EMC® DOCUMENTUM® ELECTRONIC TRIAL MASTER FILE

Ensuring documentation completeness and compliance for clinical trials

ESSENTIALS

- Accelerate trial setup and approval

- Improve productivity and efficiency with an intuitive user interface

- Seamlessly collaborate with CROs, inspectors and other third parties for document collection and synchronization

- View, upload and work on clinical documentation via an investigator portal

- Track real-time progress of clinical trial documentation

- Be continually prepared for inspections and audits

- Ensure accuracy and consistency with full support for electronic standards

- Demonstrate compliance through extensive audit trails, access control, lifecycle management and version control

- Leverage a proven, trusted, scalable platform that's available on premise or in the cloud

HOW MUCH DOES A MISSED DAY TO MARKET COST YOUR BUSINESS?

Driven by the skyrocketing costs of clinical trials, many life sciences companies rely on contract research organizations (CROs) for the vast majority of trials. But adding more resources—especially third parties—also adds enormous complexity to trial document management. The additional coordination required to collect and maintain vast numbers of trial documents from these partners can expose both you and the CRO to compliance risk.

With EMC Documentum Electronic Trial Master File (Documentum eTMF), you can reduce this complexity and risk. Part of the EMC Documentum for Life Sciences solution suite, Documentum eTMF helps you effectively plan, collect and maintain essential clinical trial documentation. Both sponsors and CROs can reduce complexity and risk by controlling and synchronizing study artifacts, tracking progress in clinical trial documentation, and ensuring fast, secure access to documentation both during and after trials. You'll realize gains in efficiency, consistently manage clinical trial documents according to Good Clinical Practices and ensure inspection-readiness.

TAKE THE COMPLEXITY AND RISK OUT OF CLINICAL TRIAL DOCUMENT MANAGEMENT

Documentum eTMF is a purpose-built solution that leverages EMC Documentum, the industry's leading and most scalable content management platform. EMC Documentum for Life Sciences solutions harness an information architecture based on the industry-standard Drug Information Association (DIA) Electronic Document Management (EDM) and Electronic Trial Master File (eTMF) reference models for consistent document modeling. Documentum eTMF takes advantage of this robust platform to address the challenges of planning, creating, collecting, tracking and maintaining massive volumes of trial documentation on a global basis.

FAST, ACCURATE TRIAL PLANNING, SETUP AND APPROVAL

Leveraging the dictionaries, taxonomies and object models of these reference models, Documentum eTMF facilitates management of accurate, consistent and complete documentation. Streamlined, automated file planning at the product, trial, country and site level, combined with automated workflows, helps you manage regulatory packages that are sent for Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approval. An electronic document repository provides centralized control over documentation and allows remote sites to easily access and share information. Authorized users can also access and navigate documents such as consent forms, indemnity contracts and investigator CVs on demand.

SEAMLESS COLLABORATION AND INVESTIGATOR PORTAL

Documentum eTMF makes it easy for sponsors to collect and provide access to relevant trial documentation from CROs and sites by integrating compliance and security models to enable controlled access.

REDEFINE

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An investigator portal streamlines the distribution and collection of eTMF documentation by providing investigators the ability to directly view key documents, upload missing documents and participate in workflows including signing documents with Part 11-compliant electronic signatures. These capabilities reduce time when monitoring clinical studies, assembling submissions and managing changes.

REAL-TIME TRACKING OF DOCUMENTATION

Because Documentum eTMF helps users efficiently find and access content (without having to navigate multiple systems), your organization can monitor clinical studies and manage trial progress in less time. The solution gives you:

- Full transparency and access to clinical documentation at all stages of a trial
- Multi-stage, automated and real-time progress tracking and risk assessments
- Study-monitoring to flag missing documents and missed deadlines

IMPROVED PRODUCTIVITY

Documentum eTMF is easier than ever for people to learn and use:

- Specific user interfaces for trial managers, librarians, site monitors and others
- Document placeholders to be easily replaced with completed content
- Centralized, distributed and mobile scanning of paper-based documents
- Ability to link and share clinical documentation in Documentum eTMF with Documentum R&D to ensure that the current, accurate version of documents such as Investigator Brochures and Study Protocols are being used

PERSISTENT INSPECTION-READINESS

With Documentum eTMF, inspectors have a dedicated interface that allows them to see the TMF categorized by study, site or date. Using faceted navigation, your team can quickly retrieve requested documents. The result is quicker responses to audits.

UNCOMPROMISED REGULATORY COMPLIANCE

With Documentum eTMF, you can clearly demonstrate 21 CFR Part 11 compliance. The solution supports detailed audit trails, access control, distribution and version control, lifecycle management, as well as support for print control services, watermarking and overlays.

AVAILABLE ON-PREMISE OR IN THE CLOUD

With EMC OnDemand, you can leverage a managed service to reduce demands on your internal IT staff while reducing total cost of ownership by 30%-60%.

With easy access by CROs and investigators paramount, a public cloud solution provides the ubiquitous access needed in a single tenant application. And as always, you can choose a traditional on premise deployment that gives you full control. Regardless of your choice, EMC offers enterprise-grade, best-in-class security, backup and recovery options from VMware, RSA and EMC so you can deploy Documentum eTMF with confidence.

GET STARTED TODAY

Documentum eTMF helps take the complexity, burden and risk out of planning, collecting and maintaining your clinical trial documentation. To learn more, visit us at www.emc.com.

CONTACT US

To learn more about how EMC products, services, and solutions can help solve your business and IT challenges, contact your local representative or authorized reseller, visit www.emc.com, or explore and compare products in the EMC Store.

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