eTMF: A Clinical Trial Enabler

By Ashok Ghone, Ph.D., Vice-President, Global Services, MakroCare, USA

As per GCP, "If it is not documented, it is not done". So, documentation is a vital part of the clinical trial process. Moreover, considering the complexities of managing clinical trials because of the involvement of different stakeholders and vendors, maintaining proper documentation is always a challenge. It's no secret that it's cumbersome to manage paper documentation i.e. collection, storage, retrieval, and archival of documents. To minimize the issues related to paper documentation, the industry slowly moved to the EDMS (electronic document management system). At the same time, regulatory compliance is a core requirement of the life science industry which is highly regulated by government agencies. In order to make the document life cycle completely digital, transparent, process supportive, and regulatory compliant, EDMS is evolving further into an electronic trial Master File (eTMF) system which automates the capture and management of TMF documents and can prevent unnecessary risks/issues over manual paper handling processes. An eTMF system automates manual paper-based Trial Master File processes.

An eTMF system offers various benefits over a paper-based system. However, to leverage these benefits, one needs to ensure the proper implementation of eTMF and the associated workflows — processes which should be managed by trained resources. The benefits of using eTMF include:

- Better compliance and transparency
- Access from anywhere to different stakeholders
- Improved productivity or increased operational efficiencies
- Enhanced quality document management
- Inspection & audit readiness
- More efficient study start-up
- Optimization of clinical trial timelines
- Simplified tracking, fast search, and retrieval
- Supports non-compliance risk-management
- Cost-savings in document management

How eTMF Is A Clinical Trial Enabler

The issues in document management and the delays happening in clinical trials are very common. If the eTMF tool is supported by the right workflows/processes and is properly managed, it can streamline the overall clinical trial process.

Speed-Up Study Start-up & Optimization Of Clinical Trial Timelines

Collecting documents from sites/investigators and vendors and sharing them with Sponsors/CROs through eTMF, which boasts efficient workflows and supports sharing, review and approval processes, can help resolve issues faster, prevent delays, and speed up clinical trial milestones. The reviews and approvals of site regulatory documents, site feasibility/qualification reports, EC/IRB approval letters, and site activation forms can be easily carried out through proper processes / workflows in eTMF. Thus, one can easily accelerate start-up activities and optimize clinical trial timelines with the proper workflows in eTMF.

Reduce Clinical Trial Operational Complexities

As the clinical trial process becomes more complex, it's imperative that the appropriate documents get to the necessary people in order for the process to move forward smoothly. Think about the process where the sponsor's medical monitor needs to approve patients' eligibility for randomization. This process can be easily set up in eTMF where patients' relevant medical records can be shared by a site so that the sponsor's medical monitor can more easily review and approve the appropriate patients for randomization. Instead of going for traditional medical monitoring communication, this kind of work-flow in eTMF can reduce the operational complexities and speed up the trial process. Another example of where an eTMF could streamline operations includes sharing lab reports with relevant stake holders for the assessment of adverse event or serious adverse events (SAEs) further to make timely decisions related to patient safety.

Increased Compliance, Better Transparency With Role-Based Ownership Model

Using eTMF, stakeholders are better able to take responsibility for documents to ensure those documents are in the system and updated for audits & inspection readiness. In doing so, they are better able to increase the quality of the clinical trial process. The specific role-based access will also increase authorized knowledge sharing which boosts transparency of the status of the clinical trial. Email escalation provisions related to the availability of certain documents enable relevant stake holders to facilitate issue resolution and improve the efficiency of clinical trial operations.

At the same time, to leverage eTMF or make it a clinical trial enabler, those managing eTMF should be properly trained so they are fully aware of their roles and responsibilities. One of the approaches is to have dedicated resources from sponsor or vendor who will look into eTMF efficient management and ensure the relevant documents are in place and updated on a timely basis so the study team can focus on core clinical trial activities.

eTMF has great potential to be a central system of the various eclinical systems being employed in clinical trials and can reflect the heath of clinical trial process. If eTMF is used effectively, it can — and will — facilitate overall clinical trial process.

About author:

Ashok Ghone, Ph.D. is Vice-President, global services at MakroCare USA. He has upwards of 20 years of experience in the pharmaceutical and clinical research industry. Ashok has good knowledge and understanding of global clinical research with hands-on experience in clinical operations, project management, clinical trial management, process development, document management, site management, and patient recruitment activities. He has led various cross-functional teams successfully by providing strategic direction and guidance for the accomplishment of local, regional, and global projects involving early and late phase clinical studies in various therapeutic areas. Ashok has been involved in the development of process, system, and training related to risk-based monitoring and centralized monitoring at MakroCare, which offers these specialized services to biopharmaceutical and medical device companies to support their endeavors in implementation of the RBM, Centralized Monitoring approach.

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