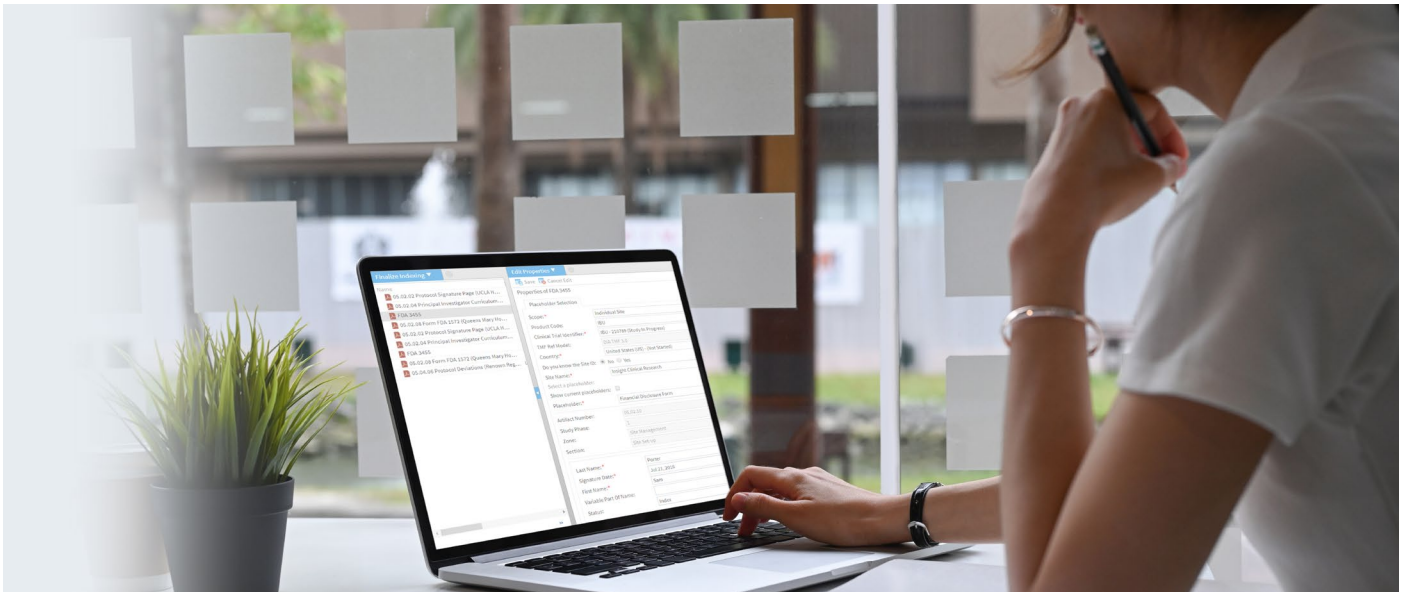
OpenText Documentum Content Management for eTMF

Connect and share inspection-ready content across your product's lifecycle



Benefits

- Simplify trial planning and document control to reduce risk
- Speed approvals and inspections with smart, audit-ready tools
- Boost team productivity with an intuitive, user-friendly system
- Scale easily and integrate with systems across your organization

Clinical trials are expensive, so many life sciences companies team up with contract research organizations (CROs) to help run them. But working with outside teams can make managing all the trial documents tricky. There's a huge number of artifacts to collect and keep organized, and you've got to make sure everything lines up with the trial's progress. If it's not done right, it can lead to delays or even compliance problems for both the company and the CRO.

OpenText™ Documentum™ Content Management (CM) for eTMF makes handling clinical trial documents easier and less risky. Sponsors and CROs can work together to plan, collect, and manage clinical trial documents in one place. You can track progress, spot missing files or approvals, and make sure everything is inspection ready. It helps you stay organized from start to finish, with safe, fast access to all the documents you need.

Take the complexity and risk out of clinical trial document management

OpenText Documentum CM for eTMF is a purpose-built solution that leverages OpenText Documentum CM, the industry's leading and most scalable content management platform. It follows standard CDISC reference model releases to keep documents organized. Whether you're planning, creating, tracking, storing, or maintaining massive volumes of trial documentation for a global trial, it puts all your clinical trial documents in one secure place. It helps you stay organized, follow the rules, and be inspection ready at every step.

Faster, easier trial planning and approvals

Smart templates make it easy to set up the files you need for each product, clinical trial, employed country, and clinical site (aligned on your study milestones) so your expected document list comes together fast. That means less time organizing and more time moving your trial forward.

All your key documents, such as consent forms, contracts, and investigator CVs, are stored in one secure, central place. Teams anywhere can safely access, index, and update files with built-in tools that support compliance. No more digging through emails or switching between systems. Everything is easy to find, organized, and ready when you need it—so you can prepare and send regulatory packages for the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approval faster and with fewer delays without digging through emails or switching between systems.

Inspection-ready at all times

Staying ready for audits is easier when you can see what's done and what's missing. OpenText Documentum CM for eTMF gives you a visual dashboard to track everything in real-time. You can quickly spot gaps, find errors, and fix problems before they slow you down.

You also get a clear view of progress by country, site, or trial stage. Built-in quality checks catch issues like low-quality scans, missing signatures, or wrong files. Plus, helpful reports show how complete, timely, and accurate your Trial Master File (TMF) really is, giving you actionable insights to keep improving, ensuring you're always prepared when inspectors come calling. Inspectors get their own view, where they can easily browse documents by study, site, or date. With smart filters and search, they can find what they need fast, so audits go more smoothly and take less time.

