EDGE eTMF

Powering clinical trials for sponsors, sites and patients

Medidata Edge eTMF makes overseeing clinical trial artifacts simple. As a collaboration platform that empowers all stakeholders, from sponsors, sites and CROs to manage and jointly work on an entire TMF lifecycle, Edge eTMF allows users to seamlessly and accurately manage both content and data while maintaining inspection readiness and compliance.

As the centerpiece of the Medidata Clinical Cloud, Edge 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.

9.3

hours spent per week per employee searching[1]

Edge eTMF powers search

Streamlining Search Results
Edge eTMF's advanced search algorithms, based on content, title and/or metadata, makes searching TMF artifacts simple. Powered by auto-naming and metadata, content is standardized and easier to find through simple, intuitive workflows accelerating study startups.

35%

of inspections have delays because the TMF is not complete or readily available[2]

Edge eTMF powers real time compliance

Strengthening Collaboration
Through simplified master data management, automation, and integration, Edge eTMF enables TMF management. By keeping clinical studies up-to-date with real-time study oversight, Edge eTMF provides visibility on study completeness, timeliness and quality through comprehensive dashboards and reporting with collaboration from all stakeholders.

32%

of documents are managed outside eTMF or enterprise content management system[3]

Edge eTMF powers TMF Filing

Reducing Complexity
Simplified and streamlined filing with instant TMF content auto-population from the industry's most complete eClinical Platform, enables automated access to regulated content and data. Edge eTMF generates new study plans in minutes and creates customizable file plans. Its intuitive workflows enable all stakeholders with remote review and approval ensuring timely, high quality and complete filings.

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

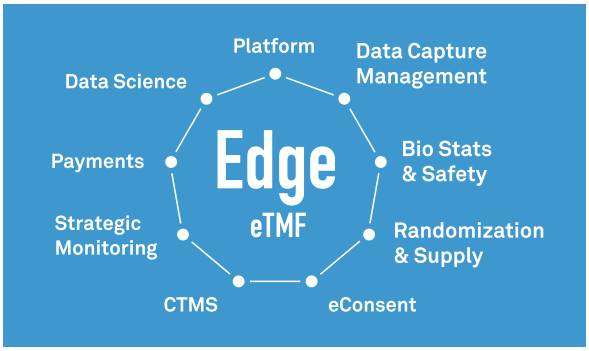
VP Clinical Affairs,
Medical Device Company
Medidata Edge eTMF + Rave EDC

The Edge eTMF ecosystem

Powering the unified platform

Over 100,000 documents can make up a TMF. Edge 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, Edge eTMF risk-proofs and accelerates clinical trials.

The Edge eTMF platform integrates the entire Medidata Clinical Cloud including Edge Archive, Quality with SOP, CTMS, Strategic Monitoring, Payments and Rave EDC, delivering the industry's most dynamic and comprehensive real-time, end-to-end TMF management platform for all regulated and non-regulated content.



100,000+ documents[4] can make up a **Trial Master File**

UP TO **76%** of your TMF Artifacts **automatically populated**

Other solutions Edge eTMF unifies

- Edge CTMS
- Edge Strategic Monitoring
- Rave EDC

"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 Edge eTMF,
Edge CSA & CTMS + Rave EDC &
Coder & Safety

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including nearly 850 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 17 of the world's top 25 global pharmaceutical companies and is used by 16 of the top 20 medical device developers—from study design and planning through execution, management and reporting.

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1 Mckinsey Global Institute, The social economy: Unlocking value and productivity through social technologies July 2012

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

3 ISR Reports, eTMF Market and Service Provider Dynamics, September 2016

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