



BACKGROUND

Since most cooperative group audits occur years apart, implementing a routine monitoring process for cooperative group studies is essential to ensure strict adherence to cooperative group policies, internal standard operating procedures (SOP), as well as research guidelines aligned with good clinical practices (GCP), and FDA regulations for cooperative group studies. Identifying and addressing major findings prior to cooperative group audits through routine QA reviews can reduce the number of data delinquencies and major findings during an audit.

GOALS

Our aim was to revamp our routine monitoring process to allow for a consistent, standardized risk-based approach to cooperative group study monitoring.

SOLUTIONS & METHODS

We have implemented a revamped monitoring plan that allows for a more strategic, risk-based, approach to the monitoring of cooperative group studies.

- Studies are selected for review based on risk (enrollment, complexity, turnover, etc.)
- Set an expected number of studies to be reviewed on monthly basis.
- A Cooperative Group QA Review Checklist was created to guide and ensure standardization across QA reviews.
- At the conclusion of these reviews, observations and reports highlighting key findings are shared with study team members.
- Reinforced an expectations that study teams have 30 days to address major findings discovered during routine QA reviews.

OUTCOMES

The benefits of these cooperative group quality reviews include enhanced data quality, reduced audit findings, improved study team confidence, and ultimately better protection of research safety and study integrity.

LESSONS LEARNED & FUTURE DIRECTIONS

- Routine audit preparation and QA reviews enable teams to maintain a constant stat of audit readiness. This proactive approach embeds compliance into daily operations, allowing teams to identify and address potential issues before they become major findings.
- Regular dissemination and discussion of findings provides study teams with the valuable learning tools and allows them to understand common pitfalls and develop best practices. This level of transparency validates the integrity of research and allows study teams to identify improvement opportunities early.
- These cooperative group reviews highlight, strengths, identify improvement opportunities and recommend specific corrective actions if needed.