Medidata eTMF Archive

In life sciences today, companies often struggle with how to store legacy-trial master files (TMF), including content from Contract Research Organizations (CROs) upon study conclusion, as part of a merger or acquisition, or content that must be retained as part of other legal or contractual requirements. Some life sciences companies store their TMFs on the original source media — such as DVD discs — but are unable to search for it there. Other companies copy their TMFs to a non-qualified infrastructure or cloud service, such as Dropbox or Box, in order to make it searchable. However, these approaches can cause a number of problems, not least of which is potential regulatory body restrictions on storing GxP content in non-qualified environments. Sometimes legacy-eTMFs are stored on large, expensive regulated content management systems which, while offering improved regulatory and security controls, tends to be costly. Life sciences companies need a more efficient, validated repository that easily imports legacy-eTMF content, provides the appropriate regulatory and security controls, generates the required content migration reports, and enables subsequent search capabilities.

Medidata introduces a new standard to address these challenges: Medidata's eTMF Archive Solution — a 21 CFR Part 11 compliant, validated, content integrity and collaboration platform for the modern digital workplace.

Achieve Stress-free Regulatory Compliance with Medidata eTMF Solutions

Medidata eTMF Archive is a unique offering, allowing for the migration, search/access, and structural preservation of TMFs and TMF- related content, contracts, CVs, IRB letters and more, coming from external sources (CRO, merger & acquisition- related events, etc.)

Key Features

- Fully validated and highly secure cloud content platform for Life Sciences
- Rapid implementation
- One-touch content import, including drag-and-drop support
- Preservation of source content file and folder structures
- Automatic generation of content migration reports, including full audit logs and signatures
- Security and permissions down to content object level
- Access to audit trail and reports
- Electronic signatures
- File access control and metadata
- Roles-based system for content search
- Mobile enabled for content search and access on-the-go

Why Medidata for eTMF Management?

- **Working with regulated content has never been easier.**
  Clean, simple and intuitive user experience makes working with life sciences content easy, while maintaining compliance
- **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 flows 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
- **Less time on setup, and more time on your expertise**
  Leverage Medidata's pre-built, pre-validated functionality and validated content migration to achieve your implementation goals quickly
- **Fully validated, highly secure**
  Medidata is built and managed on 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 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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