ERT®
Confidence at every turn™

ERT CLINICAL TRIAL MANAGEMENT

Mitigate risk faster without the burden of a typical CTMS

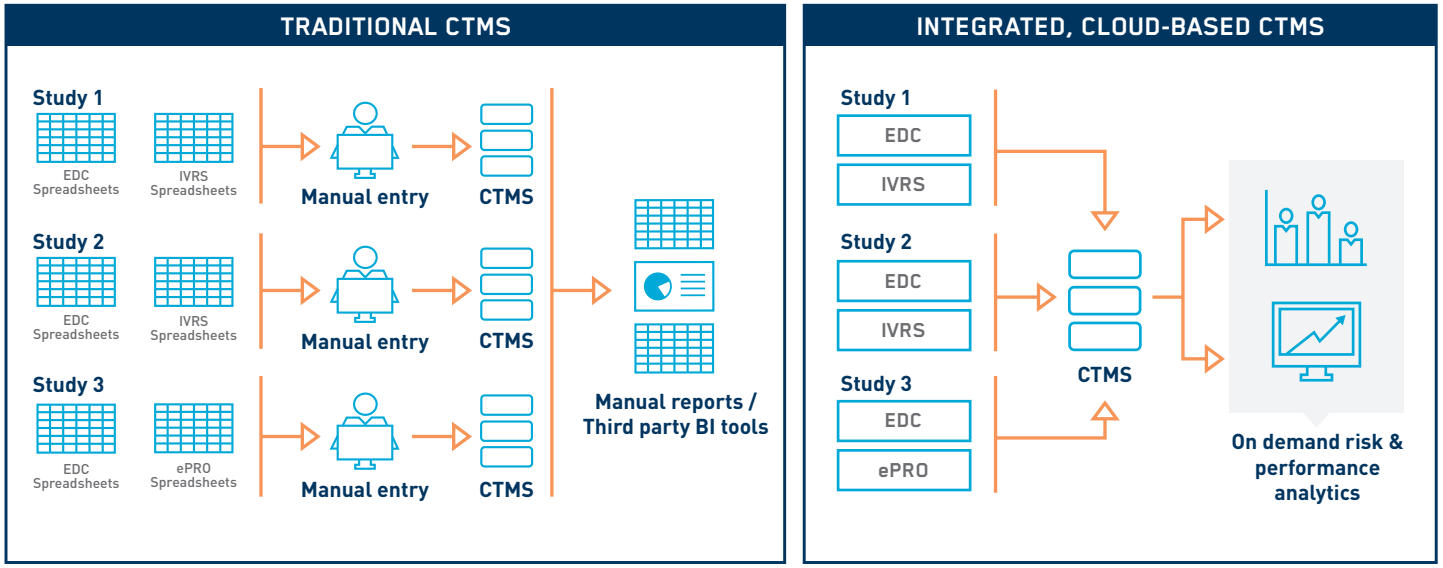
LEVERAGE TECHNOLOGY TO CENTRALIZE WORKFLOWS, DATA AND TRIAL ACTIVITIES

Clinical trials have grown increasingly complex as they require integration with multiple technologies and data sources. This increasing complexity creates challenges with targeted and timely trial oversight, requiring parallel workflows, trackers and spreadsheets. CRAs have less time than ever to complete site visits, reports and subsequent follow-up activities, and require additional internal and external resources to cover the necessary geographic reach. Compounding the problem are the multiple stakeholders who make it difficult to provide the necessary level of oversight and confidence in your clinical trial data. While certainly challenging, it is also an opportunity to leverage technology to centralize these workflows, data and resulting follow-up activities.

MULTIPLE STAKEHOLDERS MAKE IT DIFFICULT TO PROVIDE OVERSIGHT AND CONFIDENCE IN CLINICAL TRIAL DATA

ACHIEVE TRIAL MANAGEMENT EFFICIENCIES ACROSS STUDY TEAMS

ERT Clinical Trial Management harmonizes the people, processes and technologies across your trial's multiple service providers, information silos and data sources. Our solution helps you achieve a new level of day-to-day trial management efficiency across study teams with near real-time visibility into performance and risk indicators.



