Implementing a cost effective and interoperable e-TMF system

TRIAL MASTER FILES
EUROPE 2016

Trial Master Files - eTMf Case Study

The transition from paper to electronic Trial Master File (TMF) system, is a significant task, which is further complicated with the varying views and opinions complicating the route to standardisation. This is partially solved by the new directives under construction alongside the EMA's updated information providing giving insight into inspector's reviewing behaviours and what has been examined as of late for eTMFs. These much needed points of clarification help inform pharma and biotech companies on how to best create and maintain an eTMF system.

Mapping And Tracking Your Route to an eTMF

It requires a considerable amount of effort and money to implement an eTMF system. This coupled with the multiple complications with implementation, inevitably means that solid aims, goals and objectives are vital for success.

Examples of key objectives, which support the existence of an eTMF as well as guiding optimal maintenance, include:

•Maintaining TMF transparency: In the face of different studies featuring a range of compounds which will cause TMFs to vary from case to case sponsors and CROs should aim to maintain a standardised level of TMF knowledge and transparency throughout each and every study.

Process implementation and adaptability. Finding the right process for your company and utilising this method to the best of its ability using an outsourced system. Third party eTMF systems may cause this to become prominent and will demand the adaptation and introduction of new processes where required.
It's important to ensure that the team is willing to adapt to the new process for the eTMF, which might not occur naturally. Training is going to be a likely necessity for a handful of people within the business.

•Maintaining TMF inspection readiness at all times: Complying to relevant regulatory guidelines – including the ICH GCP. View our infographic on being inspection ready here:

•Increasing productivity, and effectivity to processes
Depending on the filing structure, the transference to an eTMF can be straightforward. Although, if amends are made to the filing structure in parallel to the transference to an eTMF, a lot of confusion can be encountered as this creates a huge migration project.

Key management metrics: This is useful for the maintenance of an eTMF system and can be more involved than with paper format. With paper it is fairly straightforward – a person could pull out the binders, review timelines and apply their knowledge to define a status with a TMF.

The measurement of TMF's quality is vital, using either QC or QA measures. To do this for any eTMF programme one needs the right tools and processes to monitor progress, quality and archiving procedures. Close internal collaboration will be required to devise the certain stages for this.

Increasing and maintaining a high level of eTMF quality throughout all studies.

Implementation Hurdles

One of the downfalls to the implementation of an eTMF is the expense required. In comparison to a paper TMF, it costs considerably more to implement an eTMF study, especially with a debut eTMF study. There are various updated directives focusing tightly on eTMF, like the ICH GCP addendum. As part of the implementation process consultants may be required to review and realign internal processes to ensure everything is compliant and effective, which will require funding.

In regards to key considerations for implementing a cost effective eTMF system, knowledge and experience internally and externally are crucial. Internally, professionals need to review the proposals for eTMF systems and ensure they are suitable for the company.

Externally, an apt partner needs to provide a service in both electronic capabilities as well as in knowledge. So when tasks arise such as updating documents the sponsor is aware of the vendor's previous experience can they can lend, for example providing suggestions for filing structures, TMF plans and archiving.

Another, consideration is training and ensuring that everyone knows the filing structure and is comfortable with working with a system that is going to require a lot of financial investment, rather than having the TMF confined to a group of super-users.

Managing Interoperability

When collaborating with a partner on an eTMF system, interoperability should stand as part of the agreement in discussion phases, the sponsor's expectations at this stage need to be outlined clearly. It's important to have a clear filing plan, ensure the structure

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It's often lost in translation that a sponsor is in charge of a TMF. When a CRO is contracted for a study, the CRO maintains the study, yes, but they are not responsible for the maintenance, upkeep and the overall inspection readiness of the TMF.

It's quite easy to maintain a study, but it's a different story maintaining the TMF as a whole. Although, people see it as just a filing method, a place to archive documentation, when actually that really isn't the case - it's a storyteller. It's designed to tell the story to an auditor / investigator how [the study] is structured and how a certain stage is reached in the study.

Consequences of eTMF failure

Whether it is paper or electronic, it's vital that a TMF has apt monitoring measures from a project point of view and a company compliance perspective.

If an inspector realises there are inconsistencies between the study's specifications, company policies, ICH GCP and regulatory guidelines, they could class this as a critical finding. This is a big concern and is something that could easily creep in where an idea is deployed internally that almost deviates from an SOP or a working document. In this case an inspector could assert that you are deviating from company processes.

If it's a critical finding it could result in a financial penalty, or worse, the termination of a study - something obviously no company wants. So it's important that consistencies are maintained throughout everyone's work relating to a TMF.

TRIAL MASTER FILES EUROPE 2016

13th - 15th September
Barcelona

Ensuring TMF completeness and inspection readiness in both a paper and electronic system has proven to be a difficult undertaking – especially given the number of complexities that can increase non-compliance!

Standardization efforts being well adopted by industry have certainly aided TMF management and compliance, however a number of challenges still exist.

In September 2016, join us in Barcelona to address the biggest challenges hindering the successful development and management of TMFs.

This interactive, case study-driven event features TMF industry experts from the Pharma industry and regulatory landscape. The inspiring speaker panel will share real examples of TMF development and management, the challenges encountered and how they were overcome.

Join 70+ industry experts from across Europe and exploit the opportunity to build upon your peers successes and more effectively develop and manage your TMF.

Reasons to Attend

- **INTERACTIVE CASE STUDY:** Safeguarding TMF Interoperability
  - Explore the challenges that incompatible TMFs can create
  - Offer strategies to mitigate the impact on trial running efficiency
  - Identifying key requirements of an eTMF to meet needs and ensure functionality
  - Reviewing training necessary to ensure effective system usage

- **INTERACTIVE PANEL DISCUSSION:** Optimizing Performance and Quality Metrics to Improve TMF Processes

- **Live Debate! CRO vs Sponsor Managed TMF.** Hear a CRO representative and a pharma TMF leader debate their unique benefits, and stir the pot with your own questions and points!

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