

# RAVE eTMF - THE NEXT GENERATION OF TRIAL MASTER FILE SYSTEMS



## 35%

of inspections have delays because the TMF is not complete or readily available<sup>1</sup>



## 100,000+

documents can make up a trial master file<sup>2</sup>



### DELIVERING REAL TIME OVERSIGHT & ACCESS

- Through advanced search capabilities, and comprehensive dashboards and reporting, Rave eTMF provides improved inspection readiness with real-time study oversight and easy access to documents when you need them.



### REDUCING COMPLEXITY

- Simplified and streamlined filing with instant TMF content auto-population. Rave eTMF generates new study plans in minutes and creates customizable file plans. Intuitive workflows and remote review and approval access ensures high quality, timely and complete filings.

<sup>1</sup> Viglya, as posted on the UK MHRA web site 2014. <http://viglya.com/uk-mhra-updated-definition-of-a-critical-gcp-inspection-finding/>

<sup>2</sup> MHRA, Inspection Challenges: is it the same for everyone? 2016

## BEST-IN-CLASS CAPABILITIES OF A WELL-DESIGNED eTMF



### BEST IN CLASS eTMF CAPABILITIES

Logical structure with advanced search capabilities and signposts

Greater consistency in classifying and filing documents

Auto-population of information

Links to source systems in real time

A single platform with intuitive workflows, completeness checks and the ability to review/ approve documents remotely

Comprehensive dashboards and reports

Centralized, global access

Enables Study Start-up/ Greenlight



### MEDIDATA'S eTMF CAPABILITIES

✓ Advanced search algorithms, based on content title and/ or metadata, makes searching TMF documents simple.

✓ Powered by auto-naming and metadata, ensuring content is standardized, filed correctly and easier to find.

✓ By seamlessly and accurately automating the collection and filing of data and content throughout your study life-cycle, eTMF risk-proofs and accelerates clinical trials.

✓ Integrated with the Medidata Rave Clinical Cloud, eTMF provides a single version of the truth and streamlined back office processes.

✓ A single platform that is easily accessible with single sign-on. Flexible and intuitive workflows. Fully mobile enabled for access at any time and anywhere.

✓ eTMF's real-time dashboards and missing document reporting ensures the highest quality and compliance while reducing overall TMF management costs

✓ eTMF enhances global collaboration with staging areas and artifact filing zone. Secure landing page for sites to upload and retrieve content

✓ Real time insight into site level essential document status — what has been collected vs outstanding- to assess start-up progress.

## About Medidata Solutions

Medidata is leading the digital transformation of life sciences, with the world's most-used platform for clinical development, commercial, and real-world data. Powered by artificial intelligence and delivered by top-ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata and its companies, Acorn AI and SHYFT, serve 1,300 customers and partners worldwide and empower more than 150,000 certified users every day to create hope for millions of patients. Discover the future of life science: [www.medidata.com](http://www.medidata.com)

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