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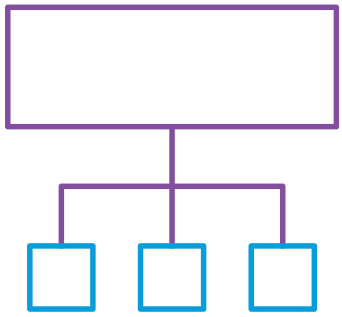
Clinical Trial Project Management in Practice:

Five Things You Weren't Taught In Project Management Class

Clinical project management is a logical and often desirable[1] career progression for those in CRA roles. While the exact path from CRA to project manager (PM) varies from company to company and person to person, the first step for the budding PM usually involves education. For most, this training comes in the form of a project management course or seminar. Course content will vary, but a typical syllabus might look something like this:[2]

- **Module 1:** Clinical Project Management Essentials
- **Module 2:** Project Planning Fundamentals
- **Module 3:** Process Mapping as a Planning and Management Tool
- **Module 4:** Project Management Technical Knowledge
- **Module 5:** Project Schedule Management
- **Module 6:** Management of Project Budgets
- **Module 7:** Project Tracking
- **Module 8:** Ongoing Project Management Needs
- **Module 9:** Communication and Team Building
- **Module 10:** Closing the Project and the Trial



Knowledge of these topics is foundational to clinical trial management. Graduating from a similar seminar, frankly, made me optimistic and overconfident. I was prepared to bend Microsoft Project to my will! I looked forward to keeping my team motivated and on schedule! I was ready to amaze senior management!

To paraphrase the Prussian field marshal Helmuth Von Moltke,[3] however, no battle plan survives first contact with the enemy. How many of us, graduates from the finest project management seminars and online courses, have plunged into the thick of a clinical trial, only to feel discouraged when course content doesn't quite match up to the realities of daily project management?

Years of experience have taught me that this training is vital but not quite comprehensive—there are a few important lessons that are difficult to capture in classes and seminars. **Here are five pearls of wisdom they don't often teach in project management classes:**

1 Understand where your boss is coming from

Once your project is fully scoped, budgeted and planned, it's full speed ahead. Protocols are written, sites are assessed and the study is in full swing. Then, it happens. You get the email or are asked a question in a project status meeting that seems to come out of left field. Or worse, "strategic initiatives" blow up your entire study schedule. Before tearing your hair out, take a breath, and seek to understand.

Your department manager (or client, if you're a consultant) has a job very different from yours. Most likely, it will involve allocating budget dollars and headcount to accomplish the department's and the company's goals. Your clinical study is an important part of this, but it is only a part.

- Understanding the marketing and regulatory strategy of a new product can help you be part of the solution and make proactive suggestions.
- Spending time with the decision-makers, if possible, will help to gain clarity on their goals, and their vision for achieving them. Building these relationships will be helpful, and may give you early warning of strategic changes.

Just like individuals, every company, department, manager, and project has a different "personality" and set of needs. Do what you can to understand the constraints; they'll often be some variation of schedule, budget or quality. Resist the urge to do things the way you've always seen them done and consider what is needed by the current stakeholders. Perhaps you previously worked for a large medical device company that had well-developed procedures and large study budgets. Needless to say, managing a clinical study for a startup company would look very different.

It's easy to get caught up in what you think should be done, or what appears to be the best course of action, or the way you've previously done things. Remember that your job is to be a problem-solver.

2 The view from 40,000 feet is nice, but you also need to spend time in the weeds

Your job as a project manager is to keep your team focused on the goal. This is most often study completion, but milestones like first enrollment or completion of subject follow-up are important to work toward as well. Keeping track of metrics and revisiting progress toward goals is a big part of your job. Ask any CRA, however, to tell you about their least favorite clinical study, and their answer will probably center on a dysfunctional project manager. Nothing is worse than working for an out-of-touch project manager—someone who is lost in the project plan or the study metrics, or making assignments without listening or making any kinds of assessments or mid-course corrections. Someone with a balanced view of the big picture and the smaller, but important, details, is bound to lead a more successful project and team.

One of the most effective things a project manager can do is to spend time with team members and listen to them. If your position or the project allows you to monitor, do it! Many successful clinical project managers retain monitoring responsibilities for a site or two during the trial to keep their skills and understanding of the study fresh.

Monitoring as a Project Manager offers important benefits, such as:

- Time with the investigator. Although they're very busy, they'll often make time to talk if they know (ahead of time) that you are on-site. Lots of important conversations about enrollment rates, compliance, and product performance can take place.
- Time with the research coordinator. Getting to know them will help you later in the study. You will be able to field their questions directly, without being filtered through a study monitor. Additionally, you will see first-hand how the study is executed at the site level, giving you insight into the challenges the sites (and CRAs) are facing.
- Time with the data and case report forms. In any study, there are subjects with very thick patient binders. These subjects might have had a difficult clinical course with many adverse events to sort out. Being on-site, with close access to source documents, gives you the opportunity to sort things out and understand the situation so you can report later to stakeholders such as management or safety committees. Spending time verifying data against the source documents gives you more knowledge of exactly how the data were obtained.

