

Best practice: Ensuring a Quality Trial Master File

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Introduction to TMF

- It is the most important trial deliverable
- It is comprised of essential documents
- It provides an organized and accessible repository of documents

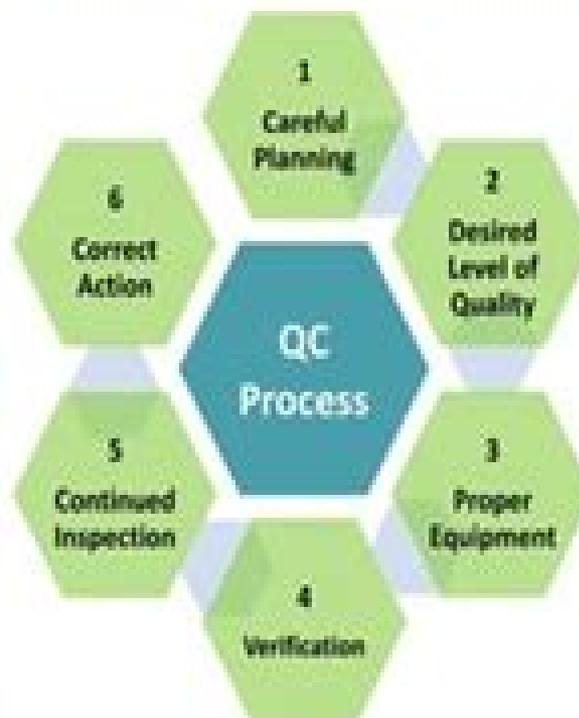
Challenges

- Stricter regulations and standardization
- Emergence of the electronic TMF (eTMF)
 - Navigating transition from paper and/or migration between eTMF solutions
- Outsourcing to CRO(s) with multiple users
 - Concerns of non-compliance and increased cost of training

Quality Control is NOT

- A simple inventory of what is present
- Addressing problems as they arise
- A moving target depending on the circumstances
- A static process that needs no re-evaluation

Six Elements of the QC process



Quality Control IS

- A systematic process
- Addresses what is expected
- Requires planning
- Relies upon predetermined benchmarks
- Requires the proper organization and tools
- Requires verification, evaluation, and continued inspection

Summary

Performing a true TMF QC review based on what types of documents you expect to see in the TMF, not just on an inventory list of what's present will ensure that your TMF is complete, accurate, and inspection ready at all times.

With careful planning, an agreed level of quality, proper equipment, verification, continued inspection, and corrective action, you can be assured your TMF is of high quality.

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