Medidata CTMS™ For Medical Device and Diagnostics

Global clinical organizations need an enterprise trial management solution that can optimize operations today—without lengthy implementation projects or costly upgrades. Medidata offers a new, different and better way to get there.

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.

Medidata 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.

Quick to Deploy and Upgrade

According to leading industry analysts,[1] Medidata CTMS ranks No. 1 in deployment due to its single code base and cloud platform. Built-in integrations to e-clinical systems eliminate the need for lengthy integrations. Study configurations are simple to set up without any engineering or technical expertise. Medidata's Agile development methodology powers regular functional enhancements to Medidata CTMS, and the cloud puts those enhancements quickly into your hands, so our CTMS always keeps pace with your clinical research processes.

Modular

Advancing beyond the legacy, monolithic, all-or nothing approach, Medidata CTMS allows you to start with only the trial management tools you need now and scale functionality up, along with your evolving clinical operations. Whether your immediate need is to help monitors deliver visit reports more efficiently or streamline study management, a focused deployment is more cost effective and can rapidly improve your trial performance.

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
- SMilestone 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

Source: (1) Ovum. Ovum Decision Matrix: Selecting a CTMS Solution, 2013–14. 10 Jul 2014.

Interoperable

Yesterday's CTMS was about manual entry of trial data in a centralized location. Today's trial management solution must effectively aggregate real-time data from multiple clinical systems. Medidata CTMS offers out-of-the-box integration with Medidata Rave® electronic data capture (EDC) and Veeva Vault electronic trial master file (eTMF) solutions, as well as highly flexible tools to integrate with any EDC, interactive voice-response system (IVRS), CTMS, data-mart/OLAP system and MS Project/Excel, including AS2, SFTP and CDISC ODM compliant data sharing.

SaaS

With its clear benefits—no up-front investments in licenses, hardware or hosting; fast deployments; pre-validated software and no costly upgrades—many CTMS vendors are scrambling to offer Software as a Service (SaaS). Few, however, have the experience to do it right. Medidata has exclusively offered SaaS-based solutions since its inception over 10 years ago, ensuring the highest levels of quality, performance and security. Without the software modernization burdens others face, all development resources can focus on customer-driven product innovation.

Actionable

Without the right tools, study managers and study team members can spend hours, days, even weeks trying to collate and visualize operational metrics in reports that are actionable and meaningful to management and outsourcing or joint-venture partners. Medidata CTMS includes more than 85 standard reports out of the box, including cross-study dashboards, as well as ad hoc capabilities that allow you to configure reports to your own specific SOPs and KPIs.

If you could optimize one thing in your operations today, what would it be?

With Medidata's modular approach you can rapidly deploy the functionality you need alongside or in place of your current CTMS solution. Robust workflow optimizing tools include:

Streamlined Monitor Visits

Site monitoring activities are typically the second-highest cost driver in a study after site reimbursement. Medidata CTMS can increase visit reporting productivity by up to 40 percent, reducing operational costs and allowing monitors to focus on value-add activities.

- Author, review, approve and publish monitoring reports directly in CTMS
- Includes checklists, notes, action items and report submission tracking
- Offline module enables remote data entry
- Automated confirmation and follow-up letters

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. Medidata CTMS provides real-time views into study progress without manual tracking or data reconciliation.

- Track internal and external study teams
- Track planned and actual subject enrollment at the study, country and site level
- Track planned and actual milestones at the study, country and site level
- Manage regulatory documents

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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