Effective Project Management For Clinical Trials

A Business Approach

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About this ebook

Projects and process are the lifeblood of every business. No matter what position an employee has within a company, chances are at some point he or she will manage or take on an active role in projects. Working efficiently and meeting company goals effectively requires more than just capable employees doing their best. The discipline of project management has been demonstrated to be the most effective way to complete project goals within cost, schedule, quality, and resource constraints.

In this ebook, we will start with the basics by defining a project and by examining different kinds of project managers. We will look at the project manager's skills, processes, and tools needed for success. We will present common mistakes in executing projects, and finally, we will look beyond the project management disciplines and show how the project manager can make it all work.

The project management tools presented in this ebook work across all companies and industries, but here we pay special attention to the clinical research professional.

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Introduction

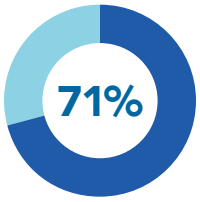
The cost of doing business is expensive, and the number of wasted dollars is staggering.

One survey shows that for every $1 billion invested in a project, more than $122 million is wasted due to poor project performance.[1] That's a substantial 12 percent.

Consider how that number impacts the clinical trial industry. Every new drug that is developed costs the sponsor an average of $250 million.[2] Twelve percent waste equals $30 million. All because of poor project management practices.

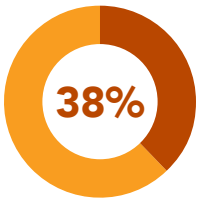
Containing costs in a clinical trial is a real struggle. The process and discipline of project management will help.

A recent survey[1] demonstrates the impact of project management. **At organizations that place a high priority on creating a culture that recognizes the importance of project management:**



of projects meet original goals and business intent, compared with **52 percent** at organizations that make it a low priority.

That's an almost 20 percent increase in achieving project or clinical trial goals. This is no secret, yet many organizations fail to make project management disciplines a priority. They don't get the connection.



of organizations place a high priority on creating a culture that recognizes the importance of project management.

1 Project Management Institute, Pulse of the Profession: The High Cost of Low Performance, 2016
2 RD Heilman, Quality Assurance, Drug development history, "overview," and what are GCPs?, 1995

Chapter 1:
The Basics: What Is a Project?

The Project Management Body of Knowledge, known as the PMBOK Guide, defines a project as "a temporary endeavor undertaken to create a unique product, service, or result."[1]

The temporary nature of a project designates a defined beginning and end. The end is reached when the project's objectives have been achieved or when the project is terminated because its objectives will not or cannot be met.

This definition clearly indicates every clinical trial is indeed a project.

In addition to defined beginning and endpoints, there are also many sub-beginnings and sub-endpoints along the way. In the clinical trial industry, we typically consider site selection or site initiation the beginning point, and last patient out or a data lock being the endpoint, but those are actually sub-endpoints. When we apply project management as a disciplined practice, a clinical trial as a project actually begins with the initiation of protocol development. And it doesn't end until after all data has been analyzed and finalized. It is a long process, and it is defined.

There are different types of projects, and a clinical trial as a project is considered large scale and complex. Trials contain many components, such as study start-up, recruitment, labs, investigational product, data, materials, and site management. These are actually considered sub-components and sub-projects within the clinical trial project as a whole, and they need to be fully managed with the same project management disciplines.

Projects are evaluated throughout for completion or termination. This process of monitoring and controlling is something the clinical trial industry does very well. Observing and checking data points throughout the project helps us make informed determinations about the current state of the project and how the project should continue.

Many details. Much to do. Welcome to project management.

1 PMBOK Guide, Fifth Edition

Chapter 2:
The Project Manager

What is a project manager? What does he or she do?

Being put in charge of a project does not necessarily make someone a project manager. Project management is not simply the practice of applying logic or common sense. A project manager systematically applies knowledge, skills, tools, and techniques to project-based activities to meet project requirements.

> One of the most common reasons clinical trials fail is unskilled project managers.[1]

A 2015 survey of work management practices[2] tells us that while 53 percent of people surveyed were identified as project managers by job description or title, almost all, 94 percent of people surveyed, actually either do or believed they do manage projects. That's prevalent in many industries.

It's more than just a job title. Project management is a critical, strategic discipline, and it is governed by the International Organization for Standardization (ISO). The Project Management Institute plans to have an auditable, ISO certification available for organizations that utilize project management within five to ten years.

The project manager is the link between strategy and execution, which is a true strategic discipline. On the strategy side are stakeholders, champions, and business leaders, who communicate the vision and the objective. The project manager then has to bridge the gap between those strategists and the team members that are working to accomplish these goals. That link is the project manager's main function.

There are 47 distinct processes in every project that should be undertaken, and they are divided into five groups. These process groups are the lifeblood of every project, and the responsibility of the project manager.

1 Artem Andrianov, PhD, MBA, Cyntegrity blog, May 2, 2014 (https://cyntegrity.com/7-reasons-clinical-trials-fail/)
2 Brianna Hansen, Wrike blog, Oct. 8, 2015 (https://www.wrike.com/blog/everyone-project-manager-infographic/)

The Five Steps of Project Management[3]

Initiating: Define vision and initial project scope, identify stakeholders.

Planning: Establish and define total scope of the project, build timelines, establish risks, milestones, stakeholder management, and budgets. Planning is a significant portion of the project.

Execution: Acquire, develop, and manage the teams, perform quality assurance, manage communications, engage stakeholders, and attain goals.

Monitoring and controlling: Make adjustments along the way and determine if the project needs to be terminated, adjusted, or continued. Control project work, scope, schedule, cost, communications, and risk.

Closing: End the project using a formalized process.

In companies and industries around the world, we tend to find three types of project managers: accidental, good, and proactive. Let's examine each.

The Accidental Project Manager: Lacking

These project managers are excellent employees. They are typically skilled or functional subject matter experts, who were rewarded or promoted into the project manager role. They often have no project management training or experience, and they aren't given the tools and techniques needed to execute the discipline that is required for true project management. The accidental project manager is prevalent in the clinical trial industry.

The Good Project Manager: Better, But Still Lacking

The good project manager has some project management training and/or experience. They understand the basics of project management and the five process groups for execution, but they tend to have a reactive approach. They don't plan well, and they don't anticipate issues. They don't always plan for contingencies, which are the things that can come up but are not expected for certain. We all know that a project, especially something large scale and complex like a clinical trial, should be loaded with contingency plans.

3 PMBOK Guide, Fifth Edition

Why are good project managers reactive? Often it's because they don't have adequate project management training or experience, something the organization likely sees as inconsequential. They have poor organizational skills, which are key to enacting the techniques of project management. They lack resources, which means they are forced to skimp on practices that are necessary.

Even in the best pro-project management environment, some project managers will never reach the level of ability required, because they lack the skill sets that are required to ascend higher than good and reactive.

The Proactive Project Manager: Ideal

The third type of project manager is the proactive project manager. These managers have project management training and experience. They understand the five process groups for execution and utilize them in all of their projects in order to ensure appropriate execution.

They also use all of their soft skills, including interpersonal skills and project management tools and techniques to proactively anticipate and handle project movements. They exercise foresight.

They make good decisions based on their experience and training. They know how to get and where to go for information. They communicate effectively to all parties at all stages of the project.

An experienced project manager with a sound skill set and process discipline can be the difference between project success and project failure. Clinical trials are a significant investment, and investing in the "right" project manager will almost surely reap dividends in trial execution.

Chapter 3:
Project Management Tools for Success

There are many tools for project management success, and these four are key: communication, leadership, negotiation, and project management discipline.

Communication

If you lack communication skills, you will not be an effective project manager. This skill is the most important. It affects everything.

Projects will falter quickly due to miscommunication or assumptions that people make regarding the information they are given. At the beginning of every project, there should be a formalized communication plan laid out for all major stakeholders who are involved. The plan must be clear and concise regarding each stakeholder's role, how those roles fit into the project as a whole, and exactly what will be delivered. Everyone must understand what it will take to make the project successful.

Projects will falter quickly due to miscommunication or assumptions.

A project manager needs to listen and understand issues. With a complex project like a clinical trial, many people are feeding the project manager information. The project manager must be able to master the issues, the trends, and the things that are going on in order to be able to respond appropriately and proactively.

Business leaders and champions for your clinical trial must also be brought on board with the plan and kept informed along the way.

One of the reasons communication is so important is it ties all the skill sets together. In one survey,[1] clinical trial leaders did not consider scientific expertise, or clinical expertise, a requirement for a project manager to be successful. It was one of the last skill sets that they look for when they look for project managers.

1 Leading Clinical Projects – Applied Clinical Trials (Johanna Schenk, M.D., PhD, Yakov Datsenko, M.D.), Jan. 1, 2013, (http://www.appliedclinicaltrialsonline.com/leading-clinical-projects)

Leadership

As mentioned in chapter two, project managers are the bridge between the strategists, stakeholders, and business leaders, so leadership skills are required to articulate strategy and vision among the different team members.

Part of the project manager's leadership role is the ability to motivate and influence team members. Clinical trials are often long and difficult, and problems such as recruitment issues or unexpected high early withdrawal rates can be demoralizing. The sites struggle, and project team members can also struggle with these issues. The project manager needs to be able to motivate sites and team members to push through these difficulties, alter the plan as needed, and execute their tasks.

Another aspect of leadership is empowering others. Because a clinical trial is a complex project with many sub-project managers and team members executing their portion of the endeavor, the project manager has to allow and trust them to do their part along the way.

Many clinical trial managers have trouble delegating and they try to handle all the details themselves. They're responsible for multiple trials on a global level, yet they get involved in minutiae, such as which products ship to which sites on what days, rather than allowing the project manager responsible for that portion to perform his or her role.

Project managers must be disciplined to the five process groups, and that can be difficult. When they are overloaded due to too many projects or reduced timelines, several of the process groups risk being neglected. Planning sometimes gets shortchanged and becomes a secondary thought.

The closing process group, which is the formal closing of the project at all levels, is often overlooked when time issues arise. At Imperial, our warehouse is full of patient and physician materials from closed projects. These materials are here because there was no formal closure process through to the materials level. It's not unusual for that part of the process to get minimized or even skipped altogether. Leadership skills allow the project manager to follow the discipline all the way through.

Negotiation

We tend to think of negotiation as a sales skill, but it applies to project management in a significant way.

Consider the adage, "Do you want it fast, cheap, or good? Pick two, because I can't give you all three." Because of the constraints they're given, project managers are constantly navigating the quality/time/cost dilemma.

Since project managers working with protocols frequently inherit the timelines, the time piece of the triangle has been decided for them.
They find themselves having to navigate the cost and quality elements with little or no control over time. Negotiating these elements early prepares the project manager to be able to adapt to unforeseen changes with ease.

When something comes up, such as a protocol amendment, the proactive project manager will have presumed it may occur, because they know it happens in a high percentage of clinical trials. They will have built amendments into their planning and budget from the beginning. Therefore, the fact that they're prepared for it saves a considerable amount of time when they have to execute protocol or project changes.

Project Management Discipline

Applying project management discipline requires utilization of a **project management organizational system**. Email strings and Excel spreadsheets are not effective ways to manage clinical trials, or even portions of clinical trials.

A true project management system will place data in a single landing spot. (I am not referring to data collected in the clinical trial; here I mean data used to execute the clinical trial.) This is important for success.

Project management discipline also requires **analyzing data** to make sound project adjustment decisions. This is something our industry does well—we look at data regularly to make large scale decisions, such as whether we continue, adjust, or terminate a trial.

For example, take a trial that has developed unexpected recruitment issues. How do we adjust early and quickly, applying the data we have, to minimize delays due

to recruitment? Cohesively gathered information that is centrally located allows us to quickly determine which addition or change to recruitment strategies are likely to add the most value in recovering our recruitment efforts, putting the project timeline back on track.

