

# WHAT IS THE ROLE OF THE PROJECT MANAGER IN A CONTRACT RESEARCH ORGANIZATION (CRO)?

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**Abstract:** *In the clinical research setting, a project is a unique clinical trial. Within a contract research organization (CRO), a project manager is the: Project team leader, primary point of contact for the team and the client, client advocate within the CRO, manager of project change, and internal business development representative. By utilizing project management techniques, the project manager ensures that the project deliverables meet or exceed the client's expectations. Project management is: "the application of knowledge, skills, tools, and techniques to project activities in order to meet or exceed the stakeholders' needs and expectations from a project." There are four critical success factors to ensure the project deliverables meet or exceed the client's expectations. These critical factors are project team formulation, establishment of the execution plan, open communication, and proactive management.*

In the clinical research setting, a project is a unique clinical trial. It has a discrete start date and end date. The project team works within a matrix reporting environment to ensure that the tasks required to complete the project are done within the project timeline and with quality that meets or exceeds the client's expectations. Using project management as a management process ensures that the team works closely together to meet the project goals. Project management is "the application of knowledge, skills, tools, and techniques to project activities in order to meet or exceed the stakeholders' needs and expectations from a project" (*Project Management Body of Knowledge*).

Within a CRO, project management can be interpreted as "delight the client," "support the project team," and "delight senior management." This is not easy process. Most of the time the project manager ends up sitting on a fence between what the client wants and what senior management wants. At the end of

each day, the project manager must ensure that both sides are happy with the project's performance.

## The Role of a Project Manager in a CRO

The ideal project manager has many qualities rolled into one unique individual. These qualities allow the project manager to: lead the project team; negotiate internally with management and externally with the client; be financially fiscal with the project budget; provide service; able to adapt rapidly to change; ensure timelines are met rapidly; and teach the new team members how to work within this changing environment. Depending on the project's status and how experienced the project team is, the project manager may need all of these qualities to ensure a positive result.

Table 1 outlines the role of a project manager in a CRO. As project team leader, the project manager is 100% accountable for team performance, the quality of project deliverables, and the budget. Within the project team, the project manager is the

**TABLE 1**  
**The Role of a Project Manager in a CRO**

- Project team leader
- Primary point of contact for team and client
- Client advocate within the CRO
- Manager of project change
- Internal business development representative

communicator, ensuring that all information passes between the client and the internal project team. Information flies to and from every possible facet, including the sites and third-party vendors. The project manager plays a critical role in coordinating the flow of information so that the entire project team has all pertinent information at all times.

The project manager is the client's advocate within the CRO. If the client wants something, the project manager must ensure that senior management understands the request

and the need. At the same time, the project manager must balance the request and determine whether the request will have an impact on the project. If the request impacts the project, then the change to the project plan will need to be developed and managed.

The project manager manages project change in both resource management and scope management. Resources may change within the project team and within the client's team. A transition plan, which clearly outlines the project status, provides appropriate training, and allows for a controlled change enables the team to continue to work together. At the same time, the project manager must adhere to the contract and the schedule of deliverables outlined in that contract. Personnel changes must not impact the performance of the project team or the quality of the deliverables.

The second area of change that must be managed is scope. Projects start with a defined list of tasks and deliverables. Over the course of a project, the tasks may vary or deliverables may change (e.g., the client asks for more visits, patients, or analyses). This change must also be managed to ensure that the project remains profitable to the CRO.

Out of scope activities includes evaluating client requests, which is a very gray area in project management. For example, if a client asks the biostatistician to add one more table, that is not a problem. But if the client has asked the biostatistician for one more table, the data manager for some edit checks, and the monitor to spend an extra day on site here and there, the cost increases but nobody knows why; this is called scope creep. Out of scope activities must be managed through project team meetings. Discuss any sidebar conversations

with the client. Ensure that the project manager is always informed about client requests.

The project manager is the internal business development representative for the CRO. The project manager may provide leads for additional business opportunities within the project and then manages those out of scope activities. For example, if the project manager sees that the client lacks biostatistical support or a medical writer, then the project manager can pass that information on to a business development representative for follow up. The project manager may also be able to provide business development with full service opportunities through repeat business.

Once business development has determined that an opportunity exists, the project manager becomes a team member that assist in developing the proposal. As a part of the proposal process, the project manager must look at the big picture, from project start to finish, and not get bogged down in the details of each functional area's tasks. The project manager must understand the business rationale behind the proposal.

