

Medidata Rave EDC

Rave EDC (Electronic Data Capture) is the most advanced and robust system for capturing, managing and reporting clinical research data. Used in Phase I–IV studies, Rave EDC streamlines the clinical trial process and assists life science organizations optimize their R&D investments. Rave EDC sits on the Medidata Rave Clinical Cloud™ and works directly with its Cloud Administration tool to allow administrators to manage basic trial components including: studies, study environments, sites, users, and roles.

Throughout a clinical trial, Rave EDC provides **early visibility to reliable data** enabling study teams to safely and quickly make **real-time decisions**. Visibility is quickly enabled through the Medidata Rave Clinical Cloud to provide 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** and **ad hoc reporting tools**, provide a robust platform to manage site-, patient- and lab-reported data from EDC and other systems. Rave EDC rapidly makes these data available for analysis and submission.

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

Medidata provides flexibility, proven tools and in-depth services to help you quickly build your visit schedules, case report forms, edit checks and workflows. A configurable and 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.

With the ability to support a full range of study build methods coupled with reusability, Rave EDC users gain efficiency and visibility into their study quickly and effortlessly. Mid-study changes, an unavoidable reality for many trials, can be introduced to sites with minimum effort and no system downtime.

THE WORLD'S LEADING LIFE SCIENCE AND RESEARCH ORGANIZATIONS CHOOSE RAVE EDC

- **One place to capture, manage, aggregate** and access all clinical and non-clinical data eliminating reconciliation and delivering realtime data visibility
- **Accelerate study timelines** by reducing study build times from months to weeks and getting First Patient In faster
- 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
- **Real-time data visibility** into workflows, study and site performance —report on or extract full trial datasets at any point in the trial

Sites Perform Better with Rave EDC Because it's Easy to Learn, Use and Access in Any Language

Medidata Rave EDC's extremely intuitive interface is designed to be friendly and familiar to CRCs and CRAs alike. If your study is global, translated forms can appear at the site level in their local language, while all the data they enter is **centrally viewable from a single database**.

With Rave EDC, a **single user name and password** is all you need to remember for your studies. And Rave EDC works equally well on a Windows PC, Apple Mac or iPad.

Rave EDC's **eLearning** helps train investigators, coordinators and monitors efficiently, cost effectively and compliantly with a set of localized, on-demand, online courses. Once training is complete, users immediately gain rolespecific access to their studies. No retraining is necessary from one study to the next.

The Power of Rave EDC on the Medidata Rave Clinical Cloud

- Single user interface across applications
- SIMT (Single Instance Multi Tenant) architecture ensures Rave EDC users are always using the latest version of Rave EDC, improving performance and simplifying URL upgrades
- Single sign-on allows easy access to all role-based permissions and applications across all studies, with unification across all data collection solutions
- A central repository for all clinical and non-clinical data that can be used for subsequent studies in the same environment
- Task Management at the study, site and subject level for efficient management of actionable tasks e.g., queries, overdue data, verification, e-signatures
- Easy navigation allows users to quickly find, select, and move within studies, sites, subject and pages
- Advanced ad hoc reports include deep links to the subject and form pages in Rave EDC, enabling one-click access from reports to relevant forms

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 Medidata 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, you are now on a truly unified platform.

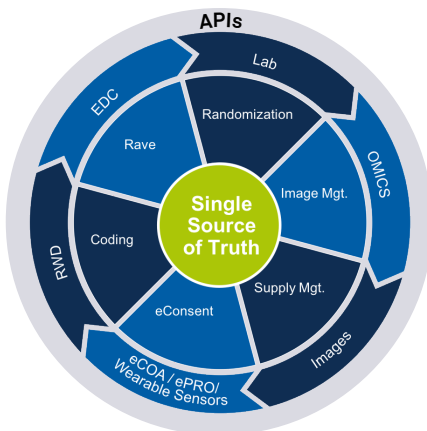
Fig 1: Fully configurable roles and workflows

	Enter Data	Open Query	Source Data Verification	Lock
Site	✓			
Monitor		✓	✓	
DM		✓		✓

Streamline Development with Interoperability Across the Systems You Choose

When selecting your EDC system, you want to work with a technology provider who provides flexibility to work on a unified platform bridging clinical trial needs such as informed consent, randomization, safety monitoring, and clinical/patient reported outcomes or with other vendors of choice supporting your clinical trials (Fig 2).

Fig 2: Unlock the Power of the Medidata Rave Clinical Cloud with Rave EDC



A unified approach to data capture and management offers:

- Robust data ingestion into the data repository
- Complete data visibility and control
- Elimination of reconciliation
- Reduction of risk and complexity

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,600 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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