

MEDPACE

CLINTRAK®

Experts. Experience. Execution.

Discover the POWER OF X®



The Medpace Advantage: Fast. Integrated. Efficient.

ClinTrak® Clinical Suite is a study management system facilitating team coordination, providing decision support for sponsors, and sites to ensure global teams are focused and organized for maximum efficiencies. ClinTrak uses a common data platform and infrastructure allowing for full service study optimization, and provides real time access with a single log in to critical study data, tracking, interpreting, and communicating information in the most timely, secure, and cost-effective manner.

Each application in the ClinTrak Clinical Suite is designed to be completely transparent and work together seamlessly at every stage of your project. Featuring an intuitive web-based dashboard interface that provides access to real-time data and study metrics, ClinTrak is a comprehensive management tool that organizes all aspects of the drug development process.

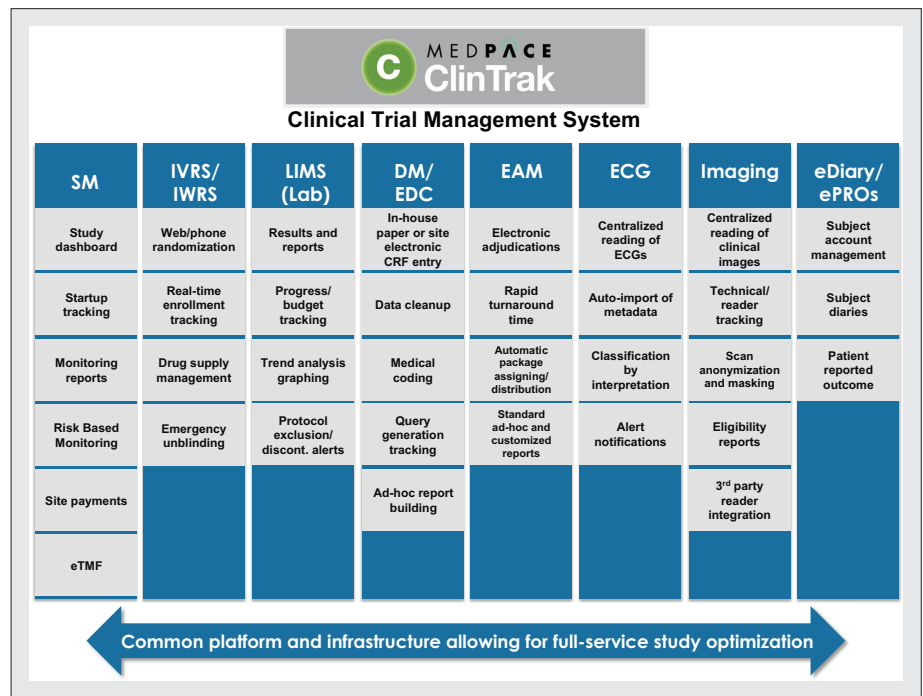
The suite is easily customizable for study-specific enhancements, accelerating turnaround time, and each application has full data exchange capabilities, allowing for easy import/export of data from other systems. Developed and maintained by a team of experts with CRO industry targeted IT and software experience, ClinTrak is built with enterprise-level technologies and features two data centers for tiered redundancy.

ClinTrak® Clinical Suite is a key resource for:

- Enrollment and status reporting
- CRA site visits, including electronic monitoring visit report
- Essential documents
- Protocol violations
- Trend Analysis
- Site contracts
- Supplies
- IVRS

Highlights of Electronic Trial Master File (eTMF):

- Real-time access to TMF through ClinTrak interface
- TMF structured specifically for studies
- Sponsor can query, view and/or download copies of the TMF documents



Clinical Trial Study Management (SM)

Study Manager is a feature-rich and fully customizable Clinical Trial Management System that utilizes multiple data streams to record trial patient data.

Interactive Voice Response System (IVRS/IWRS)

IVRS/IWIS links together and enhances communication between Medpace, the Sponsor, and research sites, and can be accessed globally via both touch-tone phone-based and web-based interfaces 24 hours a day, 7 days a week.

Labs

ClinTrak Lab is a full scale decision support management system that gives you the power to compare customized results from patients across the globe. This system provides access to daily lab reports, management information, cumulative results and trend graphing, secure access, and study-specific project management pages.

Data Management/Electronic Data Capture System (DM/EDC)

DM/EDC provides a centralized location for the data management team, allowing for secure and accurate collection and cleaning of the data from each study. This comprehensive tool provides functionality in the areas of study design, data entry, data clean-up, coding of terms, data changes, reporting, real-time web access, audit trail, and export of the clinical data for analysis purposes.

Event Adjudication Management (EAM) System

The EAM System is fully validated, 21 CFR part 11 compliant, and integrated with ClinTrak clinical suite. Formal adjudications are entered into ClinTrak EAM for inclusion in the final adjudication database with audit trails of the entire process. The result is rapid turnaround of adjudications, in days versus weeks.

ClinTrak Electrocardiogram (ECG)

All ECG data is fully-integrated into Medpace's proprietary data management system, ClinTrak® DM, which enables the lab to collect, interpret, and distribute cardiac safety and global clinical trial data more efficiently, providing Sponsors near real-time access to lab test results and data via a secure, web-based interface.

Imaging Management

Imaging readily handles the images and data, including analog images from previous studies. Analysis can be performed for inclusion/exclusion criteria assessment on an ongoing basis throughout the study to maintain quality control and as a batch analysis as subjects complete the study.

EDIARY/EPRO

ClinTrak Suite can support eDiary/ePRO requirements of studies with a late phase component or as a stand-alone module. Some highlights of this feature include subject account management, subject diaries, and patient reported outcomes.

Who We Are

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug and device development services.

M E D P A C E

FOCUSED. TRUSTED. GLOBAL.

medpace.com | info@medpace.com

North America

Europe

Latin America

Asia

Africa

Middle East

Australia