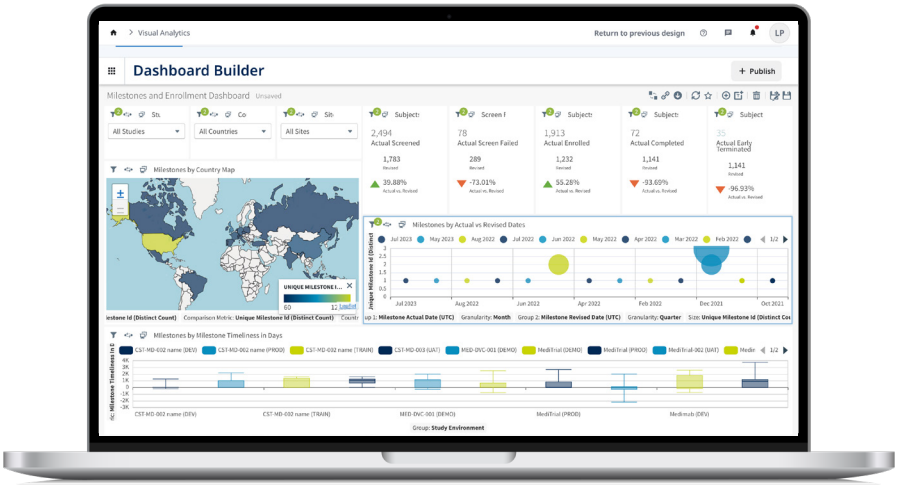
Medidata CTMS

Accelerate Your Operations with Smarter Trial Management



Medidata CTMS is a cloud-based solution that optimizes clinical trial management by centralizing clinical and operational data, streamlining activities, and providing continuous oversight. Already implemented in thousands of studies across all phases, it eliminates the inefficiencies of manual spreadsheets and trackers with an intuitive interface that prioritizes ease of use, reduces clicks, and automatically notifies users of key events. Medidata CTMS is flexible to support both sponsor-led and CRO-managed studies, ensuring effective oversight, transparency, and control within any operating model.

CTMS Benefits

Scalable and Reliable

Built on a cloud-based, single-instance, multi-tenant architecture, Medidata CTMS is designed for scale and reliability, ensuring optimal performance and future growth.

Maximize Efficiency

Centralized configuration groups and templates offer flexibility across studies while ensuring standardization. Data from multiple sources is delivered directly to drive informed decisions.

Easy to Adopt

A straightforward user experience that matches the way your team works, reducing user training and accelerating time to adoption.

White Glove Partner Ensures Success

Medidata's Professional Services experts deliver comprehensive enablement that goes beyond implementation to maximize the system's value.

CTMS Features

Trial oversight requires a broad set of focused workflows to support a holistic and adaptable approach to trial operations. The Medidata CTMS unified data architecture enables data to be entered once and used across all applications.

Monitoring Visits
A modern, configurable site monitoring workspace provides CRAs with in-context data feeds to streamline preparation, execution, and follow-up activities. Reports and letters are automatically filed to the TMF, and issues can be created from anywhere within the workspace.

Document Submission & Tracking
Track and manage required documents, submissions, and metadata at the study, country, and site levels across all stages. Templates and document packages simplify milestone and key event tracking, and integration with eTMF ensures data remains contemporaneous across applications.

Issue Management
Track and categorize all issue types, including protocol deviations, in a single location. A persistent issue slider enables users to create and manage issues and actions in real time without leaving their current screen.

ICF Review
Streamline compliance with one place for CRAs and other team members to track and manage informed consent documentation for study participants. Data flows directly from EDC so users can ensure that every participant has signed the latest approved ICFs before, during, or after a visit.

Oversight and Reporting
Self-service and out-of-the-box reporting dashboards offer dynamic visualizations and drag-and-drop functionality for intuitive data exploration across studies. Reports provide real-time visibility into trial progress, tracking KPIs and key metrics to identify trends, spot issues early, and maintain oversight with exportable charts, tables, and a library of standard reports.

Study Management
Track clinical trial progress using configurable milestones that ensure timeline adherence and preserve trial integrity. Enrollment metrics at the study, country, and site levels provide actionable insights into critical events like underperforming sites or over-enrolling countries, optimizing resource planning and protecting trial timelines.

The Medidata Advantage

Medidata CTMS is built on the industry's most comprehensive unified platform that spans clinical trial processes from planning to execution. With single sign-on and master data management across all capabilities, seamless data flow between Rave EDC, eCOA, eTMF, and Risk-Based Quality Management comes standard with no integrations required. Open APIs ensure compatibility with your existing technology infrastructure, offering flexibility and ease of integration. Medidata is the only CTMS vendor that can leverage deep data science expertise and analytics backed by over 33,000 trials to transform trial management within an unparalleled user experience.