INFOTECHSoft
Innovative Healthcare Solutions

TrialSense

www.infotechsoft.com

TrialSense means clinical trials automation. Featuring intelligent case report forms, task workflow sequencing, and robust security, TrialSense offers a comprehensive solution for the administration of multiple trials within a single integrated environment. Its user-friendly, Web-based data collection interface is the portal to a powerful and flexible software engine that continuously monitors the complete clinical trial process. TrialSense empowers clinical researchers to achieve accurate, efficient, effective clinical trials.

TrialSense COLLECTION STATION

The *TRIALSENSE Collection Station* provides a window through which subject data is easily entered. Accessed from any modern operating system using a standard Web browser, it combines strong security and privacy protection mechanisms with an easy-to-use interface where clinicians and users enroll and select subjects, enter and review case report forms, and recognize possible adverse events.

Multiple Trials, Multiple Sites, One Environment

TrialSense supports the concurrent management of multiple trials. Through a single, common user environment, clinicians can enroll subjects, and enter and review data, for different studies. Trials can be configured to be run in multiple sites around the world, enabling the instantaneous transmission of data from any point of participant contact to a central trial data repository. For locations where access to the Internet is unavailable or unfeasible, TrialSense provides offline data collection with advanced synchronization using highly portable devices such as Tablet PCs.

Task-based Data Capture

When working with a subject, the clinician is shown the specific set of tasks to be performed at a particular visit, as mandated by the trial protocol. This automated task sequencing enables stricter protocol compliance and minimizes deviations. As clinicians enter collected data and indicate the completion of each task, TrialSense immediately computes the next tasks to be performed with the same subject and advises the user accordingly.

Intelligent Forms

Case report forms (CRFs) and data entry screens contain underlying technology that minimizes errors and increases clinician efficiency by enabling automatic on-the-fly calculations, consistency verification, and conditional data collection. Responses within a form or in other forms previously filled for a patient are used to determine data validity and to require or disallow information entry. Pre-defined calculations provide immediate feedback to the user and help eliminate errors and inconsistencies.

Electronic Signatures

All case report forms must be signed by a user after data entry is complete. If the trial protocol demands it, multiple users may be required to sign off on data before the subject can proceed through the trial, minimizing the possibility of errors and omissions, and ensuring accountability from the various actors interacting with the subject.

Adverse Event Monitoring and Reporting

Adverse events are detected automatically through the continuous and unobtrusive analysis of collected data, or directly reported by clinicians and users. Upon the occurrence of an adverse event, screen and e-mail alerts are presented to the trial managers or clinical directors, and tasks for the subject are suspended until appropriately authorized individuals acknowledge the adverse event and decide on a course of action.

Multilingual, Multicultural

Many clinical trials today require the capture of information in multiple languages. TrialSense intelligent case report forms and task sequencing screens support the presentation of information in multiple languages, expanding the ability of clinical researchers to include ethnic and culturally diverse populations and to perform large, international trials.

TrialSense CONSOLE

Trial managers and principal investigators use the TrialSense Console to set up, start, and stop clinical trials, to establish security and privacy policies for every user, and to monitor and evaluate the overall performance and execution of all trials.

Security, First and Foremost

User authentication and access control mechanisms embedded in TrialSense help ensure that information is entered and accessed only by authorized personnel. Each user is specifically assigned a set of tasks to be performed on a specific set of subjects at a specific trial site, preventing both inadvertent errors and malicious tampering. Transmissions of data through local or Web connections are always encrypted. TrialSense is designed to comply with all security and privacy standards, including the Health Insurance Portability and Accountability Act (HIPAA), the U.S. Code of Federal Regulations on Electronic Records (21 CFR Part 11), and the guidance documents from the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Enrollment and Study Progress Monitoring

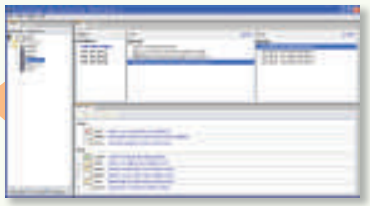
Close tracking and monitoring of enrollment levels, study progress, and protocol compliance is critical for the efficiency and even success of a clinical trial. Through the TrialSense Console, the trial manager or principal investigator reviews subjects by trial or by site, verifies and corrects information in collected case report forms, includes or excludes subjects from any trial within the system, and makes decisions regarding adverse events or other abnormalities in trials. Reports detailing the progress of each trial are easily created and viewed.

