor is looking to manage protocol authoring during the planning phase, a CRO is looking to monitor clinical sites during trials, or a clinical trial site is looking to efficiently capture and report adverse events...we have the solution for you-- perfectly tailored to your information needs.



NIH DIRECTOR'S
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AWARD



RATED #1 IT INVESTMENT ACROSS
DEPARTMENT OF HEALTH AND HUMAN
SERVICES



Systems integration seamlessly integrates components while maintaining core system functionality and minimizing system redundancies and costs. CTIS has a 20-year history of successfully providing systems integration services to clients. Our approach to systems integration consists of:

- CTRM thought leadership that allows for initial business process re-engineering to synchronize, harmonize and optimize system functions and processes.
- Ability to leverage current/existing client investments, whether they are Commercial off the Shelf (COTS) products and architecture platforms or customized products, and integrate/configure/customize additional components onto existing architectures.
- Incremental and iterative approach to progressively introduce, test and demonstrate the effectiveness of additional functionality, guaranteeing a high Return on Investment (ROI).

“I wanted to thank CTIS for the role played in launching the DAIDS Enterprise System (DAIDS-ES). Your knowledge, dedication, and commitment brought all of us to a major milestone of accomplishment. On behalf of the Division of AIDS, and the entire Institute, I commend you for your outstanding work, and look forward to continued successes through our partnership. Together, we will help find effective preventions and treatments for people with HIV throughout the world. And, if along the way, we encounter adverse experiences, we’ll have the world’s best way of detecting them so as to provide the greatest possible protection for the volunteers that make our research possible.” – Program Officer, DAIDS

“The overall speed and performance of the NHLBI-CDS Application as improved significantly (a 10-fold improvement on average). The Vascular Medicine Branch has now made 100% commitment to using this application for all our clinical trials.” - Chief at Vascular Medicine Branch, NHLBI

Layer 3 – Data Warehouse Layer

CTIS’ data warehouse layer caters to the varying needs of all stakeholders without compromising the security, privacy and data integrity of the information sources. It stores all CTRM data and allows the option to harmonize the data by building Operation Data Stores (ODSs) upon a common vocabulary layer.

CTIS Fact: Our CTRM solution has improved the trial time from Letter of Intent to Activation by 53%

Layer 4 – Business Intelligence/Analytics Layer

CTIS’ business intelligence/analytics layer provides stakeholders the ability to access and aggregate the data in meaningful ways to support informed decision-making. Through portals and dashboards, executives can:

- Monitor and track his/her total cost of ownership and perform portfolio management activities;
- Make resource allocation decisions between various clinical trials protocols and clinical sites;
- Scrutinize adverse event data across multiple clinical sites to assess the efficacy of the drug;
- Abstract data and perform comparative forecasting and predictive modeling with user-friendly interfaces. .

Research Planning

Protocol Manager

Protocol Manager allows us to plan, author, review, and scientifically approve the protocol document from concept to activation. The use of templates, configurable workflows, and business rules afford as much as a 50% reduction in the overall planning lifecycle. It enforces data compliance with CDISC, HL7, and BRIDG to minimize manual work processing efforts through pre-population of study elements to other components of the application layer, such as the IRB Manager and Data Collection Manager.

Stage Name	Role	Duration (Calendar Days)	Planned Date
Publish and Notify	Site Coordinator		Mon 11/11/2010
Review, Comment & Reply by Site	Site: Reviewer, Lead Reviewer, Site Coordinator	10	Thu 11/11/2010
Resolve Comments	Site Lead Reviewer	5	Tue 11/16/2010
Incorporate Comments	Site Coordinator	6	Mon 11/15/2010
Total Duration		21	

Research Activation

Regulatory Manager

Regulatory Manager allows for regulatory organizations to check for efficacy and safety of the protocol through collaboration, change control management, and its workflow driven process. This tool manages FDA 1571 forms, is compliant with the 21 CFR 11 standards through electronic signature, and audit trail.

User Reference Id	IRB Number	State	Short Title	Reviewer (s)	Review Date	Principal Investigator(s)
1169	1169	Granted	A Phase III Randomized Double-Blind Study of Maintenance Therapy with CD-591 (1572 # 109415, NDA 19116) in Patients Experiencing Acute Myocardial Infarction	Laura Miller	12/06/2010	

Investigator Manager

Investigator Manager consists of two modules, the first addresses the registration requirements of Investigators, both Principal and participating, by maintaining libraries of 1572 forms, current Curriculum Vitae (CV) and other required registration documentation. The second addresses the administrative needs of sponsors who must ensure that capable investigators are available to participate on their study. The application provides a configurable workflow to reduce the total cost of ownership, meets all regulatory standards such as 21 CFR Part 11, and improves the process efficiency of investigator registration process.

