The Medidata CTMS Difference - Intelligent Oversight™

Managing a study and ensuring good quality involves collaboration among many functional areas like Clinical Operations, Data Management, and Central Monitoring. Today, effective team collaboration is usually impeded by multiple and disparate systems for conducting study oversight, documenting issues and performing remediations, leading to work flow redundancies, information silos and incomplete or late issue remediation.

Rave CTMS streamlines and enhances work flows, communication, early issue identification as well as resolution by allowing data from a wide variety of sources to flow into a powerful, centralized and unified platform. With a unified platform, users can realize intelligent oversight, which enables them to be more efficient and effective throughout the trial. Intelligent Oversight means that study teams benefit from:

- Enhanced **context** of trial activities, so they can work smarter
- True **collaboration** through break of down functional silos, so information flows freely among study teams
- Early **remediation** of potential issues, which optimizes trial outcomes

Rave CTMS ensures effective issue management that prioritizes patient safety and accuracy of trial data.
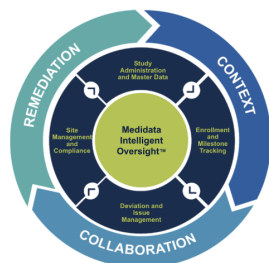
The Medidata CTMS Difference

One Source of Truth
- Enter data once and use it everywhere

Centralized Issue Management
- Proactive remediation across stakeholders

Data Driven
- Advanced analytics and reporting

Scalable
- Adapts to your workflows and architecture

Security and Data Privacy
- Global certifications (regulatory, privacy, security)

130
Customers

9,000+
CTMS Studies
(~1000 Oncology)

70+
Unique Study
Therapeutic Areas

15+
Years (avg)
Pharma Experience

Why Rave CTMS?

- Effective Trial Management
- Faster Study Start-up
- Data-Driven Decision Making
- Operational Efficiencies

Medidata provides all of the basic elements you expect in a CTMS. Because Rave CTMS is unified with the Medidata Rave Clinical Cloud, each stakeholder gets a true picture of what is happening in the context of other aspects of the trial. This enables proactive review and analysis throughout the trial to track progress, monitor sites, as well as identify and remediate issues.
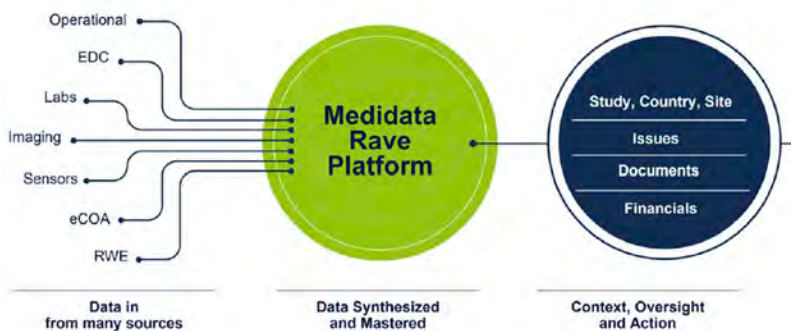
When a sponsor or CRO implements even the most basic elements of our CTMS, they are getting the power to manage and execute trials more effectively.

- Rave CTMS provides a single source of truth that ensures stakeholder alignment
- The ability to leverage any data **from any source** for any type of study provides you sustainable and scalable solutions to meet growing global expectations
- No wasted time finding, compiling and verifying data to collaborate with your colleagues and mitigate risk — all stakeholders are connected
- The near real time auto-populated data eliminates manual data entry redundancies and associated quality issues, while systematically providing the insights you need to manage studies and be confident in your compliance — in other words, you're audit ready.

DATA-DRIVEN DECISION MAKING

The Medidata Rave Clinical Cloud was primarily developed to serve as the single source of truth in a clinical trial. It not only houses all the research data from various sources, but automatically populates the trial data into best-in-class reporting and analysis tools. That means stakeholders get the insights they need to work more efficiently and effectively, so all outcomes are optimized.

Data from EDC or eCOA, for example, is entered once, stored and processed in the Medidata Rave platform and that same data resurfaces in CTMS - in context, turning data into actionable information. This is a departure from many CTMS products that are stand alone systems, document-based and/or dependent on time consuming and costly point-to-point integrations for external data.

THE PLATFORM OF CHOICE FOR CLINICAL RESEARCH

The Medidata's Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed as a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave capabilities. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

Plan Study

- Enrollment and milestone planning
- Investigator, site selection and management
- Track countries and sites from feasibility through selection

Monitor Study

- Site visit scheduling and tracking
- Monitoring reports and correspondence for any type of site contact
- Data-driven decision support for site visit preparation and conduct
- SAE, deviation and CRF verification tracking

Conduct Study

- Internal personnel, external team management
- Study, country and site issue management
- Automated enrollment and milestone calculation and roll-up
- Study, country and site Service Provider setup and tracking

Medidata Rave Clinical Cloud™
Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk