opentext™

OpenText™ Documentum™ for eTMF

Improving inspection readiness and compliance for clinical trials

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 coordination necessary to collect and maintain vast numbers of trial documents, and to keep track of required documents in the context of the trial's progress, is a monumental task and one that can expose both the sponsor and the CRO to compliance risk.

With OpenText Documentum for eTMF, you can 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 collection, and ensuring fast, secure access to documentation both during and after trials. You will 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 for eTMF is a purpose-built solution that leverages Documentum, the industry's leading and most scalable content management platform. Documentum for Life Sciences harnesses 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 for eTMF takes advantage of this robust platform to address the challenges of planning, creating, collecting, tracking, analyzing, and maintaining massive volumes of trial documentation on a global basis.

Fast, accurate trial planning, set-up and approval

Documentum for eTMF streamlines your file planning process at the product, trial, country, and site level. Through automated file-planning templates, an expected document list based on study milestones can be quickly created. An electronic document repository provides centralized control over documentation and allows remote sites to easily access and share information. Authorized users can access and navigate documents such as consent forms, indemnity contracts, and investigator CVs on demand. The end result is faster submission of regulatory packages sent for Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approval.

BENEFITS

- *Accelerate study set-up and configuration*
- *View, upload, and work on clinical documentation via an investigator portal*
- *Seamlessly collaborate with CROs, inspectors, and other third parties for document collection and synchronization*
- *Track real-time progress of clinical trial documentation*
- *Improve TMF quality via an intuitive and configurable quality check process*
- *Gain actionable insight through interactive dashboards and metrics reporting*
- *Be continually prepared for inspections and audits*
- *Demonstrate compliance through extensive audit trails, access control, lifecycle management, and version control*
- *Leverage a proven, trusted, scalable platform that is available on-premise or in the cloud*

Seamless collaboration and investigator portal

It is time to move past spreadsheets, faxes, and email for sharing and submitting critical documents. This is a recipe for inefficiency, errors, and user frustration. Documentum for 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.

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 documentation tracking

It is critical to understand what TMF document is required, what is missing and what is completed. Leveraging visual and interactive dashboard reports, Documentum for eTMF helps users efficiently find and complete missing documents and gain actionable insight into process inefficiencies.

Real-time tracking of document collection is based not only on the trial status, but also on the progress of the countries and sites providing detailed visibility. Automatic quality checks detect mismatches when the wrong document is entered, for instance, or an image is unclear, or a document is missing a sign-off. And metrics reporting provides actionable insight on TMF completeness, timeliness, and quality.

Improved productivity

Ease of use leads to fast adoption and ready conformance, and reduces compliance risk. People are much less inclined to bypass controls—reverting to email, for example—when their user interface helps them accomplish their tasks. Equally important, the solution includes built-in access controls to protect proprietary information. Documentum for eTMF is easier than ever for people to learn and use:

- Specific user interfaces for trial managers, librarians, site monitors, and others
- Document placeholders help tracking and are easily replaced with completed content
- Centralized, distributed, and mobile scanning of paper-based documents
- Access controls ensure that only authorized users view the product trials on which they are working
- One source of truth to enable linking and sharing of clinical documents with regulatory and to ensure that accurate versions of documents are used

Persistent inspection readiness

With Documentum for eTMF, inspectors have a dedicated interface that allows them to see the TMF categorized by study, site, or date. Using faceted navigation, the requested documents can be quickly retrieved. 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 OpenText™ Documentum™ as a Service, you can leverage a managed service to reduce demands on your internal IT staff while reducing total cost of ownership by 30 to 60 percent. 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, OpenText offers enterprise-grade, best-in-class security, back-up, and recovery options so you can deploy Documentum for eTMF with confidence.

Get started today

Documentum for 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.opentext.com.

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