Registration Status	Draft	Registration Status Date	03/07/2010								
Protocol Number	E-1000	Sponsor	Ace Drug Company								
Protocol Title	Phase III Randomized Study of First-Generation High-Dose With Alpha-2a in Stage T3 - T4 in HR (Gynecologic) Metastatic										
Protocol Agent(s)	Michelle PFS,										
Protocol Documents	code templates.xml										
Forms	1572 - Section wise status										
	1	2	3	4	5	6	7	8	9	Status	Signed
FDA - 1572	✓	One page CV	✓	✓	✓	✓	✓	✓	✓	To Be Signed	
Financial Disclosure Form	To Be Signed								03/07/2010		
CV-Resume	Signed								03/09/2010		

Representation of

CTIS Fact: The Office of Management and Budget (OMB) Exhibit 300 CTEP report shows more than 250% Return on Investment (ROI) to the government.

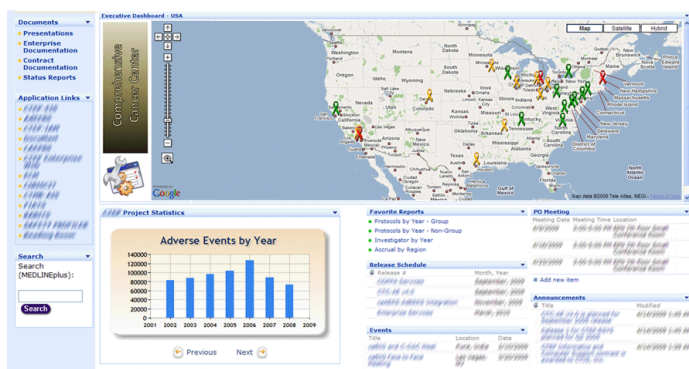
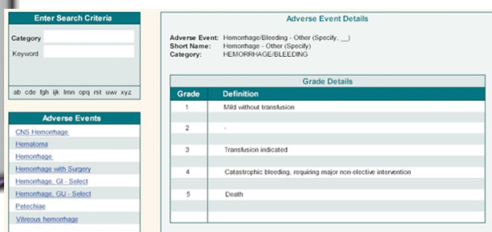
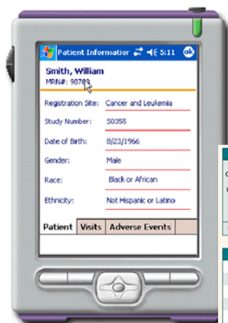
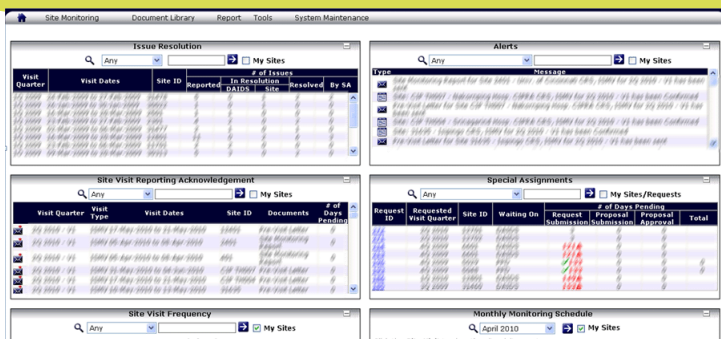




Research Conduct

Site Monitoring Manager

Site Monitoring Manager allows the real-time monitoring of trial sites through the examination of site preparedness and execution activities both, prior to and during study conduct. The application is based on a configurable workflow, which allows task assignment, tracking and schedule review of site monitoring activities. It also consists of a report module that is evidenced based which drives the execution of best practices and Standard Operating Procedures (SOPs) of the clinical site monitoring entity.



Data Collection Manager

Data Collection Manager allows the electronic capture of patient data at point of care in order to maintain data integrity. This tool also provides standard medical libraries such as MedDRA, SNOMED, and ICD, to map and accurately code the patient data. This capability also ensures the data captured at bedside is appropriately reflects the patient status according to the medical libraries and is categorized properly.

Research Reporting

Executive Information Manager

Executive Information Manager aggregates data from multiple sources and presents information in user-friendly formats for informed decision-making support and overall portfolio management. With a scalable and interoperable foundation that is built on algorithms and pre-configured and real-time data elements. The Executive Information Manager generates and uses evidenced-based snapshot status reports across multiple dimensions of clinical information which enables trend and what-if analysis to be conducted.

Application Layer Components

CTIS Facts: Our CTRM solution has:

- Reduced Organizational Redundancy by 20%
- Increase in Process Efficiency by 27%
- Increase in Productivity by 23%





About CTIS

CTIS has over 20 years of proven history in providing total informatics solutions to the health sector. CTIS provides innovative, appropriate, timely, and quality information technology solutions to health systems, health professionals, research organizations, and payors to support their goals in serving patients. To address this need, CTIS' informatics solutions converge health sciences, information technology, process reengineering, total quality management, and organizational effectiveness in order to optimize the capture, storage, and use of information in health and biomedical sciences.

CTIS is also building needed personal information solutions that serve patient directly in dealing with their healthcare providers. CTIS' leadership is at the forefront of national discussions that are defining the next generation of biomedical, clinical research, translational research, personalized medicine, comparative effectiveness research, performance driven healthcare, health disparities, elder care, and chronic disease management programs that will not only provide better patient care, but also meet the cost management goals of the health industry.