opentext™
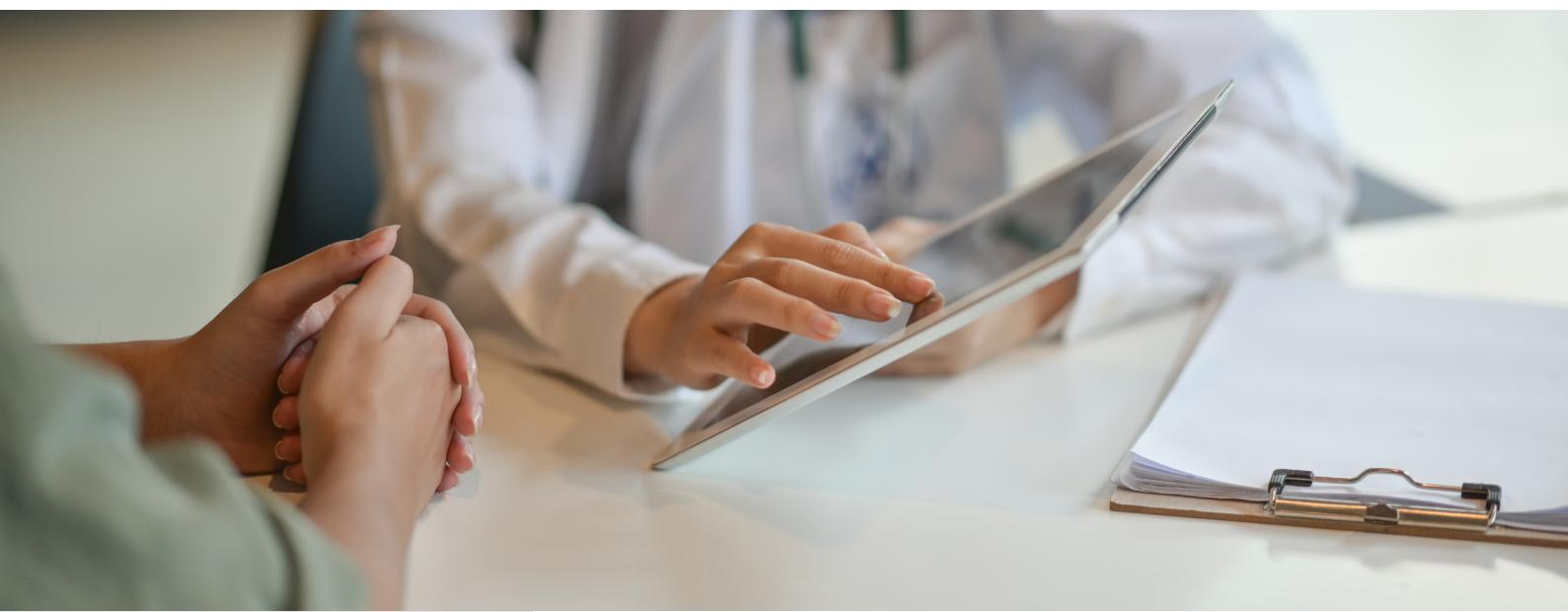
OpenText™ Documentum for eTMF

Improving inspection readiness and compliance for clinical trials

🚀 **Accelerate** study set-up and configuration

📄 **Track** real-time progress of clinical trial documentation

👥 **Seamlessly collaborate** with CROs, inspectors, and other third parties

📈 **Gain actionable insight** through interactive dashboards and metrics reporting

Driven by the skyrocketing costs of clinical trials, many life sciences companies rely on contract research organizations (CROs) for many 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.

opentext™

Feature name	Description
File planning	Automate creation of file plan and placeholders at the product, trial, country, and site level.
Seamless collaboration	Allows sponsors to collect and provide access to relevant documentation from CROs and sites by integrating compliance and security models to enable controlled access.
Documentation tracking	Find and complete missing documents with visual reports and interactive dashboards and automatic quality checks.
Document capture	Centralized, distributed, and mobile scanning of paper-based documents.
Cloud-native technologies	Centralized, distributed, and mobile scanning of paper-based documents.

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.

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.

opentext™

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 for 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.

Delivered with cloud-native technologies

By leveraging state-of-the-art technology from Docker and Kubernetes, Documentum for eTMF can be efficiently deployed on-premises and in any cloud providing streamlined deployment, management, and upgrades. These new technologies have come together to make it easier than ever to upgrade Documentum to the latest version and take advantage of new features, capabilities and updates.

opentext.com/contact