Another discipline is **managing risk**. This requires the project manager to have a thorough and complete understanding of the project, what the stakeholders are trying to accomplish, and every participant's role.

Overall understanding by all involved is important to keep everyone working toward the same objective.

We usually do a good job at the overall level for the clinical trial manager. But while sub-project managers usually know their piece, understanding what is trying to be achieved overall tends to get missed. Overall understanding by all involved is important to keep everyone working toward the same objective.

The last discipline is **continuous project management training**. Project management training courses are available online and at local colleges. It doesn't necessarily mean project management professional certification; there is also informal training.
At Imperial, our project managers undergo informal training every day regarding their role as sub-project managers for clinical trials. This informal training often involves a project manager mentor who can help with guidance regarding matters that come up during the course of a study.

Chapter 4:
Common Mistakes in Project Execution

Projects are in danger of faltering or failing by coming up short in one or more of these areas: training, resources, planning, and time management.

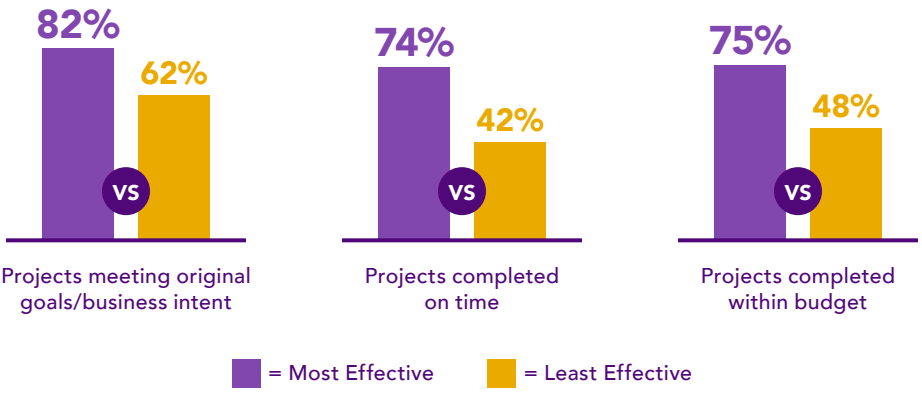
Lack of Training

A nurse would probably not treat a patient if not properly trained to treat the patient. Yet, we will give a project to someone who doesn't have project management training. From a business perspective, this isn't smart.

Project management training and a project management career path are worthwhile. We know that many people believe that project management is common sense or a set of soft skills. The actual strategic discipline of project management requires education, training, and experience to really master project management skills. Project management training is a strategic discipline that is guided by ISO standards and is afforded a nationally recognized certification program.

It makes sound business sense to invest in project managers. When organizations devote resources to ongoing project management training, offer a defined project management career path, and establish formal knowledge transfer processes, 32 percent more projects are successful.[1]

Expect Better Project Outcomes From Organizations that are Good at Knowledge Transfer



1 PMI's 2016 Pulse of the Profession: The High Cost of Low Performance

It is important to establish a formal knowledge transfer process. Knowledge transfer is the process of organizing, creating, capturing, distributing, and integrating knowledge to support mutually beneficial collaborations between departments and to ensure that the "know-how" of organizational experts is available for future employees.[2] People responsible for sub-projects in clinical trials are constantly changing. Project managers are pulled from one trial to another, and many people come and go. Without a formal knowledge transfer process, the new person stepping into the role or an experienced project manager moving to an unfamiliar area is faced with a learning curve that wastes time and money, impairs project continuity, and can result in lost or strained business with outside organizations.

Successful businesses make education and knowledge transfer a priority and create a culture that supports these activities. Capturing and sharing essential knowledge results in cost savings, decrease in error rates and risk, improved project metrics, increased production, consistency, retention of talent, and innovative ideas. Organizations that are good at knowledge transfer have an increase of 20 percent in projects meeting original goals, a 32 percent increase in projects being completed on time, and 27 percent more projects completed within budget.[2]

Successful businesses make education and knowledge transfer a priority.

Lack of Resources

Lack of resources affects projects across the board, including at the sub-project level. A smart organization and project manager look at resources regularly.

Team members are frequently required to perform activities vastly outside of where they were originally intended to operate. Consider your clinical trial managers and sub-project managers. How many projects can they effectively manage and still adhere to the five process groups? How many projects are they managing?

I have seen clinical trial managers who have global trials with hundreds of thousands of patients, and because they have sister studies that are similar in nature, they have been assigned to manage those, too. Just because similarities in different trials exist, they are still separate projects and should be managed as such.

2 PMI's March 2015 Pulse of the Profession: Capturing the Value of Project Management Through Knowledge Transfer

These clinical trial managers are in a resource crunch. If managers are faced with managing more than their own resources will allow, spreading their time across many projects, they will be limited to only skimming the surface of what they need to accomplish. This can be viewed as giving wide attention versus giving deep attention. Wide attention, with no time for moving deeply into the details, causes inability of the manager to fully understand the objectives or learn the project trends and issues. This hampers the project manager from developing proactive solutions instead of reacting after a problem forms.

There are also financial aspects to project execution. At the start of a clinical trial, there is usually a cost consciousness regarding where resources will be allocated. At this point, many activities and sub-projects are ignored or short-changed, with resources being assigned to fix a problem later on. Investing money after the fact to rescue what could have been addressed at the beginning isn't cost effective. This way of investing is more expensive, wastes time, and also causes the project manager to be ineffectively reactive rather than proactive.

Poor Planning

Planning is one of the five process groups and is critical to project success. Lack of preparation results in energy depletion.

In Stephen R. Covey's popular book *The 7 Habits of Highly Successful People*, one of the habits is "sharpen your saw." Covey illustrates his point with this story: Two men in the woods are given saws and told to cut down as many trees as they can before nightfall.

One man cuts down one tree after another. The other man stops after cutting every few trees to sharpen his saw. As the hours pass, the man who stops to sharpen his saw is able to continue cutting trees at a rapid rate.

The man who did not stop to sharpen ends up with a saw that continues to get duller and duller. As a result, it takes more energy for him to cut down each successive tree.

Preparation and planning is important to save time and money throughout a clinical trial. The team should create a plan and contingency plans, consider all the things that could go wrong (risks) and a plan to mitigate or respond to the risks. A strong plan at

the beginning of the study will prevent fatigue and chaos.

Unrealistic Timelines

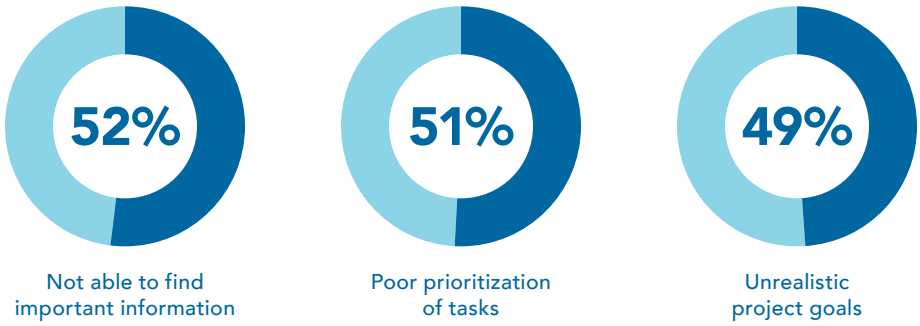
Every clinical trial is governed by a protocol. Many clinical trial managers and project managers involved at various levels are not part of the protocol development process. They have no input in the timeline development piece. Instead, they inherit the timeline by default.

When challenged with such constraints, a proactive trial manager will step back and examine all the options. He or she will determine what can be realistically achieved and how to compensate for quality and cost within the time constraints. Then they will negotiate for the resources and time needed to achieve trial success.

Lack of Standardized Project Management Techniques and Tools

A person might have thorough training and experience in project management, but without standardized tools, the job will be difficult and stress will be relentless. Only 31 percent of organizations use a standard project management approach.[3]

Top 3 Work Scenarios Causing the Most Stress



When project managers were asked which work scenarios cause the most stress,[4] these three ranked the highest.

