Improving Audit Effectiveness through Comprehensive Reviews

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BACKGROUND

- High enrolling, high-risk clinical trials with long-term followup 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.

In-Depth Audits **Monitor Visits** Frequency: Frequency: 1-6 annual months **Participant Charts Areas** (dependent on of Review: study risk) Participant Selection: 3 source documentation of participants enrolled since all assessments **Participant** previous audit, from Selection: 2-4 screening to current eligibility participants, 5protocol compliance of all 6 cycles each Investigational Pharmacy assessments consent process **Essential Documents:** Essential prohibited medications verify staff delegation Documents: All & training intervention compliance Goal: In-depth review of patient Goal: In-depth review of charts & verify adequate select patient charts monitoring

Comprehensive **Audits**

Frequency: annual

Additional Areas

of Review:

ICFs

DOICs

Re-Consents

Participant Selection: All timepoints for all patients occurred since prior audit

Areas of review: patient safety (AEs, SAEs, dose modifications), primary endpoints, secondary endpoints

Investigational Pharmacy

Essential Documents: All

Goal: Verify significant data points occurred since last audit & verify confirm adequate monitoring

Frequency: 1-6 months (dependent on study risk)

> Participant Selection: 2-4 participants, 5-6 cycles each

Areas of Review: source documentation of all assessments, eligibility, protocol compliance of all assessments, prohibited medications, EDC verification

Monitor Visits

Essential Documents: verify staff delegation & training

Goal: In-depth review of select patient charts

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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