

## Clinical Study Project Plans

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Every project should start with a plan. Project plans are most effective when they are revisited throughout the lifecycle of the project in order to maintain appropriate timelines, as well as assure that the team is meeting the project milestones and that all the right players are involved. The keys to a successful project plan and, therefore, a successful project, are that all team members have a clear understanding of how to develop the plan and the ability and tools to execute it accordingly.

### Introduction to the Project Plan

Some believe that a project plan is just a list of specific tasks and deliverables, organized across time and into larger groupings that begin and end with major project milestones. However, a project plan is not just a timeline. A complete plan covers the entire scope of the project: the assumptions used to define the project's parameters, the risks that may befall the project, the resources assigned to execute the project, a plan for communicating with all stakeholders throughout the lifecycle of the project, a team charter that outlines the responsibilities and accountability of team members, and a mission statement that provides a common vision to keep the team focused on the project objectives and end goal. It is a living document that is updated as the project moves through its stages.

The stages of all projects are virtually the same: *define* the scope of the project; *plan* the project at the operational level; *execute* the project; *control and monitor* progress; and, finally, *close* the project. Major factors in determining the success or failure of clinical development projects are how well the planning process is carried out, whether the clinical project managers are involved early enough to understand the product development goals, executive sponsorship, and stakeholder involvement.

Senior level leadership in the planning phase is common in established biopharma companies, but we recommend that the attention given to developing strategic product development plans also extend to individual clinical study plans. In smaller biopharma companies without dedicated project management offices, strategic product development planning conducted to satisfy investors usually lacks a rigorous operational component. In the absence of mid- to senior management leadership, this planning is almost nonexistent, increasing the risks for each individual clinical study.

Because the planning gap for clinical projects is persistent and widespread, managing each section of a typical project plan during the *define* and *plan* stages will be the focus of this article.

### Planning a Project: Defining Scope

The deliverable achieved as the end product of good project planning is a clearly defined outline, or scope, that describes the project: a goal and supporting objectives, assumptions, risks, deliverables, schedule/timeline, identified resources, and communication plan. During this phase, the team evaluates the practicality of the project and makes a decision on whether to proceed with it. Each piece of the project plan should reflect thoughtful analysis, enabling the project manager to define the project appropriately for both internal communications and, later, for management and control of the project. In clinical trials, the study's project manager should lead the planning effort at the protocol concept and

feasibility phase, to better understand the operational challenges that will arise during study execution and develop strategies to manage them.

A common clinical project example is a Phase I/II study conceived by clinicians and scientists to better determine potential biomarkers, to better qualify clinical responses, and to build the foundation to confirm efficacy in subsequent pivotal trials. The goal of the study may have great merit. However, at the conception stage, there may be no recognition of the complexities associated with specialty laboratories, imaging vendors, etc. Study sites in emerging regions must be secured to enroll quickly, usually without much attention being paid to the intricate challenges associated with data transmission and protocol compliance. Taking such complexities into account helps determine the project scope.

The scope of the project describes the work that needs to be done to meet the project goal. First, define the project goal and the objectives that accomplish that goal. Then, refine them against other development priorities within the organization. Is this study one of the top priorities in the company, or is it secondary to higher-priority projects?

Second, on a high-level basis, identify the resources needed to carry out the project tasks, as well as any supplies and equipment that will be needed.

Third, determine the assumptions and risks to the team's best predictive abilities. Predicting possible constraints on cost, scheduling, personnel or other limitations that may interfere with the project's overall success is critical to the planning and scoping process. A common risk is that the study will not enroll as quickly as predicted. Ramifications can be limited if risk planning identifies recruiting as a potential issue and the team develops a contingency plan for back-up sites rather than spending three to six additional months starting new sites when the recruiting shortfall appears.

Fourth, define the project tasks, deliverables, milestones and schedule, along with an effective communication plan. Finally, taking all these items together, the project plan must be synthesized into a formal working document and confirmed as representing the thinking and discussion of all stakeholders around the key areas of the study. As previously stated, the plan is a living document that will be updated throughout the project. However, during the planning phase, the greatest value of this document comes from forcing the project team to identify and address the operational challenges of the project. The team, led by the project manager, validates all sections of the project plan so that a clearly defined scope is available for continued planning activities. After all, without a clear scope and plan, the team and the project aren't likely to reach the goal. If you don't know where you're going, you aren't likely to get there. In the rest of this article, each section of the project plan will be explored in a bit more detail.

### **Project Goal and Objectives**

The purpose of determining the scope of a

#### **Figure 1: Stakeholder Interview Questions**

- How does the project fit into the company's overall goals?
- Are there specific opportunities or problems to be solved?
- What are the go/no-go criteria for implementation?
- What are the specific objectives of the project?
- What are the measurable outcomes or specific deliverables?
- What are the priorities?
- What are the limits of your authority?
- What are the assumptions?
- What are the key success indicators?
- What are the politics?
- Who are the active stakeholders?
- Are some stakeholders against the project?

project is to understand what is included and what isn't. But first, the goal and objectives need to be clear, along with an understanding of the big picture, i.e., context, in which the project resides. A project manager should seek to answer critical questions, such as: Why is this project being initiated? What are the objectives of the project? Why is it important? Who is backing the project? Who are the champions of the project? An experienced project manager will answer all of these questions during the early phases of project planning. During this process, the project manager should identify key stakeholders and take time to confirm the expectations of each.

Who are stakeholders and why are they important? A stakeholder is a person with an interest or stake in the outcome of the project and who often has the power to support or derail the entire thing. Some stakeholders include the project team members, associated departments, vendors, strategic partners, and management. One of the keys to a successful project is identifying and managing stakeholder expectations, which are the outcomes or benefits resulting from the project that stakeholders anticipate with some degree of certainty. Discrepancies between what a stakeholder expects and the actual execution of the project can be a significant source of dissatisfaction.

