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MEDPACE ClinTrak

CLINICAL TRIAL MANAGEMENT SYSTEM

SM	IVRS/ IWRS	LAB	DM/ EDC	EAM	ECG	Imaging	eDiary/ ePROS
Study Dashboard	Web/Phone Randomization	Results and Reports	In-house Paper or Site Electronic CRF Entry	Electronic Adjudications	Centeralized Reading of ECG"S	Centralized Reading of Clinical Images	Subject Account Management
Startup Tracking	Real-time Enrollment Tracking	Progress/ Budget Tracking	Data Cleanup	Rapid Turnaround TIme	Auto-Import of Metadata	Technical/ Reader Tracking	Subject Diaries
Monitoring Reports	Drug Supply Management	Trend Analysis Graphing	Medical Coding	Automatic Package Assigning/ Distribution	Classification by Interpretation	Scan Anonymization and Masking	Patient Reported Outcome
Study Team Websites	Subject Diaries	Protocol Exclusion/ Discontinuation Alerts	Query Generation Tracking	Standard Ad-hoc, and Customized Reports	Alert Notifications	Eligibility Reports	
Site Payments			Ad-hoc Report Building			3rd Party Reader Integration	

Common Platform and Infrastructure allowing for Full Service Study Optimization

ClinTrak® Clinical Suite – Fully integrated, single log-in

Medpace offers an innovative suite of proprietary, leading edge technologies. 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. ClinTrak 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.

Highlights

- 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
- 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)

Click for video

SM – Customized Decision Support

The digital hub for Medpace Clinical Operations, this Clinical Trial Management System (CTMS) provides Sponsors with real-time web access to clinical data and study metrics.

Study Manager (SM) is a feature-rich and fully customizable Clinical Trial Management System that utilizes multiple data streams to record trial patient data. This study-specific web-portal provides the entire team – Sponsors, research sites, and Medpace experts – with a set of collaboration pages for secure posting and sharing of study documents, team-meeting minutes, and other important items and features real-time tracking of:

- Submissions and site activations – including country-specific approvals, regulatory document tracking, and Institute Review Board - Ethics Committee (IRB-EC) meeting dates.
- Site Personnel and Study Contacts.
- Subject Enrollment – including exportable enrollment data available via dashboard graphs and printable reports, as well as direct feeds from ClinTrak® IVRS and ClinTrak Lab for a single, accurate source of enrollment metrics.
- Electronic Monitoring Trip Reports – automated workflow enters protocol deviations directly into database and allows for rapid turn-around time on report availability.
- Site Supply Inventory.

ClinTrak also provides centralized access to Prospective Site/Investigator Profiles for rapid identification of potential investigators and review of previously conducted feasibility information.

IVRS/IWRS

24/7 access for seamless study operations

Featuring both touch-tone phone-based and web-based interfaces, ClinTrak IVRS can be accessed globally by authorized clinical site personnel 24 hours a day, 7 days a week. IVRS/IWRS features central randomization, automated drug inventory management for seamless study operations.

Medpace's ClinTrak® Interactive Voice Response System (IVRS/IWRS) and services can be customized to provide the exact level of functionality required for your study including:

- Real-time subject status/visit tracking
- Drug supply/shipment management, and randomization
- Emergency unblinding

ClinTrak IVRS/IWRS 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.

ClinTrak IVRS/IWRS has been utilized in studies spanning 55 countries and is scalable, having recorded over 350,000 individual system transactions.

IVRS/IWRS customized services can include:

- Medpace IVRS/IWRS Project Manager assigned to coordinate all setup, programming, validation, and training activities.
- Complete Subject Enrollment Tracking (screening through end of study).
  - Real-time team notifications
  - Eligibility and visit window enforcement
- Subject Randomization
  - Block-based or centrally managed with multiple stratifications
  - Emergency/Pharmacovigilance code breaks
- Site Investigational Produce/Supply Management
  - Automated and customizable supply/re-supply schemes
  - Direct integrations with 3rd party vendors/depot for storage and distribution
  - ClinTrak SM (Study Management) Module Integration.
- A single source for site list and user management
- Team dashboard and reporting access
  - ClinTrak Lab Module Integration.
- Enforce central lab eligibility prior to randomization
- Use of lab results in stratifications.
  - ClinTrak EDC (Electronic Data Capture) Module Integration
- Auto register subjects and demographics
- Access to IVRS/IWRS data for use in CRF edit/overdue checks
  - Subject Electronic Diaries (ePRO)
- Phone/Web based collection of subject diaries
- Subject reminder calls to drive compliance
- Global 24/7 IVRS/IWRS Help Desk.

DATA MANAGEMENT AND EDC

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

The web-based data management component, ClinTrak DM 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.

Highlights

- Custom Designed Data Entry Screens
  - Designed to mimic case report forms.
- Case Report Form (CRF) Tracking
  - Status progression from received to locked.
- Rule-Based Edit Check Engine
  - Customized rules find and flag incorrect data.
  - Automated execution of jobs as data entry is completed.
- Data Query Generation and Tracking
- Medical Coding
- Flexible and Customized Reports
  - Excel and PDF report formats
  - Ad-hoc report builder

ClinTrak LAB

Fully integrates Medpace Central Lab across three continents

The point of entry is a full scale decision support management system that provides access to a state-of-the-art, proprietary system, ClinTrak Lab, gives you the power to compare customized results from patients across the globe.

