Medidata Rave® 5.6 Easy and Fast Enough for Your First EDC Study... Flexible and Powerful Enough to be the Last CDM Platform You'll Ever Need

Medidata Rave is the most advanced and robust system for capturing, managing and reporting clinical research data in Phase I–IV studies, streamlining the clinical trial process and helping life science organizations optimize their R&D investments.

Throughout a clinical trial, Medidata Rave provides early visibility to reliable data—the lifeblood of every research organization—enabling study teams to safely and quickly make sound decisions and bring life-enhancing treatments to market.

A single platform combining easy-to-use electronic data capture (EDC) and advanced clinical data management (CDM) capabilities, Rave's highly scalable, software-as-a-service (SaaS) architecture provides a cost-effective approach to quickly implement a single clinical trial or support an enterprise-wide deployment for multiple therapeutic areas, phases and studies—including post-marketing observations and registries.

Rave's extensive capabilities—including wide support of industry data standards, flexibility to implement any data management workflow with secure access for all study team members and a rich set of on-demand data extraction (ODM Apapter and Web Services) and ad hoc reporting tools—provide a robust platform to manage site-, patient- and labreported data from EDC and other systems and rapidly make it available for analysis and submission.

The World's Leading Life Science and Research Organizations Choose Medidata Rave

- Studies can be implemented very rapidly in Rave, getting to First Patient In that much sooner.
- Rave is extremely flexible, adapting to your processes and best practices for any study phase or therapeutic area.
- Sites find Rave accessible and easy to use (in any language)—so researchers enter data quickly and often.
- Rave provides extremely fast access to the data you need—report on or extract full trial datasets at any point in the trial with Rave's ODM Adapter.
- Rave's interoperability lets you easily share data across your best-in-class eClinical applications, including data warehouses, IVR, IWR, ePRO, CTM, coding and safety reporting systems.
- Fully unified randomization and supply management capabilities eliminate the need for a separate IVRS/IWRS.

Design and Build Studies Faster So You Can Recruit, Enroll and Screen Patients Sooner

At Medidata, we believe that it should be just as fast to set up an electronic study as it was once to set up a paper study. Medidata provides proven tools and in-depth services based on more than ten years of experience to help you rapidly build your visit schedules, case report forms, edit checks and workflows. An interactive implementation approach leverages Rave's unique self-documenting capabilities to quickly get you from design to acceptance testing to First Patient In at all your sites.

Rave supports a full range of study build methods:

- Custom design studies to meet your unique specifications,
- Leverage and modify CDISC CDASH standard form library,
- Build studies based on reusable components from previously built Rave studies or global library volumes, and
- Upload metadata from an external CDISC ODM library.

Technology that Adapts to Meet All Your Therapeutic Area Needs—Phase I–IV

You should never have to adapt your processes because of the quirks or limitations of technology. Rave is secure and flexible enough to meet any workflow requirements—whether implementing your own SOPs or leveraging Medidata's clinical best practices to increase efficiencies and add value to your organization.

- Use Rave's predefined roles and workflows, or configure them to fit your vision of how users interact with data and each other.
- Definitions can be therapeutic area-specific, study phase-dependent or global.

Case report form (CRF) layouts in Rave are completely configurable. Perhaps your oncology protocol requires sites to record lesion dimension changes from one visit to the next. Maybe you need left-side/right-side forms to appear appropriately in an ophthalmology study. Rave can easily handle complex study requirements. Forms can even change dynamically according to the treatment arm to which a patient belongs.

Mid-study changes (an unavoidable reality) can be introduced to sites with minimum effort and no system downtime. Whether supporting an adaptive trial, protocol amendments or updated requirements, Rave manages multiple CRF editions and seamlessly migrates existing data into new forms and visit structures.

Robust Tool Set for Monitors and Data Managers

Medidata Rave provides some of the industry's most advanced EDC and CDM functionality for data captured electronically, on paper or in labs. Unified in a single platform, so no separate tools or integrations are necessary, Rave offers:

- Dynamic lab range management, including lab range alerts and central and local lab references,
- A full query and SDV management suite,
- Targeted SDV for auditable, scalable risk-based (less than 100%) monitoring,
- Support for remote monitoring and electronic monitoring visit reports,
- Flagging and classification of protocol deviations,
- Automatic data cleaning/verification workflows and review/approval routing,
- Multiple configurable levels of data review and data locking,
- Seamless, out-of-the-box integration with Medidata Coder for enterprise-grade, real-time medical coding,
- DDE/DCF support for paper or hybrid studies, and
- A system designed to meet requirements and guidelines of regulatory agencies around the world: FDA 21 CFR, ICH GCP, EMEA and MHLW.

Fully configurable roles and workflows

	Enter Data	Open Query	SDV	Lock
Site	✓			
Monitor		✓	✓	
DM		✓		✓

Sites Perform Better with EDC that's Easy to Learn, Use and Access (in Any Language)

Recruiting sites and investigators should be based on clinical skills, not computer skills. Medidata Rave's web-based interface is designed to be friendly and familiar to CRCs and CRAs alike. If your study is global, translated forms will appear to sites in their local language (including Chinese, Japanese or Korean), while all the data they enter is centrally viewable from a single database.

With Rave, a single URL, username and password is all you need to remember for all your studies. And Rave works equally well on a Windows PC, Apple Mac or iPad. Whether your monitors or sites browse the web in Internet Explorer, Firefox, Safari or Chrome, they're immediately ready to enter and review data without any special hardware or software installation.