When a proposal goes to a client, senior management considers how badly the CRO wants the project and what it will give up to win the project. Sometimes, senior management cuts a project's budget to entice a client and you must work with a discounted budget but still produce quality deliverables. The project manager must utilize all the information that he/she has received to review the scope of work in the proposal to ensure that the budget reflects the contract and that there is enough time, effort, and enough resources to complete the job. He/she provides expertise on the client's needs, therapeutic area, or project processes.

The proposal has two components: a statement of work and a budget. The statement of work is a narrative

description of what the CRO agrees to do for the project. There are tasks associated with the different milestones (project deliverables). The budget is the total dollars that are required to complete the tasks outlined in the statement of work by the resources associated with the tasks. The total cost is the individual's rate times the number of hours it takes to get that task completed.

In order to ensure that the proposal becomes an executed contract and a successful project, the project manager must understand senior management's rationale for the budget (Table 2). Was it cut and is it realistic? How do you manage that back to your senior management? The project manager must also understand what was negotiated with the client before the project manager starts working with the team to ensure the client's expectations are met.

#### **TABLE 2 Ensuring Project Success**

- Understand senior management's business rationale for the statement of work and the budget
- Understand the client's expectations
- Know the critical project issues
- Proactive management

At times, the negotiation process may drag out due to the continual changes in the project requirements and accompany activities. The project manager may need to have a cut off date after which activities are included in the contract modification so that the contract can be agreed to and executed by the client. The decision process may be difficult in the negotiation process that is undertaken during the project award phase.

Sometimes there is a balance between maximizing service and minimizing cost. For example, when the team starts a study, the lead CRA develops

a monitoring plan. This plan may include every possible contingency that might occur at the sites. This type of plan may cause the monitoring budget to be exceeded even before the final draft is reviewed because the client has paid for a standard plan and the lead CRA has developed an advanced plan. In the CRO world, this process would be referred to as “building a limo with a Volkswagen budget.” The team must develop a workable plan that meets the needs of the contract, the expectations of the client, and stay within the costs outlined for that task.

### **Ensuring Project Success**

Understanding the client’s expectations is one of the key responsibilities of the Project Manager. Project managers are usually not involved when business development is selling the project to the company. But the project manager needs to understand what business development sold, because he/she needs to be able to manage the project and meet the expectations of that client. The project manager must be creative in meeting client needs while still staying within the framework of trial contract.

Knowing the client’s hot buttons is another key to success. Some clients are very hands-off and just want written updates. Others clients expect frequent phone calls and for the project manager to be at their beck and call. The budget may only have the project manager working on the project one hour a week but the expectation of the client is 24/7 availability. There is a balance between being accessible and not overrunning the project.

Be proactive. Always try to be a step ahead of the client. If the project manager can get into the client’s head and figure out his/her hot buttons and needs regarding

his/her senior management, then the project manager will be ahead of the game, and the project manager will not be crisis managing, which is very expensive and labor intensive.

Proactive management is comprised of selecting appropriate standard operating procedures (SOPs) for the project and developing a project management plan—a project execution plan. Discuss whose SOPs—CRO’s or the client’s—will be used to meet project deliverables. Many times, SOPs are half the clients and half the CRO’s. This split may cause a gap between the end of the CRO’s SOPs and the beginning of the client’s, and could cause compliance issues later. The project team will need to add some project-specific SOPs in order to bridge the gap and meet the project’s needs. This process of review and implementation of gap procedures should be completed at the start of the project.

The project manager must have an execution plan, a “how-to” guide on how the team will make the project successful. The project management plan usually has appended to it each functional area’s plan (e.g., monitoring, data management, statistical analysis, medical writing, and a final study report template). The project management plan also includes many additional subsections and plans. These plans include: project team training plan; the transition plan for team members rolling on/off the project; the timelines as agreed to by the client and the associated budget; a risk management plan; a change control process that details how to discuss out of scope activities with the client; a communication plan (that discusses what type of reports the project manager will provide and an issue escalation procedure to handle issues that cannot be resolved by the team); and an external vendor plan.

As the project starts, the project manager works with the senior management of each functional group (regulatory affairs, clinical

operations, quality assurance, external vendors, medical writing, biostatistics, data management, and medical monitoring) to identify the best people to serve on the team. In selecting core team members, a project manager looks for: technical expertise in the functional area, availability for the project duration, therapeutic knowledge, and dynamics of team members. Since a new team is assembled for almost every project, the project manager must ensure that synergy occurs almost immediately so the team can work together efficiently to meet project goals.