ClinTrak Labs

The point of entry into Medpace Central Laboratories, ClinTrak Lab is a full scale decision support management system that provides access to:

- Daily Lab Reports
  - Allows Sponsors to receive PDFs of the daily lab reports delivered to investigative sites. Includes user-defined flagging and filtering options.
- Management Information
  - Track overall study progress through summary (Subject Counts) or detail (Subject Collection Dates) views of Site and Visit.
  - View Exclusion Summary – View all subjects who screen failed due to laboratory results, with exclusion rule and actual result visible by Subject and Visit.
  - View Test Schedule – identify what testing is performed at each visit.
- Cumulative Results and Trend Graphing
  - View results and averages across the course of the study via easy-to-use drill-downs.
  - View study and site averages or individual patient results for an entire panel of tests.
  - View trend graphs for selected data.
  - View results and graphs in either US Conventional or SI units.
- Secure, Role-based Access
  - Secure, customized access based on role (Sponsor, Monitor, Site) and location.
  - Blinding of test results is preserved at all levels (reports, result grids, graphs).
- Study-specific Project Management Pages
  - Post and view study and regulatory documents.

ClinTrak 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, aproviding Sponsors near real-time access to lab test results and data via a secure, web-based interface.

Highlights

- Centralized reading of ECGs
- Auto-Import of metadata
- Classification by interpretation
- Alert notifications

Imaging Management

Whatever the study, ClinTrak 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. All analyses can be performed in a blinded fashion based on study-specific requirements. Features include:

- Site Personnel and Study Contacts
- Technician tracking
    - o Tracking of training, certification, and re-certification for all technicians involved in the study, sorted by country and site.
- Subject Eligibility
    - o Tracking of imaging related eligibility criteria by subject
- Subject Scan Reports
    - o Site-specific reports include eligibility, assessment of scan acceptability, and/or need for repeat evaluation.
    - o Technician-specific reports provide qualitative and/or quantitative assessments for ongoing technician feedback.
- Image tracking, anonymization, and masking for blinded assessments
- Independent reader module
    - o Study specific assessment criteria for use by Imagepace reader or other Sponsor identified reader.
- Image viewing capabilities
    - o Web based environment for view-only access of images by study team or Data Safety Monitoring Boards (DSMB).
- Web Posting
    - o Status reporting for tracking of study status.
    - o Secure, customized access based on role (Sponsor, site, et al.) for sharing of study-related documents or reports.

Electronic Adjudication System (EAM) - Rapid turnaround of adjudications

ClinTrak® Event Adjudication Management (EAM) System The system is fully validated, 21 CFR part 11 compliant, and integrated with ClinTrak clinical suite. CAC members have 24/7 web-based access for independent review of cases and receive real-time electronic notification when data packages are ready for review. 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.

Medpace Adjudication Services

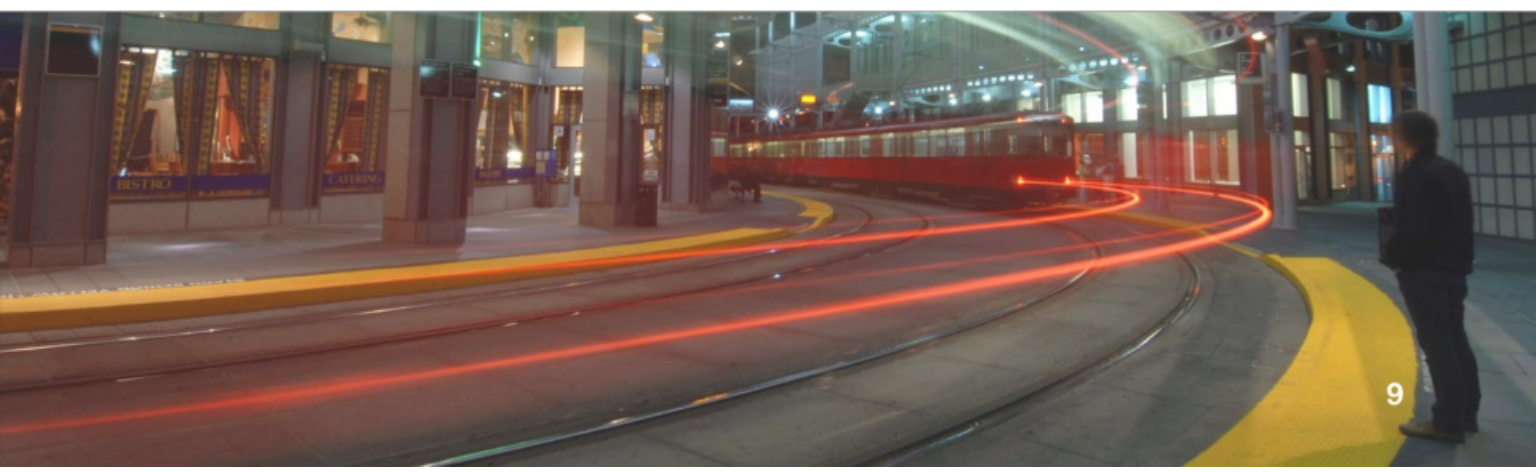
- In-house Medical Experts provide clinical oversight and support, team training, and practical experience in adjudication processing and regulatory requirements
- Associates have healthcare related degrees (i.e. RNs, pharmacists, MDs) allowing for critical and clinical review of all data prior to submission to the CAC
- Development of CAC Charters, site training tools, and other adjudication materials
- CAC management, including selection, contracting, training and facilitation of meetings
- Streamlined communications; one point of contact for events and SAEs for Sponsors, Investigative sites,and CAC members
- Event package compilation in tandem with SAE processing, including translation coordination and clinical/medical quality control reviews
- Preparation of standard and customized adjudication status reports
- Global capabilities with offices and personnel in the US and Europe

EDIARY/EPRO

ClinTrak Suite can support eDiary/ePRO requirements of studies with a late phase component or as a stand alone module.

Highlights

- Subject account management
- Subject diaries
- Patient reported outcomes



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