As with monitoring, sitting down and asking questions of your data manager or biostatistician is time well-spent. Frustrations or challenges are often voiced at team meetings or via email, but spending time observing and asking them to show you what they're working on or how they perform can help you understand or head off problems. It also shows the team that you actually care.

3 All your planning is in vain

A carefully crafted project schedule is almost a requirement for a clinical trial of any size. Before you get too attached to your plan, here are a few realities:

- You cannot actually control clinical site performance. This might seem like an obvious statement, but it is often overlooked, especially by your department manager or client. Management has been defined as "the art of getting things done through the efforts of other people."[4] This is especially true in the management of clinical trials. As a project manager, you are executing a clinical trial through the efforts of other humans; you cannot, for example, directly enroll a study subject. Despite your best efforts, some of your carefully chosen clinical sites will disappoint you. Be prepared and do your best not to take it personally. Again, your job is to be a problem-solver.
- Investigators are busy people. The most dedicated of clinical investigators often have a demanding patient practice, endless complex billing and reporting requirements, in addition to the responsibilities of serving as an investigator. Make sure that they carefully consider the time required for your study during the site assessment process.
- Research Coordinators (RCs) are also busy people, and often overworked. Again, assessment of their workload, to the extent possible, during the site qualification process is important. When you find an RC that answers your email or spends enough time with you at your monitoring visit, be extremely nice to them. They are critical to the success of research studies!
- Hospital attorneys, likewise, are busy people. The speed at which a Clinical Trial Agreement (CTA) is reviewed, redlined and returned to you is often at the mercy of a hospital's overworked legal department. In my experience, this is often the biggest delay to the site activation process. This is often made more difficult by the fact that direct contact with the attorney is reserved for the research coordinator or the investigator. Starting the budget and agreement process immediately after site selection is important to avoid delays. Once a delay is encountered, enlisting the help of the RC or investigator can help move things along.
- Whatever the investigator told you about enrollment rates, divide by 3 (or 4, or 5). It's generally accepted, tongue-in-cheek, among clinical project managers and research coordinators, that as soon as a study is initiated at a site, the targeted disease state seems to have been cured. It's important to let the site staff have some time to get going, but at some point, a careful assessment of screening logs with the RC or investigator can uncover either misunderstandings at the site level or a potential need to revise the enrollment criteria.

It's easy to get wrapped up in a complex project plan. A likely consequence is that you spend way too much time head-down in your plan—readjusting when the tiniest task is late instead of working on communicating with your team or sites. As Einstein said, "Everything should be made as simple as possible, but not simpler."[5] Applied to the context of a project schedule, plan in as few "buckets" (i.e., work breakdown structure elements) as possible.

A risk assessment early in the study can prepare you, your team and your management (or client) for some of the aforementioned issues and potential delays. This might involve assembling a group of stakeholders, listing potential threats to the project schedule and scoring the risk of each potential threat. Potential mitigations and solutions can then be planned in advance.

4 You're going to repeat yourself a lot

Another thing your project management class instructor forgot to tell you is that as a project manager, get ready to talk a lot. You will explain various aspects of the project repeatedly to stakeholders.

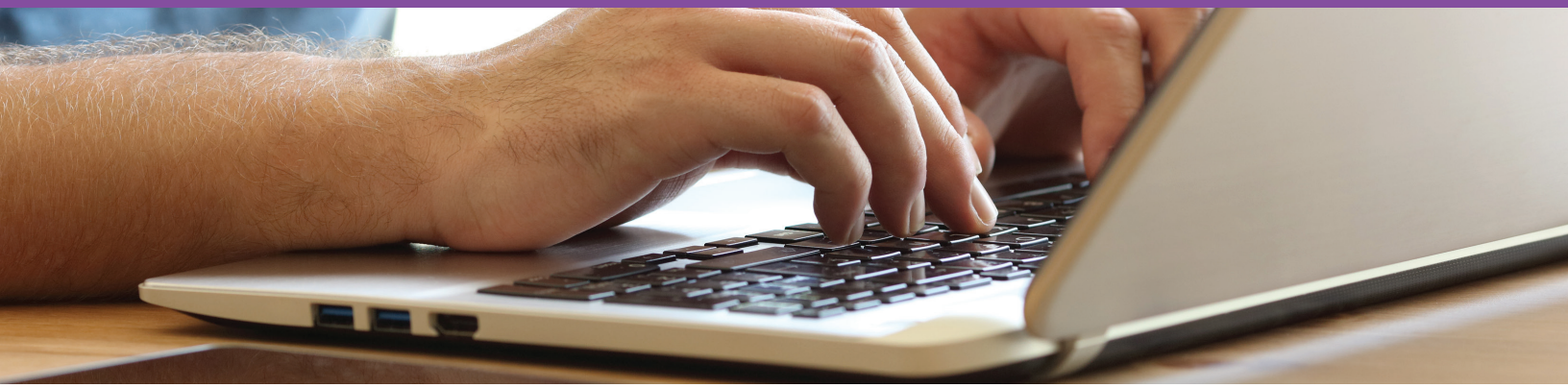
Presenting to a group, whether large or small, will be common. A few common venues include:

