cencora

TMF quality review

Identify and mitigate risk

Improve inspection readiness with expert insight into your Trial Master File (TMF)

The TMF has become a critical tool to document whether clinical trials are conducted according to Good Clinical Practice (GCP), allowing inspectors to easily identify problematic areas around essential documents and quality processes. Cencora's TMF quality review (also known as a file review) helps your TMF meet GCP standards. Gain more confidence in the inspection readiness of your TMF by quickly identifying problem areas and providing actionable insight to guide any necessary remediation.

Independent of the eTMF software you are currently using, this in-depth review is conducted by our expert TMF practitioners with experience performing hundreds of quality reviews and a deep understanding of current inspection standards.

Detailed heatmaps are just one of the advanced tools utilized by our experts to help assess the quality of your TMF and identify areas requiring further review and remediation.

Relevant sections or artifacts	# filed	Observation/recommendation	Level
01.01.02 Trial management plan	2	KTM transition plan: No Issues End of study plan: Filed under endpoint management plan, which is incorrect. Milestones and timeline are not present	
01.01.03 Quality plan	1	Noted as "not applicable" but one document is filed	
01.01.04 List of SOPs current during trial	4	Only DM SOP listings (V1-V3) are present; other functions are missing	
01.01.05 Operational procedure manual	0	Artifact is expected and empty	
01.01.06 Recruitment plan	0	This is an extension study so patients will be rolling over from a previous study. Recruitment is not necessary (per roadmap)	
01.01.08 Monitoring plan	5	V1 and V2 present; woudl prefer to have version number in the file name of V2.0	
01.01.09 Medical monitoring plan	3	V1.0, V2.0, and V2.1 present; would prefer to have version number in the file name of V2.0	
01.01.14 Audit certificate	0	NA for IQVIA eTMF	

Reduce time, cost, and risk of M&A activity

Pharmaceutical companies conducting merger, acquisition, and product licensing activities often discover too late that the product's Trial Master File is not compliant, causing submission delays and significant remediation cost and effort.

As a result, many organizations–including 5 of the top 10 global pharmaceutical companies–have made our TMF quality review a key component of their due diligence for strategic activities. These organizations gain valuable transparency into potential TMF risks, helping them avoid unnecessary delays and costs.

Key benefits of Cencora's TMF quality review

- Line-by-line evaluation of the TMF, providing detailed insight into quality, completeness, and timeliness
- Comprehensive analysis of individual studies and trends across studies
- Application of innovative, purpose-built tools such as TMF heatmaps
- Risk-based assessments to quickly pinpoint and drill down to problem areas
- Logic checks and cross-checks to validate document quality and whether documents relate to each other properly
- Detailed, expert recommendations for necessary remediation
- Flexibility to be used with any eTMF system

Ready to discover more? Visit us here