The most important part of developing team training is understanding the U.S. Food and Drug Administration’s (FDA’s) requirements for team training on the project team. FDA wants to know that the full team has been trained in the therapeutic area including the standard of care and other alternatives; that team members understand the protocol; and that the processes needed to move the data from the site through the final study report have been well defined and well controlled.

Team training covers therapeutic, protocol-specific, and process training. Therapeutic training can be done before the start of a study or in conjunction with project-specific training. Therapeutic training covers standard of care, the disease, and treatments currently available to treat the disease. Protocol-specific training covers the patient treatment regime, patient visit schedule, and any other testing procedures that are unique to the protocol and vary from the standard of care. Process training covers data flow through the project from the sites through data management and query resolution to database lock. The flow may be very different for every project. Electronic data capture methods, faxing data, and traditional casebooks all require that the full team understands the data flow.

The proposal usually has ballpark estimates for the amount of time each project phase will take. Many tasks may be completed in parallel but some must happen sequentially. The tasks that happen sequentially will help to define the critical path as the team develops the timeline.

The full project team creates a timeline, a detailed list of tasks and the order in which the tasks occur. Once the list is complete, the team decides how long each task will take and whether it is dependent upon any other task in the timeline. Once you have all tasks linked, you can define the critical path; parts of the timeline that cannot slip or the timeline will not be met. Once the timeline is finalized and agreed to by the client, the timeline will be used to manage out of scope activities and evaluate efficiencies and slippage.

Risk management is another key to being proactive. There are many risks associated with each phase of clinical trials: start up, enrollment, treatment, close-out, and database lock. Some of the risks are positive (e.g., enrollment closes early) or standard (e.g., enrollment is delayed because the drug is not available as planned).

The team works together to identify all possible risks up front in a risk management plan and to start proactively managing when those risks may occur. To create the risk management plan, the team must consider and list all potential project risks. The team will decide what the impact of each of those risks may be on the project (in terms of cost or time). They then assess those impacts for the probability (high, medium, or low) that they will occur and their overall impact on time or cost (high, medium, or low). An owner for each risk is assigned. The owner will develop a contingency plan for any medium or high risk. During regular team meetings, the risks will be evaluated frequently to see if the risk has changed in severity or to see if additional risks have been identified.

Communication is the most important part of the project manager's job. If everybody has good communication and an open communication style, then information flows throughout the project, everybody knows what everybody else is doing, and there are no questions, issues, or lack of information for good decision-making. The project manager controls communication with the team and the client through a variety of means including but not limited to regularly scheduled team meetings, weekly/periodic status reporting, monthly reporting, e-mail updates, and Web portal access to project-related materials.

Having internal team meeting occur prior to the client discussion may allow for a better flow of information from the CRO to the client. The project manager can funnel information up to the client after team decisions are made. There are numerous moves of reporting including:

- Weekly status reporting should be defined as to the frequency and content with the client. At the beginning of the study, for example, the client will need to be informed when the sites' institutional review boards are meeting. As the project progresses, the status reporting may not be required weekly, but may move to twice a month or less.
- Monthly reporting is an executive summary that states activities completed in the past month, outlines issues and how they were resolved, and details the project's financial picture.
- The team can use e-mail to inform team members and the client about decisions that have been made about the project.
- Using access-controlled Web pages is an easy way to allow clients in to certain parts of the project web site and sites in to other parts of the project web site so that information is always readily available.

Project information management covers the entire method for tracking all documents on a project. Some of the tracking that is needed includes: the project timelines, site identification (investigator grants, contracts/payments, regulatory documents, study supply shipment, and drug shipment), site initiations, monitoring intervals, monitoring reports, patient enrollment/activity (protocol deviations, serious adverse events, early terminations), case report form tracking, data entry, query resolution rates, project budget/financials (direct and indirect costs and investigator costs). These tracking summaries become the basis for the status reports that keep the entire team informed of the project status.

### **Conclusion**

There are four critical project management success factors: project team formulation, establishment of the project management plan, communication, and proactive management. By putting the proper team together so that the project manager has the best knowledge and skill set together in one team that is synergized to efficiently complete the task required for the deliverables on the project. By completing good execution plans—project management and other associated plans—up front so the project team can manage the study with the appropriate processes and tools. By ensuring that communication flows in all directions at all times between the client, the project team, the investigative sites, and any external vendors. Be proactive! Always assess what may occur so that the team has a plan in place if it does occur; this helps speed up the process and ensures a very effective program.