Compliance and collaboration made easy

DXC FirstDoc™ Electronic Trial Master File Module

Improve your life sciences document management capabilities with a centralized eTMF repository.

Document management at its best

- Seamless user experience
- Better internal and external collaboration
- Easy integration with many tools
- Automated placeholder functionality
- Full TMF Reference Model support
- Robust study-tracking features

Life sciences companies are challenged with implementing an electronic trial master file (eTMF) solution that can foster collaboration, ease reporting and meet ever-changing compliance requirements. Working closely with a leading pharmaceutical company, DXC Technology has developed an enhanced eTMF module for our industry-leading FirstDoc™ electronic document management system that is available to life sciences companies worldwide.

DXC FirstDoc Electronic Trial Master File Module is designed to ease the management of trial master files through automation and collaboration. Driven by life sciences companies' need for more robust reporting capabilities, better tracking and improved audit compliance, DXC combined our expertise with that of a client and a leading pharmaceutical industry consultant to develop an innovative solution that is not available elsewhere in the marketplace.

Key features

Providing a seamless, satisfying user experience is the primary goal of FirstDoc. The addition of the eTMF module greatly extends FirstDoc's already robust TMF capabilities. Among the many new features:

Centralized content repository. The solution features a single, central repository for all digital content that can quickly deliver information via multiple views, including libraries, collections and reports. Centralizing all content into a single platform also lets you perform functions such as study planning and maintenance, document upload and authoring with life-cycle capabilities, reviewing and approving — all from the same repository.

Seamless content management. The solution extends FirstDoc's web-enabled user experience paradigm with an intuitive interface. Multiple files can be uploaded easily with simple drag-and-drop capabilities. Linking and unlinking documents with placeholders is a breeze with the Link Manager interface that also supports drag-and-drop and provides a document-preview panel to assist with quality control.

Placeholder creation wizard. Creating placeholders in an electronic document management system has never been easier. The solution uses a dynamic multipage wizard to collect an inventory of reference model artifacts and study-related data; it then assembles that into a final list the user can preview and edit with final changes before placeholders are created. Placeholders can be created directly from the Reference Model or by using an Artifact Package, which is a custom list of artifacts that has been pre-created and can be reused any number of times.

TMF Reference Model support. The solution supports the latest TMF Reference Model, which ensures a standardized means of organizing and storing content. In addition to the Drug Information Association's TMF Reference Model, the solution has the flexibility to support any custom or hybrid reference model.

Robust tracking and reporting. The new eTMF module gives users a more granular view of the data and allows for close management and tracking of content by individual study, market or site. The "TMF Tracking" interface provides a rundown of a study's key statistics, so users can quickly gain insight into one or more studies at a glance. Reporting functions include a dynamic parameter-driven interface and support for Excel and PDF report formats, which enables users to provide up-to-date TMF information for inspectors as well as stakeholders, contract research organizations (CROs) and sites.

Key benefits

By focusing on the user experience, FirstDoc makes all functions easier to access and simpler to navigate, which empowers your employees. The FirstDoc eTMF Module provides these benefits:

Ease of use. FirstDoc has maintained its position as a leading document management system because it provides a seamless, stress-free user experience. Users are in full control of the TMF information they see and how it is presented. They can personalize their workspace, create placeholders in a snap, use simple drag-and-drop capabilities to link study content with placeholders, and easily search and bookmark their favorite documents. Simplified document templates and reports make compliance with complex regulatory requirements fast and easy.

Improved collaboration. The solution fosters collaboration among internal users and external partners in real time, so teams can work together as one across time zones, firewalls and corporate boundaries. It works with a variety of clinical trial management systems, integrating best-of-breed tools from multiple environments to allow for flexible and feature-rich deployments.

Increased compliance. In short, the solution provides life sciences companies an easier fit for compliance. Adherence to industry standards such as the TMF Reference Model means that your content will conform to the standardized taxonomies and metadata outlined in the reference definition. The solution was designed by DXC in conjunction with a leading pharmaceutical company to meet specific needs, such as better audit compliance capabilities. Also, the solution is modularized, so it can be adjusted to meet changing regulatory and audit requirements.

Enhanced security and privacy. The already robust security features in FirstDoc have been extended to all eTMF activities, from document upload and authoring to tracking, review and approval — just as securely. FirstDoc's security model lets users restrict document access to specific authors, readers and reviewers/approvers. In addition, granular security parameters can be set for a variety of internal and external user roles.

Why choose DXC FirstDoc?

DXC FirstDoc eTMF Module extends the capabilities of FirstDoc, which is built on a foundation of more than 20 years' experience delivering content management solutions to the life sciences industry. Our solution stands out in the marketplace because it is highly configurable, fosters greater collaboration and helps companies achieve compliance. The intuitive user interface delivers a pleasing, seamless experience while providing enhanced tracking and reporting capabilities. Document management in the life sciences industry has never been easier.

Learn more at dxc.technology/firstdoc

About DXC Technology

DXC Technology (DXC: NYSE) is the world's leading independent, end-to-end IT services company, serving nearly 6,000 private and public-sector clients from a diverse array of industries across 70 countries. The company's technology independence, global talent and extensive partner network deliver transformative digital offerings and solutions that help clients harness the power of innovation to thrive on change. DXC Technology is recognized among the best corporate citizens globally. For more information, visit **www.dxc.technology**.

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