Medidata Regulated Content Management Integrated with box

Life Sciences' Solution For Content Management

Many life sciences professionals require access to regulated and nonregulated 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 nonregulated 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 to manage both regulated and nonregulated content that is both cost-effective and quickly deployable.

Medidata, the leader in cloud-based clinical technology, and Box, the leader in cloud content management, offers a new standard to address these challenges. Introducing Medidata's Regulated Content Management Solutions integrated with Box — 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, Medidata Regulated Content Management Solutions deliver required processes and controls out-of-the-box by ensuring confidentiality, high integrity, traceability and availability.

- **Medidata Edge Quality (formerly SOP Management) – Fully Integrated with Box** 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).
- **Medidata Edge Archive (formerly RCM Archive) – Fully Integrated with Box** 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 includes complete TMFs, TMF related content, contracts, CVs, IRB letters and so on.
- **Medidata Edge eTMF (formerly eTMF) – Fully Integrated with Box** 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. Medidata Edge eTMF platform is flexible with configurable TMF folder structures.

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
- Deep integration with Box, the leading enterprise content management platform, allows you to search and manage both regulated and nonregulated content through one interface

Edge Trial Planning and Management

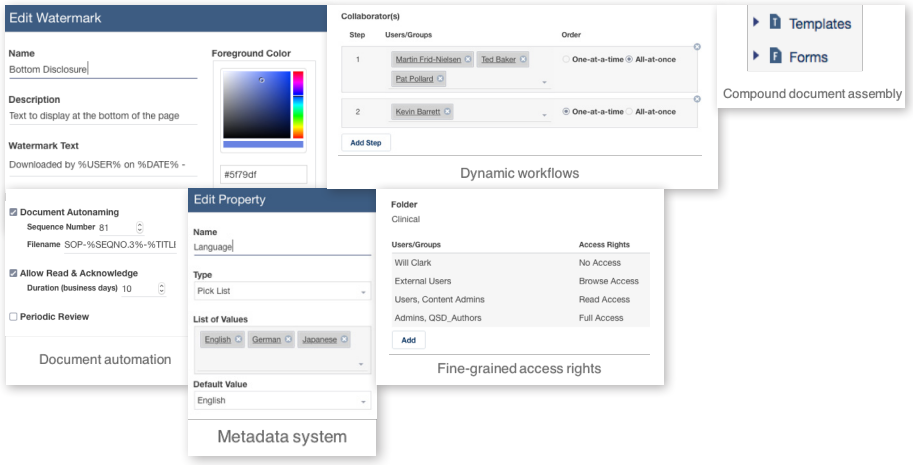
Pioneering Analytics Accelerates Clinical Operations

Edge Trial Planning and Management is a product suite that increases patient enrollment, retention, and study execution. Medidata Edge Design Optimization, Site Feasibility, Site Grants, and Payment solutions use historical benchmarks and automation from MEDS to reduce patient burden and site feasibility as well as site grants and payments. This has been proven to increase patient recruitment and retention rates.

Medidata also solves many of the biggest challenges in trial management. Medidata Strategic Monitoring and CTMS holistically address regulatory requirements for RBM by combining anomaly detection with intelligent workflows to enable sponsors, CROs, and sites to confidently move away from 100% SDV. Medidata master data management means that up to 76% of an eTMF's artifacts can be pre-populated from other sources.

Why Medidata for Regulated Content Management?

- **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.**
  Leverage Medidata's pre-built, pre-validated functionality and validated content migration to achieve your implementation goals quickly
- **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
- **Fully integrated with box**
  Deep integration with Box, the leading enterprise content management platform, allows you to find both regulated and nonregulated content in one search



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 over 950 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 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

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