Essential Features of a Future-Proof Automated eTMF System

Managing the Trial Master File (TMF) is one of the most critical and challenging aspects of running a successful clinical trial. In fact, the February 2021 inspections report from the UK health authority reveals that TMF essential documents caused the most findings within commercial sponsor organizations for the past 10 years.

Despite the growing number and variety of clinical endpoints and cross-functional collaborations in today's clinical trials, many biopharmas and CROs are still relying on the same decades-old tools to manage the TMF. Legacy systems using outdated file sharing technology and homegrown systems using spreadsheet trackers or paper result in critical data and essential documents falling through the cracks.

Today's Clinical teams need a collaborative solution– flexible enough to fit their workflows and accommodate contributions from sponsors, investigators, CROs, institutions, and other stakeholders, but reliable enough to ensure the TMF meets regulatory standards. The first wave of electronic TMF (eTMF) systems was a step in the right direction, but they fell short of delivering compliance for collaborative research teams, as evidenced by the 10-year trend of rising inspection findings.

As you evaluate a new eTMF solution, use this checklist to ensure the one you choose has the essential functions and capabilities you need to deliver comprehensive and compliant TMFs – now and into the future.

Approachable Automation

Clinical decision makers have embraced automation in recent years after seeing its demonstrated value and reliability in drug Safety software. Automating key eTMF capabilities will save invaluable time and allow your team to focus on higher-value initiatives.

- [ ] **Auto classification of essential documents**
  Auto classification is a high-impact use of artificial intelligence in clinical operations. Using natural language processing and other methods, modern eTMF systems move uploaded essential documents to the right place within the TMF.

- [ ] **Auto naming**
  Auto naming of records, documents, and data objects with predefined and customizable metadata.

- [ ] **Report generation and distribution**
  Automatically generated reports help Clinical teams track the completion of TMF documents and stay on top of necessary follow-up.

- [ ] **Team notifications**
  Notifications should be sent to the appropriate stakeholders when a task is completed to keep teams aligned and documents moving to reduce timelines.

Clean, intuitive UI/UX

eTMF systems are meant to make managing trial documents simpler; but if the user experience is cumbersome, the efficiency gains are negated. An intuitive, configurable user experience lends itself to better collaboration.

- [ ] **Customizable, real-time dashboards**
  Configurable dashboards allow Clinical teams to easily keep track of the status of all documents and metadata in real-time, based on the organization's workflows and trial specifics.

- [ ] **Inspection-ready TMF viewer**
  With a dedicated TMF view function, Clinical teams can develop stronger relationships with regulatory bodies by bringing health authority inspectors up to speed on the system in minutes.

- [ ] **Multilingual capabilities**
  Multilingual systems – including support for non-Latin characters – allow organizations to use a single platform across all sites worldwide and eliminate the need to manually translate documents.

- [ ] **Global searchability**
  The eTMF should come equipped with a search feature that makes it easy to find documents at the study, site, and country levels.

Reliable Security & Adjustable Permissions

The sensitive nature of trial data dictates the importance of security. Ensure that your eTMF solution has security measures that allow only authorized users to access certain databases and documents.

- [ ] **User-, role-, and group-based security rules**
  The eTMF should allow users to be designated access based on roles and responsibilities to ensure consistent, reliable security across internal and external teams.

- [ ] **Permissions management**
  eTMF systems are designed to manage multiple studies at once, meaning it's important that each user is only able to access the documents pertaining to their own work. Specific permissions, set by your organization, control the data and documents each user has access to.

Platform Capability

An eTMF system designed to be part of a larger clinical platform gives companies more options and data continuity as their research grows.

- [ ] **Seamless integration across life science R&D systems**
  It's important that the eTMF system is able to integrate with other systems, including CTMS and EDC. As you modernize and expand the technology stack, you'll want these systems to be able to share data easily.

- [ ] **Configurable templates**
  Pre-configured templates, tailored to your organization's needs, align expectations among stakeholders, ensure consistency across studies and sites, and provide collaborative capability for the authoring and finalization of TMF related documents.

- [ ] **Repeatable, standardized workflows**
  By standardizing workflows in the eTMF, Clinical teams can reduce startup time at sites and achieve greater consistency across individual documents as well as different TMFs.

Future-Proof Compliance & Validation

A powerful eTMF system will have built-in quality controls and workflows that help the Clinical team maintain compliance and mitigate findings in the TMF.

- [ ] **Support for the TMF Reference Model eTMF Exchange Mechanism Standard (EMS)**
Support for the EMS is crucial for today's complex research collaborations. The standard provides a framework for seamlessly sharing TMF documents and data across organizations and platforms, ensuring no valuable information is lost and providing real-time insights into every aspect of the trial.

- [ ] **Alignment with Drug Information Association (DIA) TMF Reference Model**
Seek an eTMF with pre-configured workflows and document support that align with industry best practices.

- [ ] **Electronic signature support**
The system should support e-signatures, including responsibility and authorship, and must meet 21 CFR Part 11 requirements to be a turnkey solution for your organization.

- [ ] **Controlled data entry and interactive quality control workflows**
The eTMF should be able to control data entry based on validation rules and mandatory fields to restrict data capture. It should also come equipped with built-in quality control that brings internal and external users together, such as document review.

- [ ] **Audit trail recording**
The eTMF system should automatically record operator entries and actions that create, modify, or inactivate electronic records through a secure, computer-generated, time-stamped audit trail, including time zone, that can't be disabled.

Looking to learn more about modern eTMF systems?

Download our eBook

Exploring Advanced Clinical Collaboration in Modern eTMF Systems

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