- Management reviews, milestones, or compliance committees
- Study team kickoff meetings and trainings
- Investigator and/or coordinator meetings
- Initiation visits, site trainings
- Team meetings
- One-on-one meetings

Needless to say, you'll need to repeat yourself quite a bit. As you initiate sites, your training presentation will become very familiar. An unfortunate truth is that research coordinator (and yes, CRA) turnover is high, resulting in frequent retraining.

Every study has a detail or a quirk that makes it unique. It could be an unusual inclusion criterion, or a unique medication regimen. You'll be reminding sites about these specifics often. Those quality, schedule, or budget constraints mentioned above? You'll be repeating them to internal stakeholders frequently.

There's not much you can do to mitigate this issue. Seek ways to ensure that your communication is consistent. Consider adding study-wide memos, tip cards and periodic RC teleconferences to your usual communication avenues. Consider how you can repurpose study presentations. Encourage and remind your team members to access their resources for answers to common questions. A FAQ resource might help!



5 If you think you are documenting your work enough, think again

Imagine a day when you have three internal meetings, a teleconference, an RC retraining call, a monthly report to write and two CRAs at your door asking about their visits and schedules. An upcoming safety committee meeting also means you need to summarize 13 events before tomorrow, so the committee members can get a jump-start on review. This is not uncommon in the middle of a study. Clinical trials can move fast, which necessitates quick decisions.

The "nightmare" consequence of this scenario is facing an FDA inspector 18 months from now, and being asked to justify a decision you made on a day like the one just described. From experience, I can tell you that your memory will fail you.

Be kind to your future self and write it down. The old adage, "if it wasn't documented, it wasn't done" applies here. Hold your CRAs accountable for timely report completion. Ensure your trial master file is kept current and complete, and tells the (right) story of your study. Make judicious use of notes-to-file and memos to document unusual steps taken in a given situation. As we say at IMARC, "you've done the work; now write it down to take credit for your work."

When (not if) things go sideways, it's all about the relationships

It should be obvious by now that no clinical trial goes exactly as taught in project management class. Delays in IRB approvals, investigator non-compliance, countless questions and product malfunctions are but a few of the complications that might be encountered. Risk assessments can help predict where trouble may occur and provide options of mitigating actions. Frequent, effective communication with all study stakeholders is of course critical. Perhaps most importantly, it's all about the relationships.

An important strategy for common project management challenges is to invest in and build relationships with the folks that are executing your studies. Conferences, investigator meetings and site visits are great venues to meet your clients where they are and get to know them beyond your day-to-day work together. Cultivating relationships with team members and site personnel will pay dividends when plans go awry – and most project managers know that they will even, if they their courses skipped that part.

In summary, formal training provides great instruction, and experience offers crucial lessons in the areas you wish were included. Remember to think about things from your manager's (and stakeholders') point(s) of view, to balance the big picture with a focused approach, to remember that plans will change and you will have to repeat yourself often, and you need to document more than you thought. And, perhaps most importantly, project managers must exercise their relationship-building skills with members of their teams to navigate each new and exciting challenge in a clinical study.

Jim Moat

Jim has over 28 years of experience in the medical device industry. Throughout his career, he has held positions in premarket and post-market clinical research, clinical research consulting, and management of not only clinical research professionals, but groups as diverse as Quality Systems, Biological Safety, Microbiology/Sterilization Validation, Biostatistics, Data Management, and Regulatory.

Jim is an experienced clinical project manager, having managed all phases of clinical studies—from initial strategy to post-market surveillance. Most of his work has centered on cardiology products, but he has also led orthopedic, stroke, and obesity projects. His focus is on ensuring that clinical studies are completed with the highest quality, while staying on schedule and under budget.

Jim holds a Bachelor of Arts degree in Biology from Minnesota State University Moorhead. He has been a Certified Clinical Research Associate (via ACRP) since 2001

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