

Rave eTMF

Simplify your TMF

Medidata Rave eTMF makes overseeing clinical trial artifacts simple. Unified with Rave, eTMF powers trials to run faster, lowers risks managing regulated content and delivers higher quality real-time data management while requiring fewer resources and reducing complexity.

The most flexible and intuitive eTMF solution available

Whether you are just starting out with an eTMF and need basic functionality, or you're rapidly growing and need to expand to capabilities like remote site oversight and real-time inspection readiness, we've got you covered.

ENHANCED SITE COLLABORATION

- Provide CRAs with real-time status of the TMF for their sites
- Provides an integrated platform for sites to interact directly securely with the TMF
- Accelerate site startup and management with real-time collaboration

REDUCED OPERATIONAL COMPLEXITY

- Faster study set-up with document and master data auto-population
- Extensive reporting and real-time dashboards
- Easier document filing and reclassification
- Faster discrepancy reconciliation

EFFORTLESSLY DEMONSTRATE INSPECTION READINESS

- Faster retrieval with search algorithms based on content, title and/or metadata to find content simply
- Easily share relevant information with sponsors or regulators

OPTIMIZED SEARCH AND ACCESS

- Provide all participants with TMF access, anytime, anyplace, anywhere
- Simple and yet sophisticated search, enabling rapid content retrieval driven by cutting-edge search technology
- Fully mobile enabled; leveraging leading edge biometric technology

"Efficiently maintaining and extracting both data and content in a compliant manner are paramount to successful trial outcomes."

VP Clinical Affairs, Medical Device Company Medidata Rave eTMF + Rave EDC

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 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.

::: medidata



The eTMF ecosystem

POWERING THE UNIFIED PLATFORM

Over 100,000 documents¹ can make up a TMF. eTMF simplifies overseeing clinical trial artifacts by automatically populating up to 76% of the TMF artifacts from Medidata's eClinical platform. By seamlessly and accurately combining data and workflows, eTMF risk-proofs and accelerates clinical trials.

The Medidata eTMF platform is unified with the entire Medidata Rave Clinical Cloud — including Archive, Quality with SOP, CTMS, Risk Based Monitoring, Payments and Rave EDC — delivering the industry's most dynamic and comprehensive real-time, end-to-end TMF.



Other solutions eTMF unifies

- Payments
- CTMS
- Rave EDC

Rave eTMF is built on the Rave Clinical Cloud's unified data platform, which enables a single source of truth for all study-related data across your entire portfolio. This ensures you can minimize risk and accelerate trial time lines surrounding management of key artifacts by eliminating the need for multiple data entry for site qualification visits, site initiation visit and site interim monitoring documentation. This can be accomplished because once data is entered, the platform masters and populates it throughout the end-to-end suite of Rave applications. The power of the platform allows you to accurately unify content, data and work flows from study planning to close if using Rave EDC, Rave CTMS and Rave eTMF.

1 MHRA, Inspection Challenges: is it the same for everyone? 2016

Medidata Rave Clinical Cloud™

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics Reduced costs | Improved time to market | Faster decisions | Minimized risk "Streamlining multiple technologies for a more efficient, manageable and cost effective clinical trial process."

Sr. Vice President, Clinical Development and Operations

Biotech Company, +\$1B Revenue

Medidata Rave eTMF, CSA & CTMS & EDC & Coder & Safety

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 <u>www.medidata.com</u> and follow us @medidata, The Operating System for Life Sciences[™].

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