

PhlexTMF eTMF technology

Take control of TMF management

Electronic Trial Master File (eTMF) innovation driven by customers

Increase TMF health and organizational efficiency through an eTMF with built-in best practices, artificial intelligence (AI)-assisted indexing pre-trained on millions of TMF documents, and an embedded, configurable quality review module.

PhlexTMF software incorporates innovation based on input from our worldwide customers to address the business challenges they face every day—from developing and implementing TMF best practices throughout their organization while reducing time-consuming manual effort to effective contract research organization (CRO) oversight and communication.

Phlexglobal's team of global TMF practitioners, quality management professionals, and technologists leveraged these customer-driven insights into innovative eTMF software. The result? You can obtain authoritative, real-time intelligence and management control regarding the completeness, timeliness, and quality of your TMF—whether internal or outsourced to a CRO—with the ability to easily identify gaps and take corrective action quickly.

What's more, our AI-powered filing and indexing lets you significantly increase the speed and accuracy of document processing, freeing up internal resources for more important projects.

PhlexTMF is more than transactional eTMF software, offering a comprehensive management system with an executive overview, pragmatic visibility for study owners, and embedded workflows that:

- Provides a complete solution for managing TMF processes throughout the study life cycle, from initial planning and study startup to closeout, inspection, and final archive
- Embeds TMF best practices in an intuitive design so that you and your team can master the software quickly and easily, getting business value from day one
- Allows for easy configuration of the software to align with your own workflows and best practices, or to embed more efficient workflows due to organizational improvements
- Delivers a steady cadence of software releases incorporating industry-driven best practices, while leveraging business-enabling technology advances such as machine learning and natural language processing (NLP).

Technology innovation reduces time and manual effort while improving inspection readiness:



AI-assisted indexing

AI-assisted eTMF speeds up document processing, improves accuracy, and frees study teams from time-consuming manual filing to focus on more critical, value-added tasks



Embedded quality review

Replace manual processes and spreadsheets with built-in quality review tools that enhance TMF quality management and inspection readiness with less effort



Intelligent placeholders

Define where documents are expected, driving completeness metrics; simplify uploads by removing the need to fill in numerous fields for every document

Benefit from purpose-built features and functionality

eTMF built on and driven by TMF best practices

Manage quality, completeness, and timeliness of your Trial Master File through all stages of a trial and across the document life cycle.

Unlike eClinical “platforms” or generic electronic content management systems built for other industries, we leverage our extensive TMF expertise and innovation to develop customer-driven, purpose-built eTMF technology with embedded best practices:



AI-assisted indexing

Proven, scalable AI technology leverages pre-trained neural networks to identify and extract attribute values from TMF documents—increasing speed and accuracy while reducing manual effort.



Intuitive user interface

A simple interface with a unique combination of tree and search navigation offers flexible document location options, which are preferred by auditors and inspectors.



eTMF event management

Capture study changes such as protocol amendments that affect expected documents, plus track collection and quality control event stories to verify completion.



Oversight and reporting

User-configured dashboards dynamically filter results and can use heatmap visualization to show TMF timeliness and quality.



TMF quality review

PhlexTMF quality review tools let you quickly and easily conduct regular, risk-based, or milestone-driven completeness reviews.



Simplified study setup

Capture what is unique about a trial with study setup questions to address specific trial parameters and document requirements, while still enforcing filing standards across the organization.



Intelligent placeholders

Define where documents are expected, driving completeness metrics; simplify uploads by removing the need to fill in numerous fields for every document.



eQuery tracking system

Identify, communicate, and track remediation of TMF issues, eliminating multiple communication paths and capturing all relevant information in one place.



Automation-driven completeness tracking

Easily and visually identify missing documents with views that show documents received vs expected in real-time across trial, country, site, zone, vendor, and other parameters.



Process management

Flexible workflows help designate the path of a document from upload to inspection readiness.

Ready to discover more? [Visit us here](#)