



ELECTRONIC TRIAL MASTER FILE

Why Do You Need to Effectively Manage Your 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 baseline content structure
- **Process** - more active use of the TMF content within business processes (both as an input and output)

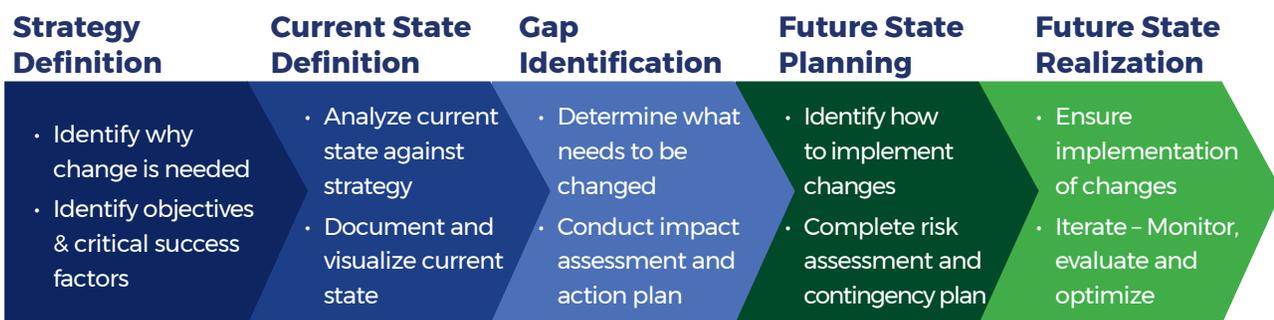
These shifts have come with many benefits to Sponsors but they all require a systematic approach to implementing.

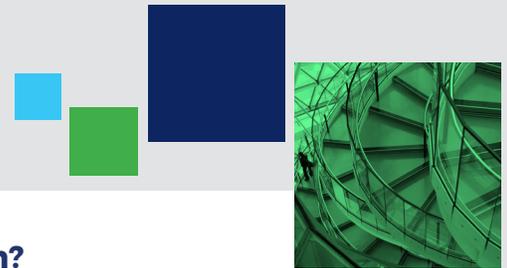
What Challenges are there Around Managing a TMF?

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

Paragon’s Approach to Improving TMF Management





What Challenges are there Around Managing a TMF?

We understand that any change to how you manage your TMF can be a daunting process. We focus our efforts on the following topics with our clients:

Visioning - what do you want TMF management to look like at your organization?

- Is the status quo sufficient or do we need to change?

Process and Operating Model - how do we manage the TMF?

- Who is responsible for creating, loading, reviewing content?
- Do you want to outsource TMF management to a third party?
- How do we perform oversight of processes and content?

Technology

- Do you want to implement an eTMF system?
- How do you know which eTMF is right for you?
- How do you implement the eTMF?
- Is vendor standard configuration satisfactory?
- Which systems do we need to integrate with?
- What do we do with legacy content/information?

People

- How do we increase adoption of the solution?
- How do we make sure that people are trained to use the tool?

Why Paragon?

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

- Paragon has worked with more Sponsors than any other firm around trial master file management.
- 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



About Paragon Solutions

Paragon is a consulting firm that helps health and life sciences companies become high-performing, compliant, and digitally connected. Paragon powers business transformation and delivers better business outcomes by providing valuable consulting services as a trusted partner to our clients. We do this by building long-term client relationships based on our domain expertise, creative ideas, pragmatic consulting services, and quality delivery of solutions.

For more information, visit us online at www.consultparagon.com, or call 1.800.462.5582.

Paragon Client Roster

Our client roster includes life science industry leaders such as:

- **AbbVie**
- **AstraZeneca**
- **Bausch & Lomb**
- **Bayer**
- **Bristol-Myers Squibb**
- **Celgene**
- **CSL Behring**
- **Daiichi-Sankyo**
- **GSK**
- **Lilly**
- **MedImmune**
- **Merck**
- **Novo Nordisk**
- **Otsuka**
- **Roche**
- **Shire**
- **Chiltern**
- **inVentiv Health**
- **Worldwide Clinical Trials**
- **Regeneron**