Electronic Trial Master File (TMF)

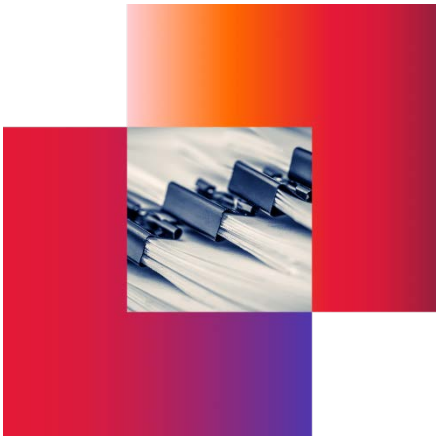
Successfully managing your TMF is vital to ensure the success of your organization. Having a complete TMF supports business development activity (acquisitions and divestitures) in a more efficient manner. Additionally, newer technologies can actually improve operations by shifting the TMF from an archive to a supporting solution that is integrated into study start-up, drug shipment and other clinical processes. On the flip side, not having a complete and accurate TMF can result in observations (e.g., FDA 483), warning letters, delayed approvals and fines.

Evolution of trial master file management

Over the years, we have seen the management of Trial Master Files evolve on several fronts:

- System of record – shifting from paper to an electronic content management system
- Operating model – more active use of TMF content by stakeholders
- Content structure – use of the TMF Reference Model as a base line content structure
- Process – more active use of the TMF content within business processes (both as an input and output

These shifts have come with many benefits to sponsors, but they all require a systematic approach to implementing.



Why CGI?

Choosing a partner to help improve your trial master file management is important in order to successfully improve your outcomes. CGI is the correct partner for four simple reasons:

- We have managed and lead TMF projects for 5 of the top 10 global pharmaceutical companies, including eTMF systems implementations, process optimization and data migrations.
- Our team has extensive expertise around Trial Master Files
- Several are members of the TMF Reference Model (including Steering Committee)
- Diverse backgrounds including: Sponsor clinical, CRO clinical, and IT/system experience deploying/supporting TMFs
- We partner with all the top eTMF vendors, so we can help you determine which solution is best for your unique situation.

Challenges

In many organizations, the complexities in TMF management present significant compliance risks, including such scenarios as:

- TMF records, paper and electronic, filed in disparate repositories, resulting in significant challenges to ensure TMF completeness and allow direct access for inspection
- Gaps in TMF management oversight, especially when delegating trial responsibilities to CROs/partners
- Artificial TMFs content boundaries, resulting in inspection findings for record gaps
- Significant downstream efforts to prepare for audits and inspections
- TMFs are often scanned to support portability, resulting in a need to define the original record and reconcile copies
- Lack of integration with corporate taxonomies and metadata standards
- Manual effort for records management, retention and litigation holds

CGI's approach to improving TMF management

Strategy definition

- Identify why change is needed
- Identify objectives and critical success factors

Current states definition

- Analyze current state against strategy
- Document and visualize current state

Gap identification

- Determine what needs to be changed
- Conduct impact assessment and action plan

Future state planning

- Identify how to implement changes
- Complete risk assessment and contingency plan

Future state realization

- Ensure implementation of changes
- Iterate – monitor, evaluate, and optimize

About CGI

Insights you can act on

Founded in 1976, CGI is among the largest IT and business consulting services firms in the world.

We are insights-driven and outcomes-based to help accelerate returns on your investments. Across hundreds of locations worldwide, we provide comprehensive, scalable and sustainable IT and business consulting services that are informed globally and delivered locally.

For more information

Visit cgi.com
Email us at info@cgi.com