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CHOOSING A SKILLED

CLINICAL RESEARCH PROJECT MANAGER

STRONG COMMUNICATION SKILLS

Your project manager is the primary point of contact for your trial and must manage interaction between all parties. He or she must be able to clearly and assertively communicate what needs to be done, help team members prioritize tasks and hold them accountable.

QUESTIONS TO ASK:

- Describe a time when you had to work with multiple parties to accomplish an important task.
- What is your preferred method of communication? (This should vary depending on the situation.)

EFFECTIVE LEADERSHIP

A project manager should be more than just a task-master. He or she should have enough experience in the field to be respected by other team members, have the ability to keep team members motivated and hold them accountable.

QUESTIONS TO ASK:

- How would your colleagues and direct reports describe you?
- What would they say is your greatest weakness as a leader?
- A team member has consistently missed several deadlines, which is delaying progress for everyone. What would you do to get him or her back on track?

DETAIL-ORIENTATION

A project manager must be able to sort through large volumes of data efficiently and with an eye for errors or inconsistencies. Previous experience in clinical research monitoring or specific training in this area is a valuable asset.

QUESTIONS TO ASK:

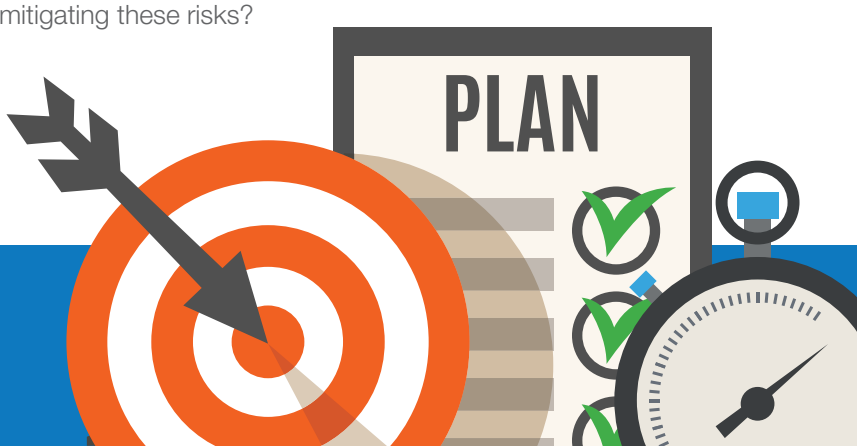
- Tell us about your previous experience with clinical trials.
- What experience do you have with FDA/ICH regulations?
- What experience do you have with ISO/ICH guidelines?

A PROACTIVE APPROACH

A strong project manager will take ownership of your study, be able to anticipate the next steps and make recommendations for process improvements. He or she will have a good sense of the potential safety and compliance risks and be able to recommend steps for mitigating them.

QUESTIONS TO ASK:

- How would you improve our existing process?
- What are the most common risks you foresee with a study like ours?
- What are your recommendations for mitigating these risks?



A COLLABORATIVE PROCESS

The best project managers know clinical research is a team effort. Although they should bring their own perspective and recommendations, they need to understand how your team works best and be willing to discuss changes with the team. They should maintain a transparent project schedule and be able to keep the team updated.

QUESTIONS TO ASK:

- Tell us specifically how you would work with our team.
- How would you keep us on track?

COMPREHENSIVE KNOWLEDGE WITH SPECIFIC EXPERTISE

Having a background in other areas of clinical research and relevant training gives project managers a strong sense of your trial's needs and establishes credibility. It also can be helpful to know that your project manager has worked in specific research areas that align with your trial's needs, especially if you are conducting a medical device trial that carries different risks and requirements. Being part of a larger team, such as a CRO, gives project managers a wider knowledge base and access to additional support as needed.

QUESTIONS TO ASK:

- What training or certifications do you have?
- What types of trials have you managed or participated in before?
- Do you have access to a larger support network that you can consult as needed?

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IMARC is a medical device CRO with extensive expertise managing a wide range of clinical research trials. Our project management services include project planning, risk analysis, managing vendors, coordinating lab results, managing site protocol, assisting with data queries and data submission, study closeout and data locks. We can be involved from start to finish or anywhere in between, depending on your goals and your in-house resources.

When you partner with us, your trial will experience fewer delays and will result in data that's beyond reproach so you can bring your device to market faster. To learn more about our project management services, contact John E. Lehmann, Director of Business Development, at 440-801-1540.

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