Medidata Edge CTMS
Driving the Future of Trial Management

Leading pharmaceutical, medical device and research 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 evolve.

Medidata offers a new and better way to get there.

Optimize your operations with Medidata Edge CTMS

Global clinical organizations need an enterprise trial management solution that can optimize operations—without lengthy implementation projects or costly upgrades.

Medidata Edge CTMS takes a fresh approach to providing global sponsors and CROs tools that can make a significant difference in their operations today, with a broad and flexible platform to support their business challenges of tomorrow. Furthermore, with Medidata's modular approach, you can rapidly deploy the functionality you need alongside or in place of your current CTMS solution.

Global Study Management

Trial managers are faced with time-critical decisions that can impact downstream trial progress, and they need high quality, proactive insights to inform those decisions. Medidata Edge 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

Plan Study

- Enrollment and milestone planning
- Investigator, site selection and management
- Study projections, including predictive recruitment

Monitor Study

- Site visit scheduling and tracking
- Monitoring visit reports and correspondence
- Telephone contact reports
- Action item tracking
- 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
- Essential document tracking
- IRB/ethics committee submissions and health authority submissions tracking

Streamlined Monitor Visits

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

- Author, review, approve and publish monitoring reports directly in Edge CTMS
- Include checklists, notes, action items and report submission tracking
- Automatic confirmation and follow-up letters

Top 5 Benefits of Medidata Edge CTMS

Modular

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

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 Edge CTMS offers out-of-the-box integration with Medidata Rave EDC(formerly Rave) and Medidata Edge Site Payments (formerly Payments). Medidata Edge CTMS can also integrate with third-party EDC and CTMS systems as well as Electronic Trial Master Files (eTMFs), Interactive Response Systems (IxRS) and planning solutions.

Quick to Deploy and Upgrade

According to leading industry analysts, Medidata Edge CTMS ranks first in the industry in deployment due to its single code base and cloud platform[1]. Built-in integrations to eClinical 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

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 950 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

info@mdsol.com | mdsol.com
+1 866 515 6044

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

to Medidata Edge CTMS, and the cloud puts those enhancements quickly into your hands. Our Edge CTMS always keeps pace with your clinical research.

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 Edge CTMS includes more than 60 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.

Rave Data Capture and Management

It Starts with Data Capture

Rave Data Capture and Management is a product suite that powers clinical trials of the future including virtual, mobile, adaptive, and master protocols. It seamlessly captures and integrates all data streams and biomarker measurements that today's targeted therapies demand, going beyond clinic and lab data to also include data from sensors, apps, images, genomics and RWE (Real World Evidence)

By capturing and integrating such a wide array of study data, **Rave Data Capture and Management** also automates many of the most challenging data management workflows across randomization, supply, coding, and safety. It is now possible for a patient to be electronically consented, randomized, provided their first supply, and automatically be coded – all in their first visit.

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