Not being able to find important information caused the most stress. The number of project managers and sub-project managers looking for information compounded by the vast number of different files and data points clinical studies create, confirms the

3 PMI's 2016 Pulse of the Profession: The High Cost of Low Performance
4 Brianna Hansen, Wrike blog, Oct. 8, 2015 (https://www.wrike.com/blog/everyone-project-manager-infographic/)

need for a central file repository. Centralized landing spots, such as SharePoint sites, databases, and shared drives provide a cohesive place for any team member to easily access study and overall project information and prevents the need to hunt through email strings and Excel spreadsheets for elusive information.

Poor prioritization of tasks. It is stressful to be forced to focus on something that is ultimately of low importance. Devoting time to the planning process will mitigate this, and communicating priorities as a leader and a trial manager will help people feel they are working on the right pieces to accomplish the trial objectives.

Unrealistic project goals. This involves the time/cost/quality issues. Sometimes it's not feasible to negotiate for all three of them, and we are forced to live with something that is less than ideal. This can create difficulties and stress for the team.

Poor Time Management

Time management can be considered a soft skill, but it is an essential part of the project management discipline. Project managers that exercise conscious control over the amount of time spent on specific activities are inherently more effective and efficient.

It is not uncommon in a complex project like a global clinical trial to see a lack of understanding regarding individual team member actions and accountability. When focus gets fuzzy, time is wasted.

At Imperial, we deal constantly with study materials, including development, printing, and shipping. It is not unusual to have different members of a study team give us instructions to send the same materials to sites. Team members are obviously unsure of their roles, and they are struggling with their responsibilities, causing duplication of effort and time that could have been spent elsewhere on other important activities. Clarity is critical to maximizing effective use of time.

Conflicting or unknown priorities can lead to people devoting time to the wrong activities. This forces us to be reactive instead of proactive, responding to or correcting poor decisions or poor use of time, because it was spent in the wrong arena.

Lack of organization is a costly time management mistake. With a clinical trial and all the sub-projects that go along with it, organization becomes key. There are too many

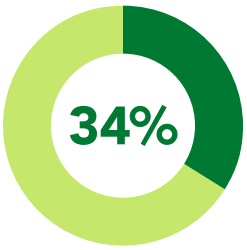
essential details that can be missed or neglected. The amount of lost time in searching through email strings, moving papers from one part of the desk to another, and looking for misplaced information adds up to significant portions of disorganized people's days. Being disciplined about organization creates "found time" to think about and act on critical activities that otherwise may never be completed.

Finally, lack of trusting others to do their part is another danger of poor time management. It's not effective for project managers to be involved in every detail, rather than allow other team members to carry out their own assignments.

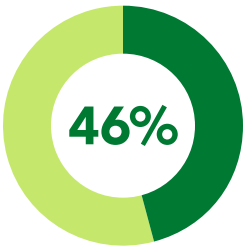
This doesn't mean the project manager should stay away from those people and processes. It is important for a project manager or a clinical trial manager to trust but verify. To have a conduit of communication to ensure that sub-project managers are doing their part but to not do the work for them.

Chapter 5:
Fostering Success

Understanding the discipline of strategic project management practices is the first step toward achieving success, but that is not enough. Effective project management is the practical implementation of these tools and skills. It is a consistent utilization of the processes, activities, and disciplines that training and experience have provided, even when it seems difficult or counterintuitive. An effective project manager always keeps the end goal in mind, and all actions and activities support execution toward the final objective. Movement, not motion, dictates success.

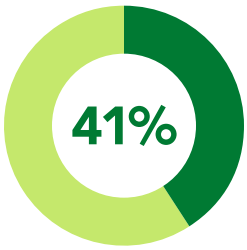


Say that they attend at least 6 meetings a week



Say most or all of their meetings focus on status updates

Say they only meet deadlines some of the time or even rarely



Say most or all of their deadlines shift due to unexpected changes

Meetings Aren't Always the Answer

Meetings can be costly drains on time. In a survey of project managers,[1] 34 percent said they attend at least six meetings a week. It's possible that the number is higher, since many of the project managers I know attend more than six every week.

