

Championing Project Management and Leadership When Identifying a Gap in Clinical Research

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1. Background

The randomization, blinding, and unblinding processes in clinical trials are essential cornerstones in clinical trial methodology, ensuring unbiased participant allocation to treatment groups and the eventual disclosure of study results. Standard Operating Procedures (SOPs) are indispensable tools for maintaining consistency and quality in such processes. However, the absence of a defined SOP for randomization, blinding, and unblinding poses significant risks to participants' welfare, trial integrity and regulatory compliance. This case study delves into how Memorial Sloan Kettering Cancer Center's (MSK's) Clinical Research Quality Assurance (CRQA) team identified the absence of a randomization, blinding, and unblinding guidelines, and proactively addressed this gap.

2. Goals

The principal aim of this project was to provide guidance, tools, and templates to all study personnel involved in the development and implementation of the randomization, blinding, and unblinding process, to ensure consistency, regulatory adherence, and protect the health and welfare of participants. Moreover, the project sought to exemplify effective project management and leadership in navigating cross-functional collaboration and overcoming inherent challenges in SOP development.

3. Solutions and Methods

The CRQA team initiated the project by conducting an exhaustive assessment of existing processes and documentation concerning randomization, blinding, and unblinding processes. Through stakeholder engagement and cross-functional collaboration with pertinent departments such as Clinical Research Operations, Regulatory Affairs, Institutional Review Board (IRB), Pharmacy, Nursing, Biostatistics, etc., the team pinpointed essential requirements and best practices for randomization, blinding, and unblinding processes. Leveraging project management methods and regular communication channels, the team facilitated meeting sessions, drafted the SOP, solicited feedback, and iteratively refined the document.

4. Outcomes

The collaborative endeavors of the CRQA team culminated in the expedited and successful development and implementation of a robust SOP for randomization, blinding, and unblinding processes. Moreover, the institutional protocol template was updated to incorporate instructions and place holders to describe randomization, as required by the new clinical research SOP. By assuming the leadership role and effectively managing the project, the CRQA team ensured that all stakeholders were engaged, and their expertise was harnessed throughout the process. The new SOP not only rectified the identified gap but also elevated overall quality assurance practices within the organization. Furthermore, the project served as a testament to the significance of proactive problem solving, effective communication, and strong leadership in propelling continuous improvement initiatives in a clinical research program.

5. Lessons Learned and Future Directions

This case study underscores the pivotal role of project management and leadership in addressing critical gaps in protocol management processes within clinical trial operations. By spearheading cross-functional collaboration and steering the development of vital SOPs, quality assurance (QA) teams can uphold the

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highest standards of quality, integrity, and compliance in clinical research programs. Through proactive identification and resolution of deficiencies, organizations can fortify their processes, ensuring the reliability and validity of trial outcomes while adhering to regulatory standards. As exemplified in this case, effective project management and leadership are indispensable in navigating complex challenges and driving transformative change in clinical research programs.