

Rave EDC One Place to Capture, Manage, Clean and Report Clinical Research Data

<u>Rave EDC</u> (Electronic Data Capture) is the most advanced and robust EDC system for capturing, managing, cleaning and reporting site-, patient- and lab-reported data. Rave EDC is the cornerstone of the <u>Medidata Platform</u> - our unified clinical research platform that streamlines workflows, eliminates the need for data reconciliation and delivers cross-functional and cross-study insights.

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Rave EDC Benefits

Rave EDC delivers many benefits to sponsors, CROs and sites including:

Faster Study Start and DB Lock

- Global libraries enabling standardization and reuse across studies; and built-in field and form edit checks to reduce the need for custom functions
- Configurable and interactive implementation with (user acceptance testing) UAT performed as the study is built
- Studies can be locked with a single click, enabling analysis to start sooner

Flexibility for Mid-Study Changes

- Protocol amendments and incremental changes are implemented with no system downtime. Medidata and our customers execute over 30,000 mid-study changes each year
- For adaptive trials, the management tool allows fine granular control over extensive study design changes, by configuring and testing the changes before deployment, with a full audit trail
- Multiple versions of a protocol are managed across subjects and sites based on IRB approvals etc. with the ability to move subjects from one version to another

Improved Site Experience and Performance

- <u>Rave Companion</u> aids site users with quick and accurate completion of EDC forms using existing EHR (Electronic Health Record) data
- eLearning helps train sites efficiently, cost-effectively and compliantly with a set of localized, on-demand, online courses
- Site users have a single username and password for all studies
- Outstanding queries can be easily viewed and actioned in the EDC Tasks list

Real-Time Insights through the Medidata Clinical Cloud

- Real-time data visibility into workflows, study and site performance — report on or extract full trial datasets at any point in the trial
- Data captured through any Medidata solution (including: <u>Rave RTSM</u>, <u>Medidata eCOA</u>, <u>Medidata</u> <u>eConsent</u>, <u>Rave Imaging</u>), or from an external system, is automatically available for reporting and extraction without the need for data reconciliation
- Centralized data reviews, automated query posting, and AI-assisted data reconciliation can be performed with <u>Patient Data Surveillance</u>



FACT SHEET RAVE EDC

Rave EDC Features

Centralized Administration

Manage users, roles, studies and sites across all Rave EDC (and other products on the Medidata Platform) studies through Platform Administration.

Real-time Data Validation

Ensure data is correct at the time of entry. Validation is performed when data is entered into each field, not when a complete form is saved.

Streamlined Data Review and Querying

Build multi-dataset listings using drag and drop, and automatically generate and post multiple queries with <u>Patient Data Surveillance</u>.

Intelligent Coding

Code verbatim terms automatically or manually with coding suggestions through <u>Rave Coder</u>.

Reporting and Analytics

Make informed decisions with real-time study insights through dashboards and standard/ad hoc reports, and one-click access from reports to relevant forms.

Interoperability

Ingest data from, or extract data to, any external system using sophisticated and secure integrations.

"The best qualities of Rave EDC are how user-friendly [it is] for the sites to enter data..., how the query management is very efficient, and [the ease of] getting the data out."

- Vijay Chundru, Senior Director, EDC Programming Team, Global Clinical Data Operations, Jazz Pharmaceuticals

The Medidata Advantage

The world's leading biopharmaceutical and clinical research organizations choose Medidata because they trust our unparalleled experience and expertise in providing clinical trial technologies to over 30,000 studies with over 9 million patients and healthy volunteers. Rave EDC is the most preferred and most used EDC system, and is recognized as the market leader*.

From Phase I to IV studies and across all therapeutic areas, our Rave EDC customers are enabled to:

- Execute with agility: Rapid deployments and upgrades, reduced study build times and faster database lock
- Work with the cleanest data: Real-time data validation and coding accuracy
- Manage complexity and scale: From the simplest to most complex protocols and adaptive trials; and from small patient populations in rare disease studies to phase III studies with 10,000's of patients

*Source: EDC Benchmarking and Market Dynamics (5th Ed.), Industry Standard Research, June 2023.

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences. Discover more at **www.medidata.com** and follow us **@medidata**. Contact us at **info@medidata.com** | **+1 866 515 6044**