Improving Audit Effectiveness through Comprehensive Reviews

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BACKGROUND

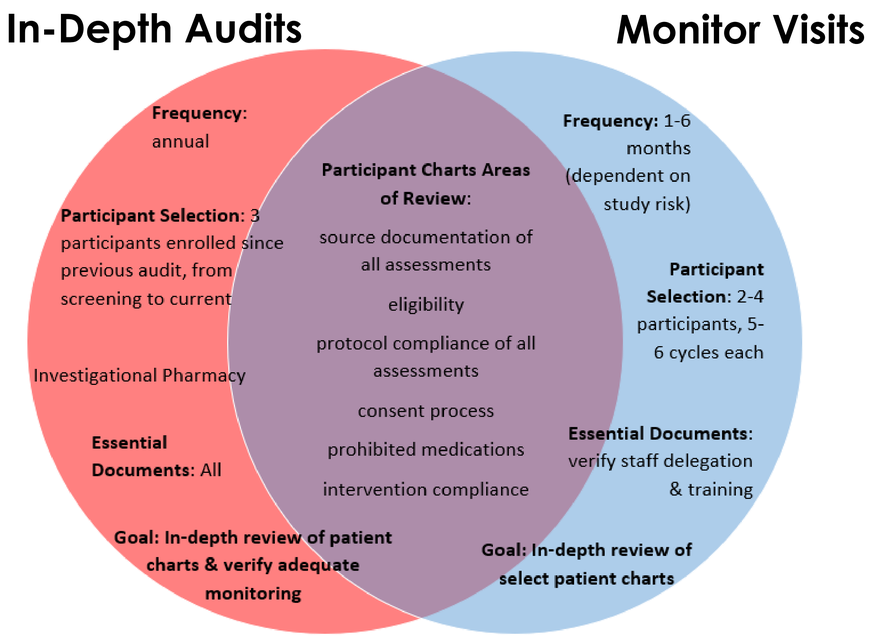
- High enrolling, high-risk clinical trials with long-term follow-up accrue large amounts of data. Compliance teams do not have the resources to complete 100% source data verification.
- Routine, in-depth reviews are productive in catching deviations in real time but may miss study-wide patterns of recurring noncompliance.
- In order to verify effective monitoring, in- depth audits include reviews of previously monitored charts, potentially wasting time and resources.
- At study close out, wide spread data collection and protocol compliance discrepancies are sometimes identified. Some issues can be resolved with significant coordinator efforts and other require amending study endpoints.

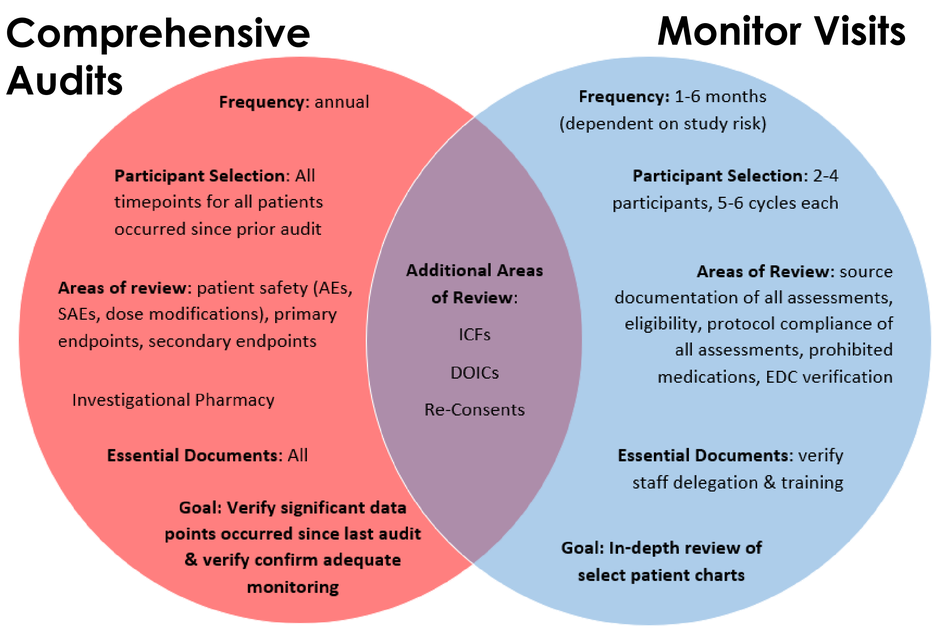
GOALS

- Review and validate all safety, primary, and secondary endpoints occurred since prior audit.
- Identify patterns of recurring noncompliance sooner.
- Identify significant deviations of safety, primary, and secondary endpoints
- Identify gaps in monitor reviews.

SOLUTIONS AND METHODS

- The comprehensive audit is tailored to the trial characteristics (safety risk, endpoints, etc.) and current compliance needs.
- The auditor reviews the targeted data points for every patient using data exports from the electronic data capture system.
- Findings are discussed with the study team. A corrective and preventive plan is required for major findings.
- Recurring findings are discussed with the site monitor to ensure future reviews are consistent and informed.





OUTCOMES

- Recurring patterns of protocol noncompliance and data errors across multiple participants were identified early on.
- More significant endpoint and safety deviations were identified.
- Opportunity to recognize teams exhibiting patterns of strong protocol compliance and documentation.
- These patterns facilitated in identifying training needs, confusion in CRFs, and gaps between investigators' intention and actual data collected.

LESSONS LEARNED AND FUTURE DIRECTIONS

- An annual review of all patients helps identify recurring data discrepancies earlier allowing room for improvement
- Comprehensive review allows for a more effective audit of the most significant data while also verifying monitoring reviews
- Compare % of validated CRFs & # of deviations from before & after implementing comprehensive reviews
- Use audit results to drive data audit reviews

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