

Managing Clinical Trials in India: Project Leadership

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Abstract:

The increasing number of clinical trials being conducted in India provides a unique opportunity to examine current clinical research practices in order to harness the advantages of the country in meeting the challenges of the pharmaceutical industry. In this article, we discuss how the role of project management in a clinical research organization can be broadened to that of project leadership to be able to look at the project as a whole and manage the relationship between the project team and other key stakeholders, such as regulators, sponsors and investigators, effectively.

It is crucial that the project leader understands the requirements of the Indian regulatory authorities as well as the authorities of other countries where the trial data will be submitted, and is able to ensure the conduct of the trial accordingly. The ability to improve site selection by conducting accurate site feasibility results in accelerating the study conduct and hence reducing costs. Furthermore, improving patient recruitment and retention in the study, and involving experienced investigators while not missing out potential investigators with access to a large pool of patients, improves the efficiency and quality of the study. Enhancing the capacity of investigators by building a clinical investigator management programme can help in developing investigators, which is crucial to the study. In order to comply with international agreements on data protection, understanding and maintaining data confidentiality as it flows through the various departments involved in processing these data are vital. Effective coordination among all in-house teams to deliver high-quality study data is the key in meeting the confidence of sponsors, regulators and investigators in the results of the study. Finally, project leadership should also be involved in liaising between the sponsor and investigators to ensure data integrity in publications. Thus, the scope of project leadership in India should be enhanced to encompass all of these responsibilities and thus play a comprehensive role in the clinical development programme.

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