Almost half of the survey respondents, 46 percent, said that all of their meetings focus on status updates. That isn't surprising; status meetings are the dominant purpose of meetings that I see project managers attending.

Only 29 percent of respondents say they meet their deadlines some of the time or rarely, and 41 percent say they change their deadlines due to unexpected changes.

These numbers suggest that organized dissemination of information outside of status meetings might be wise to free people to better utilize their time.

1 Brianna Hansen, Wrike blog, Oct. 8, 2015 (https://www.wrike.com/blog/everyone-project-manager-infographic/)

Understand the Objective/Outcome of the Project and All the Deliverables

To manage a project effectively, the project manager needs to fully understand the project and all of its deliverables. This is the responsibility of not just the clinical trial manager but really all of the sub-project members as well. Sub-project managers who understand the overarching project objective are more likely to steer the activities within their sub-project to meet the project goal, not just their own sub-project objectives.

Know the Team Members and Their Roles

Know your role. Know your sub-project managers and their roles. All should know where they fit in so all can effectively perform their roles in the project.

Frequently, I will be part of a conference call for the purpose of determining what study materials are needed at sites. Yet during these calls, team members will have a long discussion ironing out the details regarding who is responsible for what. Such things should have been nailed down long before. Fog wastes precious time.

Communicate Effectively

As mentioned in chapter three, effective communication is the number one skill required to be successful as a project manager. Project success is dependent on the appropriate dissemination of information, both to the strategist and to those doing the execution.

You want to make sure you're communicating at all levels of the organization and within project teams. Ask questions. Make sure you understand meeting objectives when you're going into a meeting.

Utilize Standardized PM Tools and Techniques

It is natural to use all five process groups at the primary trial level, but it is important to also utilize them in every sub-project. Once you start planning activities for the sub-projects, the five processes are often short changed. Some managers might be tempted to skip planning for one trial aspect or to ignore a formal closing step in a

sub-project. Don't let that happen. To be effective and to minimize waste, stay disciplined with the five process groups.

When asked about how they track project progress, 41 percent of project manager respondents said they use several different platforms. Lack of standardized techniques and tools can create highly stressful situations, such as lost project information, poor prioritization, and unrealistic project goals, leading to unmet expectations and missed deadlines.[1]

Make sure to create appropriate landing spots for information for tools, such as dashboards and Gantt charts, which are all important in managing the life cycle of a project.

Don't Micromanage

If you are managing complex projects, like a clinical trial, there aren't enough hours in the day to do it all yourself. Rely on other project managers who are part of your organization or perhaps outside vendors. It's OK!

If an organization has a culture that values the discipline of project management, the trial manager will be comfortable with sub-project managers and confident that they will perform their roles effectively.

Hold Accountable and Be Accountable

Everyone involved in a project must be expected to perform. Hold the sub-project managers accountable for their portions of the trial and ultimately, the trial managers accountable for how the trial is executed and the success of the trial as a whole.

A Good Experience for the Client Is Essential

At Imperial, the client experience is a major part of the project manager's responsibility.

They have full support teams that perform much of the individual execution of materials, such as development and logistics, but client communication and the overall client experience is ultimately a key component of the project manager's accountability.

1 Brianna Hansen, Wrike blog, Oct. 8, 2015 (https://www.wrike.com/blog/everyone-project-manager-infographic/)

About the Author

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Hope Cullen is a respected operational executive with nearly 10 years of clinical research experience. She leads a team of cross-functional project managers as well as manufacturing and support personnel to provide production, procurement, assembly, and logistics services for client study materials in support of global clinical trials. In addition, Hope directs Imperial's client interaction, workload management, and work process improvements, and ensures continued revenue growth through exceptional customer service and relationship development.

If you have questions about project management and clinical trials, Hope and the team at Imperial would love to hear from you.

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