Medidata Rave CTMS For Medical Device and Diagnostics

Leading medical device and diagnostic organizations understand the necessity of a centralized, enterprise clinical trial management system (CTMS) to effectively deploy critical resources, proactively address performance issues and streamline operational workflows. Getting there quickly and cost effectively can be challenging, especially as clinical needs continuously evolve. In reality, a CTMS is a disconnected, pieced together solution and a painful part of everyday life for anyone responsible for delivering a clinical trial. For a study team member managing a multitude of systems, milestones, Clinical Research Associates (CRAs), and deliverables with no clear insight to the right data at the right time is nothing but spreadsheet hell.

Medidata Rave CTMS takes a fresh approach to providing global sponsors tools that can make a significant difference in their operations today, with a broad and flexible platform to support their business challenges of tomorrow.

Our unique data-driven CTMS allows you to consume data when you need it to gain a more accurate, timely and actionable oversight of your studies rather than data entry and integration. Companies can grow their study portfolio faster by breaking down data silos and providing clinical operations teams with easy access and visualization of data to understand enrollment and progress of a clinical trial. Experience significant operational gains, superior trial visibility and oversight and optimized monitoring efficiencies with Rave CTMS. Scroll further to read about what's included with Rave CTMS.

Global Study Management

Trial managers are often faced with time-critical decisions that can impact downstream trial progress, and they need high quality, proactive information to do that. Rave CTMS provides real-time views into the daily details of your study progress to the bird's-eye-view of executive oversight without manual tracking, multiple systems or data reconciliation. Generate cross-study reports that summarize study enrollment and milestones. Track study progress, team assignments, documentation status, tasks and vendors, all from the cloud.

Study Planning

- Timeline and milestone planning
- Study projections, including predicted recruitment

Study Startup

- Investigator, site selection and management
- Investigator and site assessments

Study Conduct

- Vendor and contact management
- Internal personnel and team management
- Milestone and enrollment tracking
- Study, country and site issue tracking

Regulatory Compliance

- Essential document tracking
- IRB/ethics committee submissions tracking
- Regulatory authority approval tracking

Monitoring

- Subject, visit, CRFs and query tracking
- Site and subject deviation tracking
- SAE tracking
- Site and subject deviation tracking
- Monitoring visit reports
- Visit report review/approval workflow, including notifications
- Action item tracking
- Monitoring visit confirmation and follow-up letters
- Full offline/remote client

Streamlined Monitoring Visits

Site monitoring activities are typically the second-highest cost driver in a study after site reimbursement. Rave CTMS can increase visit reporting productivity by up to 40 percent, reducing operational costs and allowing monitors to focus on value-add activities. You can handle workload inefficiencies and increase visit report productivity while reducing time investment and operational costs and increasing data accuracy. Author, review, approve and finalize monitoring visit reports directly in Rave CTMS. Track and provide visibility on open actions including confirmation letters and monitoring reports.

Issue Management

Rave CTMS offers a centralized, cross-functional issue management capability that provides timely oversight of all issues, near misses and associated action items at study, country, site, and subject-level throughout the clinical study. This enables you to take timely actions to address regulatory issues, improve site performance and support consistent data quality.

Interoperability with Medidata Rave CTMS

Yesterday's CTMS was about manual data entry of trial data in a centralized location. Today's CTMS must effectively aggregate real-time data from multiple clinical systems. Rave CTMS enables interoperability at a platform level that ensures no work is being repeated especially when already done by other team members upstream. Rave CTMS works with Medidata Rave EDC, Medidata Rave eTMF and Medidata Rave RBM seamlessly so you allow your study teams to focus on high value study, site and country oversight activities.

Rave CTMS and Rave EDC

Rave CTMS ensures you and can find, access and reuse EDC data when you need to, eliminating costly integrations, duplicate data entry, data reconciliation and manual tracking activities.

Rave CTMS and Rave eTMF

Rave CTMS works seamlessly with Rave eTMF providing TMF auto-population of key artifacts allowing you to accelerate trial time lines and minimize risk. Rave CTMS combined with Rave EDC and Rave eTMF delivers the industry's most comprehensive platform from study planning to close, by unifying content, data and work flows accurately.

Rave CTMS and Rave RBM

The unified platform enables both Rave CTMS and Rave RBM to share data elements with each other facilitating an optimized site monitoring approach that allows you to redeploy resources to where risks and issues lie.

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

The Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with 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 applications. 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 and excel sheets, you are now on a truly unified platform.

About Medidata

Medidata is leading the digital transformation of life sciences, with the world's most-used platform for clinical development, commercial, and real-world data. Powered by artificial intelligence and delivered by the #1 ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata and its companies, Acorn AI and SHYFT, serve more than 1,200 customers and partners worldwide and empower more than 150,000 certified users every day to create hope for millions of patients. Discover the future of life sciences:

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