Always ready for audits and inspections

OpenText Documentum CM for eTMF gives you a real-time dashboard to track progress by country, site, or trial stage, making it easier to be audit-ready. You can quickly spot gaps, fix errors, and catch issues like low-quality scans, missing signatures, or misplaced files—before they become problems.

When inspectors arrive, they get their own easy-to-use view of the TMF, with filters to browse documents by study, site, or date. Smart search tools help them find what they need quickly, so audits run smoother and take less time. Built-in quality checks and detailed reports also show how complete, timely, and accurate your TMF is—so you can be confident and always prepared.

Boost productivity with tools people actually use

When a system is easy to use, people stick with it. OpenText Documentum CM for eTMF is built to support real work, not slow it down. It helps teams avoid risky workarounds like emailing documents. Instead, they can get their job done quickly and securely with features made for their role.

Key features include:

- Simple interfaces for trial managers, monitors, and document staff.
- Placeholders that track collected artifacts through trial closure.
- Strong access controls so only the right people see the right content.
- A single source of truth to share accurate, approved documents across clinical and regulatory teams.

- Signposting of artifacts retained in other repositories, which reflect progress on these artifacts and provides instructions to access the source artifact in the other repository.
- Incremental locking and archiving of clinical trials, countries, and sites to ensure content is static for a pending inspection and incremental archiving of the trial as sites and countries complete their work.

Built-in compliance with industry rules

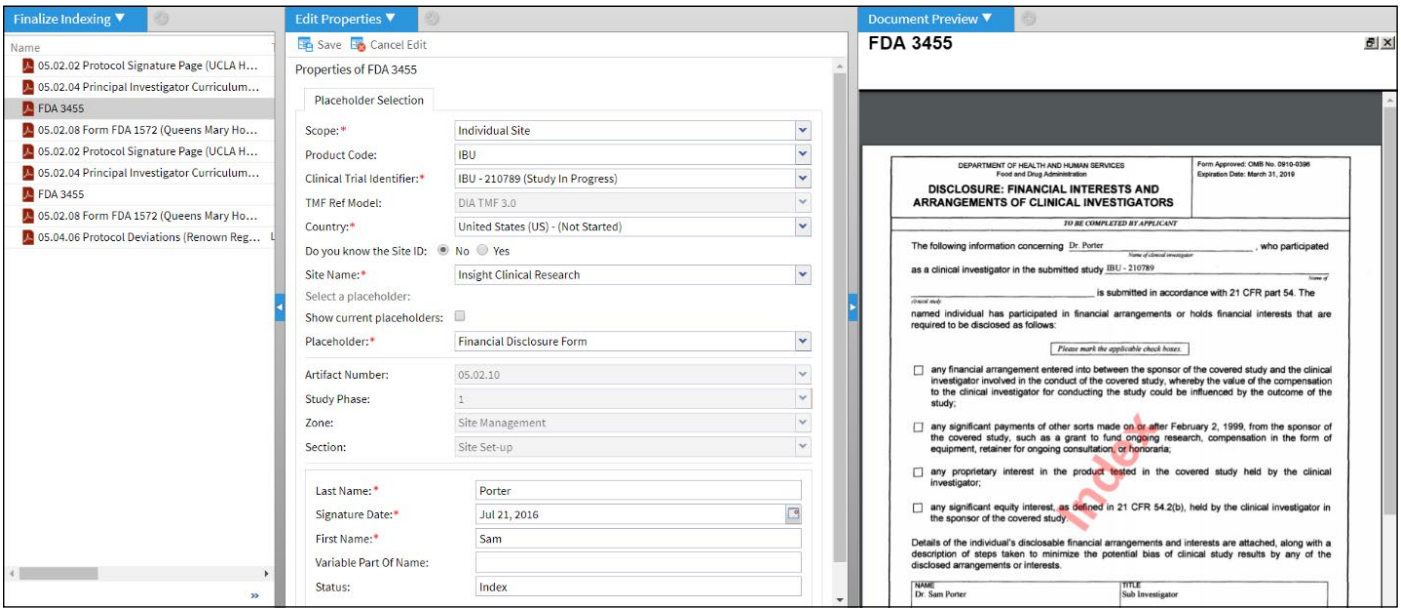
You can confidently meet regulations like 21 CFR Part 11 with Documentum for eTMF. The system includes audit trails, version control, and role-based access and watermarks—all built in to help protect your data and prove compliance.

Modern technology for today's needs

OpenText Documentum CM for eTMF runs on cloud-native technology, which means you can use it on premises or in any cloud. Whether you're managing one trial or dozens, this flexible platform keeps you moving forward, without the tech headaches. And because updates happen seamlessly, you'll always have the latest features without disrupting your work.

Summary

OpenText Documentum CM for eTMF helps life sciences companies and CROs manage clinical trial documents with less hassle and more confidence. From planning and collecting to tracking and sharing, everything is handled in one secure, easy-to-use system. Built on trusted industry standards, it keeps your documents organized, compliant, and always inspection-ready. With smart tools, real-time tracking, and modern cloud technology, OpenText Documentum CM for eTMF supports faster approvals, stronger collaboration, and better control across every stage of your trial's lifecycle.



Easily index your investigator financial disclosures

Feature name	Description
File planning	Automate creation 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.
Signposting	Signposting of artifacts retained in other repositories that reflect progress on these artifacts and provides instructions to access the source artifact in the other repository.
Trial locking and archiving	Incremental locking and archiving of clinical trials, countries and sites to ensure content remains static for a pending inspection and incremental archiving of the trial as sites and countries complete conducting their work.

Associated OpenText products

- OpenText™ Documentum™ CM
- OpenText™ Documentum™ CM for Life Sciences
- OpenText™ Documentum™ CM for Quality and Manufacturing
- OpenText™ Documentum™ CM for Regulatory

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