Rave's eLearning helps train investigators, coordinators and monitors efficiently, cost effectively and compliantly with a set of localized, on-demand, online courses and assessments that are a seamless component of Medidata software. Once training is complete, users immediately gain role-specific access to their studies. No retraining is necessary from one study to the next.

Get the Data You Want—When You Want It—and Make Faster, Safer Decisions

Using EDC in a clinical trial only makes sense if it allows you to immediately view data as it's entered into the system. Some solution providers struggle to give you quick access to your data once they've captured it and even charge you for the effort. With Medidata Rave, data is as easy to get out as it is to get in—via standard on-demand data extract tools such as ODM Adapter or built-in ad hoc reports. Custom reports can also be designed to serve your unique needs.

Clinical data reports are automatically generated in Rave, even after studies are amended, based on the specific security access rules defined in your study. Reports are immediately available with no additional effort and each user only sees what he or she has permission to see.

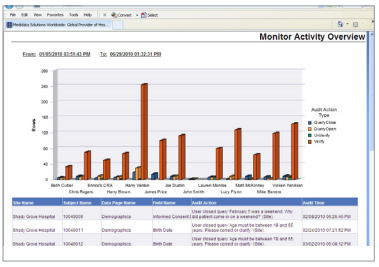
Using ODM Adapter, clinical data can be extracted on demand from your study and downloaded in one complete dataset to SAS or any other tool of your choice for interim review and analysis, either at the click of a button or at scheduled intervals, in SAS, CSV or XML formats.

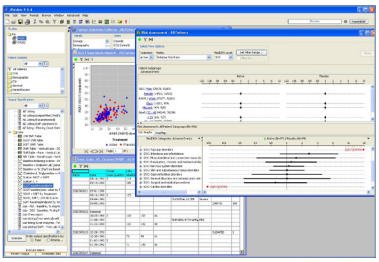
Use EDC to Randomize Patients and Manage Supplies

With Medidata BalanceTM, sites can now interact with just one system to randomize and dispense treatments via instructions delivered on electronic case report forms (eCRFs) in Rave, rather than cumbersome, phone-based data entry using a separate IVR/IWR system. Balance offers:

- Very simple set up and ease of use,
- Guided, self-service randomization design,
- Configurable Dynamic Allocation randomization algorithm,
- Immediate simulation testing of randomization balance, and
- Unified solution for EDC, randomization and supply management—no integration required.

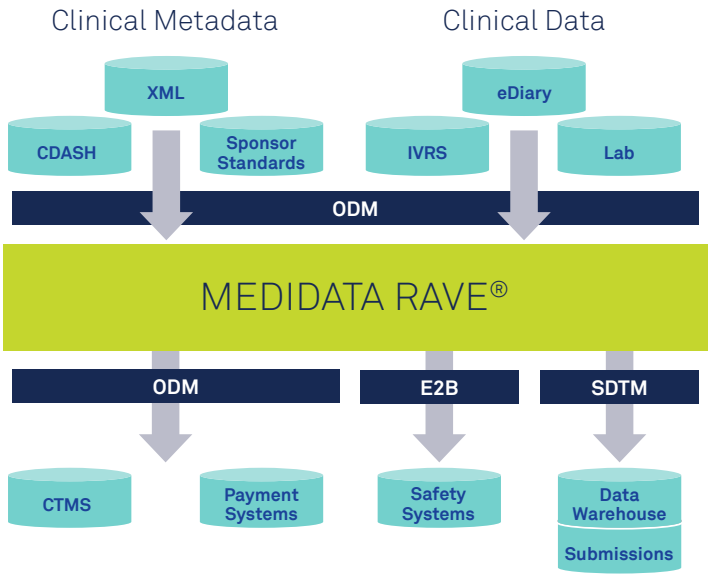
Robust operational and clinical reporting





Streamline Development with Interoperability Across the Systems You Choose

When selecting your EDC system, you want to work with a technology provider who plays nicely with the other vendors supporting your clinical trials. Being able to choose the best eClinical tools for your needs at the right time and share data across the tools to streamline development requires the proper integration tools, partners and the ability to fully leverage industry standards.



Leading research organizations have consistently been able to translate their complex IT architecture visions into reality thanks to Rave's wide array of scalable, CDISC and ICH standards-based real-time web services and batch data import and export tools—including **Rave Safety Gateway** for electronic E2B transmission of adverse event data to your safety system.

A Sound Investment: Right for Today... Ready for Tomorrow

Medidata's continuous innovation, constantly extending what Rave lets you do, ensures a powerful, flexible and scalable solution that's not only ready for today's rigorous clinical research needs but also for what lies ahead.

- Ready for dynamic, adaptive research with immediately actionable data
- Ready to be your global standard for EDC and CDM
- Ready for trials conducted anywhere in the world

Empowering You for Success

- Medidata's Knowledge Transfer program empowers you to take ownership of your studies. In-depth best practices consulting and training help you efficiently implement and manage Rave trials on your own.
- Medidata's accredited CROs and other outsourcing organizations offer a range of Rave-related services, including complete trial implementation and management.
- Medidata's Developer Central online community promotes interoperability with our open web APIs, creating an ecosystem of best-in-class solutions that work with Rave to streamline your trials.

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.

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