

## Rave RCM

### Life Sciences' Solution For Regulated Content

Many life sciences professionals require access to regulated and non-regulated content. While principal users such as clinical operations and quality/regulatory teams at small-to-medium sized companies use inefficient hybrids of paper and computer-based systems, larger companies maintain at least two point solutions — one for regulated and one for non-regulated content, which typically results in high costs for software, services and validation. These legacy solutions are dated, siloed and provide disparate user experience for access, search and workflow, leading to low system adoption and increased compliance risks. There is a clear need, therefore, for a unified solution that is both cost-effective and quickly deployable, to manage all content and act as a single source of truth.

Medidata offers a new standard to address these challenges. Introducing Rave RCM, Medidata's regulated content management solutions – a 21 CFR Part 11 compliant, validated, content integrity and collaboration platform for the modern digital workplace.

### Achieve Stress-free Regulatory Compliance with Medidata Regulated Content Management Solutions

Purpose built for life sciences, Rave RCM solutions deliver required processes and controls out-of-the-box by ensuring confidentiality, high integrity, traceability and availability. Rave RCM solutions include:

#### Rave EDC to Imaging

- **Rave eTMF** is a collaboration solution that allows users to create, store, view, edit and jointly work on an entire TMF life cycle in a single application with cutting-edge UX capabilities. Rave eTMF is flexible with configurable TMF folder structures.
- **Rave SOP Management** is a comprehensive, validated and pre-configured solution with full content creation/editing/approving, user/workflow management and read & acknowledge capabilities, with complete mobility (phone/tablet).

#### KEY FEATURES

- Audit trail and reports
- Compound document assembly (including templates, forms and watermarks)
- Content auto-naming
- Electronic signatures
- Flexible document workflow & tasks
- File access control and metadata
- Roles-based system
- Read & Acknowledge workflow
- Advance search algorithms based on the content, title, document type and/or metadata
- Mobile capabilities for document upload, editing, approval

#### THE PLATFORM OF CHOICE FOR CLINICAL RESEARCH

The Medidata's 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 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.

- **Rave Archive** is a unique offering, enabling the migration, search/access, and structural preservation of regulated content coming from external sources (Contract Research Organization (CRO), merger & acquisition related events, etc.). Types of regulated content include complete TMFs, TMF related content, contracts, CVs, IRB letters and so on.

## Rave RCM capabilities also include:

- **End of Study Media** is a capability for sites, CROs, and sponsors to compliantly close out studies and store and deliver EOS Media without the use of CDs or DVDs. EOS Media automates and standardizes the ingestion of EOS documents while providing a digital platform for controlled access.
- **Content Repository** is a place to store all content that is created by any application within the Rave Clinical Cloud. Providing a single source of truth, the Content Repository prevents users from creating multiple copies of the same document which in turn reduces regulatory compliance risks.

## Why Medidata for Regulated Content Management?

- ▶ **Single source of truth for all your content needs.**  
Single repository for all content created and managed within application on the Rave Platform.
- ▶ **Working with regulated content has never been easier.**  
Clean, simple and intuitive user experience makes working with regulated life sciences content easy while maintaining compliance
- ▶ **Regulated content in the cloud. Literally.**  
Search, review and approve regulated content from anywhere with your pre-registered tablet or smartphone. All you need is an internet connection
- ▶ **Workflow that works for you.**  
Medidata's pre-configured workflows are incredibly intuitive. With real-time graphical status updates you will always know where things are and what is happening
- ▶ **Spend less time on setup and more time on what you do best.**  
Cloud based, single instance multi tenant, means you get the newest technology features and functionality without any of the costly and time consuming updates.
- ▶ **Fully validated and highly secure**  
Medidata is built and managed to the highest standards of validation and security but we've made it extremely easy to be secure and compliant

## 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 1,400 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. Discover more at [www.medidata.com](http://www.medidata.com) and follow us [@medidata](https://twitter.com/medidata), The Operating System for Life Sciences™.

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