Medidata Rave EDC 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 EDC (formerly 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 EDC 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 EDC'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 EDC'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 Adapter and Web Services) and ad hoc reporting tools—provide a robust platform to manage site-, patient- and lab-reported data from EDC and other systems and rapidly make it available for analysis and submission.

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 EDC's unique self-documenting capabilities to quickly get you from design to acceptance testing to First Patient In at all your sites.

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

- Studies can be implemented very rapidly in Rave EDC (formerly Rave), getting to First Patient In that much sooner.
- Rave EDC is extremely flexible, adapting to your processes and best practices for any study phase or therapeutic area.
- Sites find Rave EDC accessible and easy to use (in any language)—so researchers enter data quickly and often.
- Rave EDC 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 EDC'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.

Rave EDC 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 EDC 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 EDC 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 EDC'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 EDC 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 EDC 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 EDC manages multiple CRF editions and seamlessly migrates existing data into new forms and visit structures.

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 EDC'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 EDC, a single URL, username and password is all you need to remember for all your studies. And Rave EDC 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.

Robust Tool Set for Monitors and Data Managers

Medidata Rave EDC 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 EDC 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 percent) 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 Rave Coder (formerly Coder) for enterprise-grade, real-time medical coding,
- DDE/DCF support for paper or hybrid studies, and
- Medidata's solutions are designed, developed and maintained in a manner compliant with a broad range of national and international clinical, data protection/data privacy and electronic record/electronic signature regulatory requirements.

Fully configurable roles and workflows

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

Rave EDC'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 and track the progress of data acquisition and cleanup as data is captured by 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 EDC, data is as easy to get out as it is to get in—via standard on-demand data extract tools such as ODM Adapter and SAS on Demand, via ad hoc reports using JReview or BusinessObjects (which are included with Rave EDC, or via numerous standard reports. Custom reports can also be designed to serve your unique needs.

Medidata Rave EDC ad hoc reporting capability has been upgraded from BusinessObjects XI to BusinessObjects 4.1. This upgrade provides significant new capabilities:

- Deep linking: With this upgrade,Rave EDC ad hoc reports can include deep links to the subject and form pages in Rave EDC This is a significant enhancement that gives you one-click access from reports to relevant forms within Rave EDC. It eliminates the multi-step process previously required to navigate from a report to a subject or form and shortens distance from data to action.
- Enhanced interactivity and visualization capabilities: New visualization options available with this new version include mixed line and bar charts, bubble plots, heat maps, tree maps and tag clouds. These all allow you to deliver intuitive visualizations of high-dimensional data and quickly detect correlations or outliers that require attention. In addition, new interactivity capabilities allow you to build reports where users click on chart elements to drill into the data. This allows intuitive and effective data explorations that will result in more precise and efficient actions.
- Modern platform and improved performance: This version comes with a modern, fast and reliable architecture that provides better performance. It enables working with the latest versions of Chrome, Firefox and IE. It also maintains compatibility with the latest versions of Java (7 and 8), but does not require the use of Java.

Clinical data reports are automatically generated in Rave EDC, 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.

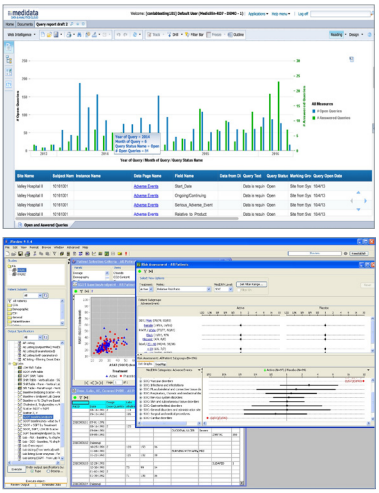
Using ODM Adapter, clinical data can be extracted on demand from your study and downloaded in one complete dataset to SAS or any other tool of your choice for interim review and analysis, either at the click of a button or at scheduled intervals, in

Use EDC to Randomize Patients and Manage Supplies

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

- Very simple setup 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.

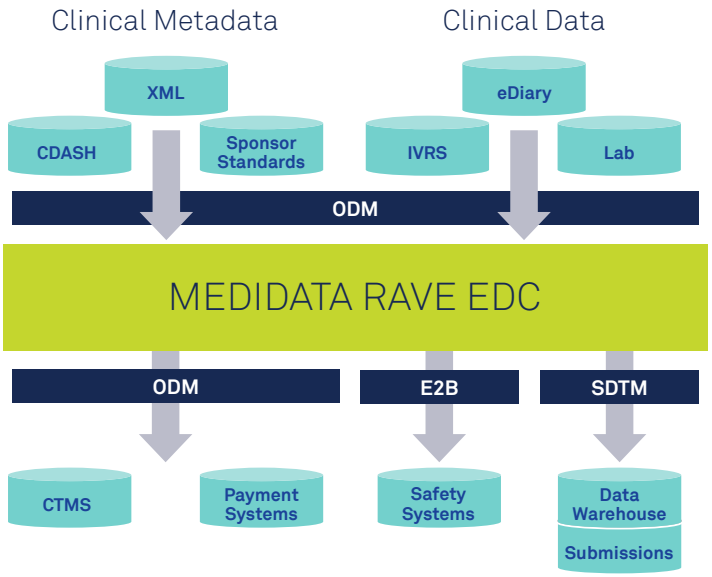
Robust operational and clinical reporting



SAS, CSV or XML formats.

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 EDC'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** (formerly 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 EDC 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

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 EDC trials on your own.
- Medidata's accredited CROs and other outsourcing organizations offer a range of Rave EDC-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 EDC to streamline your trials.

Rave Data Capture and Management

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.

- Ready for trials conducted anywhere in the world

Medidata Rave EDC and CDMS Capabilities

Medidata Rave EDC goes beyond traditional EDC and offers value added data management and reporting capabilities.

Medidata Rave

EDC + CDMS

Cloud Hosting
- Fully-managed, scaled hosting
- Fully-managed, scaled disaster recovery

Database Capacity
- Unlimited study database size
- Access to unlimited database capacity at no extra charge

Help Desk & eLearning Support
- Unlimited help desk support
- Integrated, unlimited eLearning

Study Build, Data Capture & Data Integrity
- Dynamic CRF workflow and branching at the field, form and folder level
- Investigator signature
- Real-time field-level edit checks
- Real-time cross-form edit checks
- Real-time data derivations
- Configurable intelligent data management and clinical operations workflows
- Study-specific configuration options for data entry and view permissions (e.g. blinding, endpoint adjudication)
- Viewing, updating, querying and locking data
- Self-service creation of multiple study environments for DEV, UAT, TRAIN, PROD and OTHER
- Self-service deployment of CRFs to any environment
- Self-service unlimited mid-study changes in any environment
- Self-service administration of users, studies and sites
- Role-specific task lists
- Ability to track multiple role-based reviews, e.g., medical monitor or safety
- Ability to raise queries directly to site with no need for candidate query review
- Ability to track SDV
- Ability to track SDR

Audit
- Fully-integrated user-accessible audit trail

Reporting
- 49 standard out-of-the-box reports
- Unlimited ad hoc, user-driven reports
- Operational metric reporting
- Unlimited reporting licenses
- Self-service role-based report administration

PDF & SAS Dataset Generation
- Self-service unlimited blank PDF generation
- Self-service unlimited annotated PDF generation
- Self-service patient data PDF generation
- End of study PDFs & media generation
- Self-service unlimited online SAS dataset generation

Data Integration
- Unlimited use health record (EMR/EHR) integration APIs
- Unlimited web service data integration access
- Unlimited batch file data uploads
- Self-service unlimited central and local lab administration

Standards Management
- Global Library to enable reuse of standard forms and form components
- Spreadsheet exporter/loader for offline study design and metadata sharing

Data Management
- Query management facility for bulk management of queries
- Unlimited self-service batch data management & clinical operations functions, e.g., reviewing, verifying, freezing and locking data (by form, visit, patient, site)
- Complex sponsor/site/CRO query workflows

Value Added Services
- eCRF creation services
- Custom function creation services
- Global Library best practices services

About Us

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.

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