ERT CLINICAL TRIAL MANAGEMENT: NEAR REAL-TIME VISIBILITY INTO PERFORMANCE AND RISK

Integrated, centralized CTMS for on-demand risk and performance analytics

OPTIMIZE TRIAL PERFORMANCE WITH NEAR REAL-TIME VISIBILITY

Unlike traditional clinical trial management systems, ERT Clinical Trial Management is lightweight, data-driven, automated and accessible from any web browser. This interactive and intelligent solution helps you optimize clinical trial performance, project teams, clinical systems and service providers. You can view near real-time data, including status of your study, investigators, contracts, documents and schedules, while measuring site and vendor performance against timelines, milestones and deliverables.

Better visibility across all trial stakeholders.

Shared visibility into enrollment, query resolution times, site performance, data quality and monitoring activities enable all trial stakeholders to work together seamlessly.

Eliminate administrative burdens.

Empowers study teams to automate repetitive manual tasks across trials to streamline operations and reduce cycle times.

Minimize trial delays.

Near real-time visibility into mission-critical study trends and milestones enables proactive operations so you can prevent delays and keep your trial moving.

Improved oversight with standard visual analytics.

Standard visual analytics can be accessed online, providing the appropriate level of insight into monitoring, issue management, target vs. actual performance metrics and critical insight into cycle times and mitigation processes.

Built for collaboration.

You can share information, track trial activities and measure performance using the most current and accurate information possible.

End-user configurable.

An intuitive interface allows you to easily configure study timelines and milestones, set site enrollment targets, add contacts and configure study documents using system libraries that control data integrity.

Data-driven dashboards and analytics.

System-level reports are driven by operational status against configured timelines, milestones, documents and monitoring visits to support operational workflow performance across studies and teams. Optional integration to leading EDC & IxR systems enables extended site performance metrics and reporting.

Mitigate risk faster without the burden of a typical CTMS. For more information, go to ert.com or email sales@ert.com.

Study planning & start-up

Hit first patient in faster with reduced site start-up cycle times

- Global investigator and study personnel library
- Configurable site / study targets, timelines, and milestones
- Site & study (planned vs. actual) performance tracking
- Automated document tracking, reporting, and collaboration

Study conduct

Maintain complete visibility across all trial activities with rapid identification of risk and performance issues

- Global contact management for investigator activity, CRA allocation, scheduling and personnel activation / deactivation
- Site issue and protocol deviation workflow module with action item assignment, email notifications, visual audit trail and metrics on cycle times
- Real-time KPIs on site and patient recruitment, monitoring metrics, protocol deviations, document status, enrollment, discontinuations, screening failures and other operational performance indicators to rapidly identify at-risk geographies, lagging indicators and oversight modeling
- Configurable email notifications based upon status

Online trip reporting

Cloud-enabled trip reporting and protocol deviation management processes

- Plan and model site visits based on site risk indicators (missing data / protocol deviations / open issues / action items), as well as source data verification workload, visit schedule compliance, query response times and missing or expiring documents
- Electronic trip report prepopulates with data from system (site personnel, missing or expiring reg docs, open issues, unresolved protocol deviations, subject lists, etc.)
- Capture site issues / action items / protocol deviations directly through the report, with real-time integration into site issue log
- Configurable review & approval workflows, alerts and email notifications
- Generate confirmation & follow-up letters with auto-populated data from trip reports

Essential document tracking

Ensure TMF and site document compliance with automated status tracking capabilities

- Global tracking and analytics on missing, expiring, expired and filed documents
- Configurable TMF and site document repository using the DIA Reference model for easy set-up and tracking
- Online regulatory document audit

Financial tracking

Track and report on vendor and site accruals, invoices, and budgets

- Configure vendor work orders for accrual and invoice tracking
- Create site grants with procedures library
- Track site payment criteria based on source data status via direct EDC integration

Trial management dashboards and analytics

On-demand site, study and vendor performance metrics and risk indicators

Dashboards

- Global enrollment performance by country region and site
- Subject discontinuation distribution by reason and country
- Screening failure rates
- Data entry compliance / lag
- Country & site activity
- Top protocol deviation sites

System Reports

- Monitoring metrics
- Protocol deviation trending
- Study contacts
- Document status
- Milestone tracking

ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With more than 40 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so we can adapt without compromising standards.

Powered by the company's EXPERT® technology platform, ERT's solutions enhance trial oversight, enable site optimization, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. Since 2014, more than half of all FDA drug approvals came from ERT-supported studies. Pharma companies, biotech and CROs have relied on ERT solutions in 9500+ studies spanning three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.