Medidata Rave® for Medical Device & Diagnostics: Streamlined Studies Are Faster To Market

Committed to Medical Device & Diagnostics Research

Medidata Solutions is a leading global SaaS-based provider of clinical development solutions. Offering a unified clinical trial solution that uniquely combines robust, flexible and user-friendly technology with deeply embedded industry experience of the medical device and diagnostics market. Medidata is committed to medical device and diagnostics research. By using best practices established through experience on hundreds of studies—from the simplest feasibility studies to the most complex PMA studies—across a wide range of therapeutic areas, Medidata's Professional Service Organization offers a variety of services to help you optimize your medical device and diagnostics studies.

Greater Value Drives Trial Cost Efficiencies

Medidata Rave includes unique functionality that drives greater trial efficiency. All of this functionality comes standard with Rave so there are no hidden add-on costs later. You have what you need right from the start. Some key areas of Rave EDC efficiency are:

- **Configuration** – A fully configurable and intuitive web-based interface eliminates the need for custom programming and significantly shortens your study start-up timeline. Rave improves productivity costs by reducing efforts for custom programming. Specifically, Rave reduced one customer's EDC study build times up to 40 percent. Learn more about this customer's success with Rave in a case study.

- **Training & Online eLearning** – Training and online eLearning empower you with the expertise to build your own studies in-house. Training your sites is a breeze with Rave's 'one and done' online eLearning. The online training module can be accessed from anywhere, and once training is complete, it can be applied to any study conducted in Rave. Save countless hours of travel and training time by using Rave.

- **Endpoint Adjudication** – As the number of trials with mortality or major morbidity endpoints, and concerns for patient safety, increase, conducting adjudication of major endpoints becomes more and more important. Adjudication is complex, arduous and time-consuming and Medidata Rave simplifies it for you. Rave comes with adjudication process functionality included and allows global, internal as well as 3rd party users to access the system down to the data point level, providing the power needed to electronically manage the adjudication process end-to-end.

- **Clinical Cloud** – Safety, coding, randomization, supplies management and payment capabilities all unified with Rave within the Medidata Clinical Cloud eliminating the need for integrating separate systems.

- **Quick and Easy Startup** – Get up and running quickly with fully configurable roles and workflows.

- **Flexible** – Rave adapts to your unique processes and working practices, including an EDC, paper or hybrid study design, to streamline a study in any device class or therapeutic area.

- **User-friendly** – Intuitive interface, already used by 300,000 sites around the world, plus role managed eLearning drives adoption and process compliance.

- **Seamless** – Works seamlessly with Medidata Patient Cloud (ePRO) applications.

- **Full Data Access** – On-demand, centralized access to study data allowing for viewing, reporting (40+ standard reports) and analysis.

- **Compliant** – Designed to meet global regulations (FDA, ICH, GCP, EMA and MHRA), including 21 CFR Part 11 and HIPAA.

- **Lab Data Management** – Manage lab data dynamically, including lab range alerts and central and local lab references.

Centralized On-demand Data to Streamline Clinical Trials

Get the data you want, when you want it, at no additional cost. In Medidata Rave all your data is centrally accessible providing self-sufficient, fast, on-demand reporting, reviewing and downloading of your data allowing for interim analysis using SAS or any tool of your choice. Have data from another system that you want to add to your clinical database? No problem. Using Medidata API (Rave Web Services), a system-to-system integration can be created that requires no ongoing programming, only simple, non-technical configuration that can be done in-house by anyone. Data from any external data source, including core and central labs data, can be automatically pushed into Rave. And with data that is entered into Rave you can say goodbye to expensive, time-consuming and error-prone reconciliation. Rave also comes with 40+ standard reports, including ad hoc reporting tools such as JReview and Business Objects as well as a variety of ad hoc reporting tools, all at no extra charge saving you time and money while streamlining your study.

Easily Add Image Data to the Study Database

With the exponential increase in image volumes and more integrated imaging end points coupled with progressively aggressive study timelines, integrating your image system with Medidata Rave is a solution that can reduce inefficiency and eliminate any steps that have the potential for human error, while centrally locating your image data in your clinical trial database. Using Medidata API (Rave Web Services), a system-to-system integration can be created that requires no ongoing programming, only simple, non-technical configuration that can be done by anyone with basic computer skills. The integration has the potential to transform image quality control and processing.

The benefits of integrating your image system with Medidata Rave:

- All clinical study data is centrally available in the Medidata Clinical Cloud in real time for viewing, reporting, analysis or exporting.

- Image QC and processing effort is reduced through automation and integration.

- Full images are available for viewing directly from within the Rave interface without having to log into a second system.

For more information on this topic read a case study and watch a short video.

Experienced Service Providers

Medidata professional services offer unmatched expertise in medical device and diagnostics trials and broad knowledge in studies of all sizes and therapeutic areas. Our deep and unique understanding of the latest technology, R&D practices and business processes—including risk-based monitoring, clinical trial supply chain optimization, CRO governance and more—enables us to provide flexible implementation services, sponsor enablement and CRO partner support, and strategic consulting to maximize the value of your clinical research. Whether you are a leading multinational organization, an innovative start-up or a CRO, Medidata professional services has the skills and experience to meet your needs.

- Medidata Study Implementation Service delivers fast, flexible, optimally designed trials. Our proven methodology and consultative approach will save you time and money. The Services team handles all aspects of designing and implementing your medical device and diagnostics study, including providing you with consultation on best practices when there is more than one path or option from which to choose.
- Medidata Sponsor Enablement Service lets you continuously realize the full value of your Medidata solution. Training and mentoring enable you to take full ownership of your clinical trial systems and process.

What Our Customers Say

Easy
"Medidata Rave is an intuitive, easy to use solution – even for users who were new to the system. Using Rave, Clinical Research Associates (CRAs) can access data and site information earlier and become better prepared for more productive site visits." – *Array Biopharma*

Cost-effective
"With Medidata, we are not only getting a state-of-the-art EDC tool with Medidata Rave and the service and support our team needs, but we are also able to eliminate unnecessary costs and manage the project on a lean budget." – *U-Systems*

Affordable
"Like many organizations, cost was a critical factor in our selection, but with Medidata's business model, we found that we didn't have to settle on a 'good enough' solution, but could in fact afford the best." – *Ludwig Institute for Cancer Research*

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.

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Medidata Clinical Cloud®

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk