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 Clinical Cloud</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

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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
- 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

- For global studies, translated forms can appear at the site level in their local language, while the data enter is centrally viewable from a single database
- eLearning helps train sites efficiently, costeffectively 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 product (Rave RTSM, Medidata eCOA, Medidata eConsent, Rave Imaging), or an external system connected to the Medidata Clinical Cloud, is automatically available for reporting and extraction without the need for data reconciliation



Rave EDC Features

Centralized Administration

Manage users, roles, studies and sites across all Rave EDC (and other products on the Medidata Clinical Cloud) studies through Cloud 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

See what tasks are outstanding in the Tasks Overview dashboard and quickly action them individually or in bulk through the Tasks list.

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.

"Medidata Rave EDC was the runaway first-choice preference for all trial types – about 40% of respondents deemed Medidata their top pick for Phase I/II, Phase IIb/III, and Phase IV, post-marketing trials."

> ISR report: EDC Market Dynamics and Service Provider Performance (4th Edition), Dec 2020

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 27,000 studies with over 8 million patients and healthy volunteers.

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

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**