Medidata eTMF

Life Sciences' Solution For eTMF Management

From trial master files (TMF), contracts, CVs, IRB letters, SOP workflows, and more — clinical trials contain a variety of content from multiple sources. While principal users like clinical operations and quality/regulatory teams at small-to-medium sized companies use inefficient hybrids of paper and computer-based systems, larger companies maintain multiple solutions which typically result 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 for a unified solution to manage TMF content that is both cost-effective and quickly deployable. Introducing our new standard offering for addressing these challenges: Medidata Regulated Content Management (RCM) — a 21 CFR Part 11 compliant, validated, content integrity and collaboration platform for the modern digital workplace.

The first end-to-end data & content collaboration platform that actively maintains inspection readiness

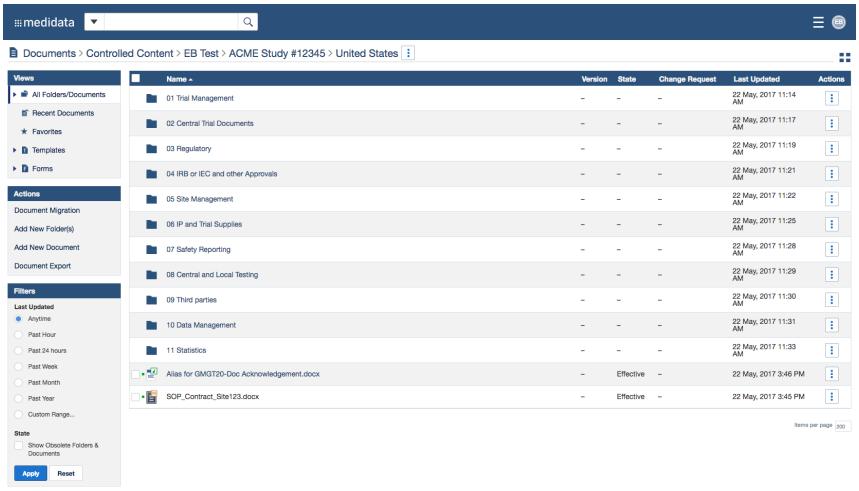
Medidata eTMF is a collaboration platform that empowers everyone — sponsors, sites, CROs — to seamlessly manage regulated content and actively maintain inspection readiness. Unified within the Medidata Clinical Cloud, Medidata eTMF is flexible and configurable, allowing users to create, store, view, edit and jointly work on an entire TMF life cycle in a single application with cutting-edge UX capabilities. With live content integrity verification, life science companies can now use this fully-validated 21 CFR, Part 11 and Part 820-compliant system to ensure constant compliance throughout the clinical trial lifecycle.

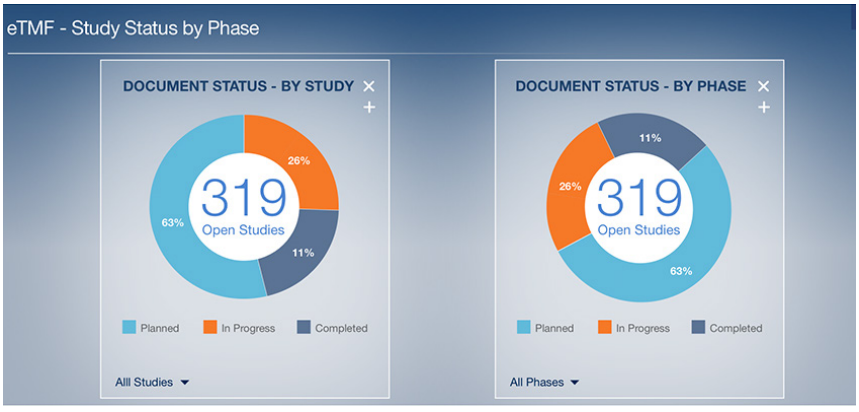
Key Features

- Complete TMF lifecycle workflow
- Robust notifications on change requests, expiring documents, etc.
- Role-based workflow
- Intuitive status reporting and dashboard(s)
- Configurable TMF folder structures
- DIA eTMF Reference model out of the box
- Document placeholders provide the ability to create full "package" of required documents for study, country, site, and investigator objects
- Support audit readiness
- Import/bulk upload supporting migrations
- Rapid implementation as quick as six weeks
- Mobile enabled for content search and access on-the-go
- Deep integration with Box, the leading enterprise content management platform, allows users to find both regulated and nonregulated content in one search

Why Medidata for eTMF Management?

- **Always Compliant**
  With a first of its kind, Live Content Verification technology, content integrity is verified every time content is read or written. Introducing an advanced compliance standard that actively ensures inspection readiness.
- **Enhanced User Experience**
  Built with incredibly intuitive workflows and mobile functionality. Access, review and approve content from anywhere, anytime.
- **Quick & Simple Implementation**
  One platform that can be implemented in weeks — not months — with minimal resources. Leverage Medidata's pre-built, pre-validated functionality and validated content migration.





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.

info@mdsol.com | mdsol.com
+1 866 515 6044