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Posted by James Moat on Wed, Oct 23, 2019

6 QUALITIES OF AN EXCEPTIONAL CLINICAL TRIAL PROJECT MANAGER

Business presentation on laptop computer

Running a clinical trial for a new medical device can be challenging. With so many moving pieces, it can be a struggle to make sure the study is on schedule, the data are of high quality, and patient safety is maintained, while everything is done within budget.

The right clinical trial project manager can be the key factor in a trial that is completed on time and on budget — and one that ultimately earns approval.

Here are the top qualities to look for in a clinical trial project manager.

Hiring A Clinical Trial Project Manager? Look For These 6 Qualities

1. Excellent Communicator

Because of the constantly shifting nature of a medical device trial, a project manager will need to communicate and present information on an ongoing basis. He or she will need to lead meetings with various groups, provide reports and metrics to vendors and team members as the trial continues, and train staff as new research sites are brought on.

The ability to communicate clearly with sponsors, practitioners and new team members is critical, especially if you're working on a global medical device trial, which may also require the project manager to coordinate translations and work across multiple time zones.

2. Strong Leader

A clinical trial project manager will be responsible for keeping the entire team motivated, no matter how long the trial lasts and no matter what happens during the study. They will need to inspire stakeholders at all levels, including those who have been with the trial since day one and those who are just joining the team today. The key is to set the vision for a successful trial and equip and encourage the study team to do their best work.

3. Detail Oriented

While seeing the big picture is important, your clinical trial project manager needs to be able to dig into the details and take appropriate action. A site might be struggling to enroll study subjects, and a strong project manager will work with the staff to understand why. Root causes of excessive protocol deviations might need to be analyzed. The project manager needs to assess who needs to know what and potentially identify conflicting information.

4. Proactive

Clinical trial plans guide a study and ensure it stays focused on the main goal. But there are often unexpected hurdles, and it's a project manager's job to resolve them. An experienced project manager will be able to anticipate potential risks that stand in the way of achieving FDA approval and take steps to mitigate them.

5. Collaborative

A skilled clinical trial project manager understands research is a team effort. They will actively engage all necessary stakeholders and discuss updates as needed. They'll also guide their team through any changes that need to occur to correct course or account for unforeseen risks.

6. Compliance-Minded

The ultimate goal of your clinical trial is to secure regulatory approval, so your clinical trial project manager needs to be knowledgeable about all applicable requirements.

That includes understanding Good Clinical Practice (GCP), being able to apply FDA regulations governing medical device trials and also understanding global regulations such as the new MDR requirement.

Hiring the right clinical trial project manager is crucial to keeping your study on track.

If you're planning to hire someone soon, this project manager checklist will help guide your selection process and ask the right questions during interviews.

Not able to bring a full-time project manager on board? IMARC's project management services can help train project managers, provide on-site assistance or manage your entire trial for you.

Learn more about how our team works with yours.

Topics: clinical trial project management

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