Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Targeted Review of Standard Operating Procedures for Enhanced Efficiency and Compliance

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1. Background
Reviewing standard operating procedures (SOPs) for compliance and accuracy is crucial to ensure that an organization's operations remain efficient, effective, and aligned with current industry standards, regulations, and best practices. Over time, processes and technologies evolve, and what was once an effective procedure may no longer meet the desired outcomes or adapt to new challenges. Regularly reviewing SOPs and monitoring SOP compliance allows identification of inefficiencies, gaps, training needs, or outdated practices.

2. Goals
- Confirm that SOPS are being followed
- Ensure that SOPs contain current/accurate information

3. Solutions and Methods
- Five high-risk SOPs are reviewed per month, and five research subjects are reviewed per SOP.
- The following SOPs are reviewed:
  - Consenting, Deviations, severe adverse events (SAE)/adverse events (AEs), Documentation, Database/Data Entry
- The language in each SOP is used as a checklist for compliance - elements of the SOP are either followed as written or not followed. Any instance of a SOP not being followed is considered out of compliance.
- Findings are shared at the monthly quality assurance and compliance meetings and communicated to supervisors for correction/re-education with their teams.
- SOPs are updated as applicable if barriers to compliance are identified.
- Larger re-educations are held if consistent themes are identified.

4. Outcomes
Since monitoring SOP compliance was implemented, a dramatic overall increase in compliance has been observed. The overall number of findings decreased from 2022 to 2024, including one compliance metric that decreased from 48 percent to 5 percent due to increased awareness and implementing trainings and accountability.

5. Lessons Learned and Future Directions
Reviewing SOPs for compliance and accuracy fosters continuous improvement, enabling our organization to maintain consistency, and ensure that employees are equipped with the most up-to-date guidance to perform their tasks efficiently and safely. This process also supports better training, easier onboarding for new staff, and overall organizational agility in responding to changing conditions.