Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Quarterly Quality Assurance Reviews to Help Reduce Major Findings for IND-Exempt Investigator-Initiated Trials

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1. Background
Naturally, investigator-initiated trials (IITs) that are under a Food and Drug Administration (FDA) Investigational New Drug (IND) take priority for routine Quality Assurance (QA) team monitoring. It is critical to have a routine and standardized process for IND-exempt IITs to ensure strict adherence internal standard operating procedures (SOP), good clinical practices (CGP), FDA regulations, and external regulatory agencies.

2. Goals
The aim is to revamp our current monitoring plans for IIT-IND exempt studies to create a consistent approach for monitoring that standardizes the monitoring of regulatory compliance, source data verification and the reporting of key findings.

3. Solutions and Methods
To ensure regulatory and protocol compliance remain consistent and accurate, we have implemented a consistent quarterly QA review process. This includes the following steps:

- Scheduling quarterly QA reviews by sending calendar invitations to QA personnel and the Research Coordinator (RC) to confirm the date and time.
- Emailing all observations, both minor and major, to the RC to maintain open communication between QA and the research team.
- Distributing the official QA Review Report and observations to the Sponsor Investigator (SI), RC, and applicable management for both clinical and data/regulatory teams. This increases awareness and accountability to any findings.
- If major observations are identified, the research team is immediately notified by email and given a 30-day deadline to complete the necessary corrective actions. This structured quarterly review process provides a routine monitoring approach with a clearly outlined communication plan to disseminate and resolve any findings.

4. Outcomes
Since the routine QA review rotations of IND-exempt IITs were implemented, major findings are being observed less frequently. Additionally, the ongoing review process has fostered a trusting and lasting relationship between the QA and research teams. This collaboration helps ensure the highest standard of safety and compliance are maintained for all clinical trials.

5. Lessons Learned and Future Directions
Implementation of quarterly QA reviews has set clear expectations and has held the study teams accountable for ensuring that their studies are up to date with regulatory documentation and data management. Looking ahead, the QA department will continue to review IND-exempt IITs on a quarterly basis. This will help confirm these studies remain compliant and up to date with all relevant regulatory and patient safety requirements.