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Checklist: Will Your Trial Master File Pass The Test?

Your Trial Master File (TMF) tells the story of your entire clinical study, often years in the making. This comprehensive body of documents is what the FDA will review to evaluate your performance in running a well-controlled clinical study that resulted in protected patients and data that has integrity. Sponsors should follow this checklist to ensure their TMF passes the test.

Essential Records Every TMF Should Contain

Organization and Personnel

- ☐ Roles and responsibilities of departments and key individuals involved
- ☐ Agreements with and responsibilities of outside vendors
- ☐ Criteria for selecting monitors, job descriptions and qualification documents

Selection and Monitoring of Clinical Investigators

- ☐ Agreements with all investigators
- ☐ Qualification documents for investigators and delegated site staff
- ☐ Evidence of study information being provided to investigators prior to his/her study involvement
- ☐ Handling of deviations and how compliance was secured

Monitoring Procedures and Activities

- ☐ Monitoring procedures
- ☐ All monitoring activities, including pre-trial and periodic monitoring reports
- ☐ Evidence showing the monitoring of site and subject records
- ☐ Documentation of how site issues were addressed

Safety and Adverse Events Reporting

- ☐ Correspondence with FDA regarding adverse events
- ☐ Procedures for the receipt, evaluation, and monitoring of safety information
- ☐ Documentation of adverse events experienced in the study
- ☐ Evidence that important new information was shared with investigators and IRBs if/when needed

Data Collection and Handling

- ☐ How data was generated by investigators
- ☐ The number of study subjects (consistent with the number reported to the FDA?)
- ☐ Why certain subjects were not included in the analysis
- ☐ Procedures for handling data

Additional Questions

- ☐ Are records maintained according to retention requirements?
- ☐ Are there adequate records of financial disclosure information?
- ☐ Are electronic records and signatures compliant with 21 CFR 11?
- ☐ Are/were test articles being stored appropriately?
- ☐ Are/were they shipped securely and labeled properly?
- ☐ Are test article records sufficient for complete accountability during the study?
- ☐ If applicable, was the study registered appropriately on clinicaltrials.gov?

Don't Wait For The FDA To Point Out Errors!

An independent audit of your TMF will assess your study's records to identify process issues, gaps in documentation and any compliance concerns. By identifying weaknesses in documentation that can be addressed prior to an FDA Inspection, an independent audit can help position your study team for a more favorable outcome on "test day."

IMARC, a medical device CRO, has nearly two decades of experience conducting Trial Master File audits and can even do them remotely to save your staff time and money.

Learn more about the benefits of a Trial Master File audit.