Audit Trails

Every interaction between a user and the TrialSense system, from data entry to adverse event reporting, is logged, time-stamped, and saved. Through the TrialSense Console, trial managers can review these audit trails, to ensure accountability of users in performing tasks within the system.

Electronic Data Sharing

TrialSense is built around the open XML standard, allowing collected information to be easily shared with other software applications such as patient record systems and statistical analysis tools. Using the TrialSense Console the clinical investigator can export or expose any amount of data in a variety of industry-standard electronic exchange formats.



TrialSense ARCHITECT

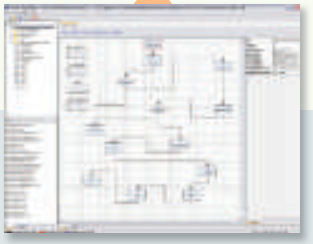
The TrialSense Architect is a graphical toolset that assists the clinical investigator in designing a clinical trial. It provides intuitive graphical user interfaces to create and modify the trial protocol sequences and the case report forms and entry screens.

Graphical Protocol Workflow

The TrialSense Architect allows for drag-and-drop protocol design using graphical representations of actions, tasks, and decisions to define the workflow of a study. The graphical interface provides trial developers with the ability to easily describe and visualize the complex sequence of events required in a clinical trial. Tasks are associated with case report forms and defined in sequences, while decision points indicate either the automatic selection of a path based on some previously collected or calculated value, or the need of a manual choice by an authorized user. Parallelism and iterations can be easily configured, and tasks can be grouped together conforming visits. Protocols defined through the TrialSense Architect are realized and saved in XML, enabling protocol reuse and refinement.

Intuitive Form Design

Case report forms and data entry screens are easily created in the TrialSense Architect through a comprehensive interface, where the trial developer designs the data capture mechanisms and the look-and-feel of each form, inserts intelligent expressions and instructions, and defines versions in different languages. Standardized forms are easily saved and reused at different stages within a trial protocol.



INFOTECHSoft develops next-generation information technology solutions for health care and the life sciences. Our experienced and highly qualified technical staff, working with top-of-the line consultants in diverse medical fields, apply the latest advancements to address current and emerging issues in health care information technology. Our cutting edge research projects, funded by the National Institutes of Health, continuously expand the state of the art to produce powerful and easy to use systems. Located in multicultural and vibrant Miami, Florida, INFOTECHSoft has the innovative solution for your needs.

INNOVATIVE HEALTHCARE SOLUTIONS

ASPECT Mental Health Assessment System

ASPECT is a novel mental health information system designed with mobility and intelligence in mind. The ASPECT Rating Station combines the simplicity and ease of use of traditional paper forms with the power and flexibility of computer-based assessment. The ASPECT Control Center provides a powerful suite of tools to create the user interface and manage the computational logic of complex psychiatric instruments. Together, they constitute an indispensable tool for mental health treatment and research.

Medical Records

INFOTECHSoft EMR is an advanced, highly customizable electronic medical record system, meeting the information management, storage, and retrieval needs of clinical practices while offering an effective mechanism for tracking patient information, medical records, progress reports, and clinical response. Configurations of INFOTECHSoft EMR currently include cardiology, nephrology, pediatrics, and primary care.

Preventive Care

PreventaMed is a comprehensive, automatic, and secure web-based system for tracking the management and delivery of preventive care services. PreventaMed's artificial intelligence engine provides timely and accurate decision-support based on the United States Preventive Service Task Force (USPSTF) guidelines. PreventaMed can be used in conjunction with INFOTECHSoft EMR or integrated with existing information systems.

Healthcare Information Integration

INFOTECHSoft integration accommodates systems running on different platforms, written in different programming languages, and based on healthcare standards - such as HL7 and DICOM - or legacy information systems. INFOTECHSoft integration provides medical staff with a coherent view of the data contained in each system without having to worry about which underlying system contains the information or how it is being stored.

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TrialSense

Clinical Trials Automation System

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