Therefore, the project manager needs to find out who the stakeholders are and ascertain their expectations. Figure 1 presents sample stakeholder interview questions. Input from each of the stakeholders can be condensed into SMART objectives and eventually synthesized into a prioritized list of deliverables for the project (Figure 1).

Example of an initial statement of objectives:  
250 eligible subjects enrolled within 8 months  
of the opening of the study and less than a 1%  
error rate for monitored data.

### **Project Schedule: Tasks, Deliverables, Milestones and Timeline**

The project schedule is a road map for activities and time estimates that provides direction for the project. The role of the project manager is to provide oversight and problem-solving capabilities, rather than performing operational tasks him or herself. Therefore, one of the key components of the schedule is a work breakdown structure, whereby tasks are identified and set forth with defined skill sets (or roles) to complete them. The work breakdown structure serves as a framework for laying out both the timing and the interdependencies among tasks, deliverables and milestones, to ensure appropriate team members are available and properly assigned.

Once the tasks have been identified, the project manager and team obtain estimates for both task durations and interdependencies, the building blocks used to create the timeline for study activities to be completed sequentially and in parallel, also known as the Gantt chart. The Gantt chart is a valuable tool for tracking the progress of a study and troubleshooting unexpected challenges in timing. The timeline and Gantt chart should be updated regularly to ensure that they reflect the most accurate current schedule. In addition, effective use of a Gantt chart identifies tasks on the critical path, which, if delayed, will delay completion of the entire project.

### **Figure 2: SMART Objectives**

- Specific: clearly defined and precise
- Measurable: not "collected data" but "monitored, collected, cleaned, finalized" etc.
- Attainable: don't ask for the impossible
- Relevant: is the criterion actually related to the aim of the project?
- Time-based: is there enough time to achieve this? There is no point expecting a year's worth of work in a week.

Examples: Enrollment rates of 2 eligible patients/site/month; data that is monitored, cleaned and finalized within 30 business days; and query rate less than 2% of data, entered within 90 days.

## **Resource Plan**

Resource planning and allocation is critical to the success of a project. Resources include money, people and other items necessary to complete the project. The two main steps in allocating people to a project are (1) assigning a person to a specific task and (2) ensuring that the total allocation of that person's tasks is appropriate to both his or her skill level and availability. For example, it is relatively easy to calculate the number of CRAs needed to monitor 50 study sites, based on the frequency and duration of monitoring visits. However, it is more difficult to match CRAs with sites based on geographical location, level of experience, and assignments to other projects. Thus, resource planning and allocation is an art requiring expertise in assigning the right person for the right duration to the right study activity, rather than a simple mathematical formula.

Coordinating the estimates of how many people with which skill sets are necessary for any deliverable often falls to the clinical project manager. In an ideal scenario, the project manager aims to utilize all team members to their most productive roles at close to 100% of their capacity.

Budget planning typically begins with high-level numbers from upper management prior to even the rumor of a project plan. Project managers are often given a target cost. During project scoping and planning, it is important for the project manager and team to estimate more accurately and negotiate for additional funds, if needed, early in the process. Using the project goal, work breakdown structure, timeline, assumptions and risks, the team estimates the costs associated with the planned number of sites (e.g., per-subject payment, ethical review board fees, administrative costs), human resources, vendors (e.g., laboratories), and CROs for monitoring, project management, data handling, etc., as well as travel and meetings (e.g., the investigator meeting). By considering all aspects of the project plan, the team can give a more robust estimate of the number, nature and cost of the resources necessary to complete the project.

## **Assumptions and Risks**

The design and execution of a project are based on a set of assumptions that characterize the boundaries that the project management team has defined. If an assumption changes or proves to be untrue, the project plan may become invalid. Some common examples of assumptions are that appropriate people with available time are available, document drafts are reviewed and approved in 48 hours, and there are an estimated X case report form (CRF) pages for each subject, which will be monitored in Y time.

Clinical development is inherently risky, with many uncertainties. Assessing and managing risk is thus a major concern. Project risk is a function of the probability that some adverse circumstance will occur that may affect schedule, resources, quality or performance, combined with the likely impact of each risk. The combination of probability and impact determines the severity of the risk. Managing risk is the process of anticipating risks, raising awareness and visibility, preparing resolution and contingency plans to maximize positive events and minimize negative ones, and then taking mitigating actions as required.

Risks can come from many sources and may affect the project, product or the business as a whole. Figure 3 presents common clinical trial project risks:

**Figure 3. Clinical Study Risks**

<b>Risk</b>	<b>Description</b>	<b>Probability</b>	<b>Impact</b>
Staff turnover	Experienced staff will leave the project before completing their duties		
Management change	There will be a change of management with different priorities		
Clinical trial material unavailability	Investigational product that is essential for the project will not be delivered on schedule		
Subject unavailability	Eligible subjects are not enrolled on schedule		
Protocol changes	There will be unanticipated changes to the protocol		
Underestimation of complexity or size	The project is found to be larger or more complex than expected		
Performance	Team members do not perform as anticipated		
Standard of care changes	The underlying rationale for the study is superseded by new medical practice		
Product competition	A competitive product enters trials or is marketed		

A risk management plan is a structured method for defining, prioritizing and managing risks to minimize their impact on the project. In recent years, risk management planning has become a higher priority at many biopharma firms, which have significantly improved their processes.

### Communications Plan

The success of any team is dependent on effective communications, which depends on properly defining and communicating each individual's roles and responsibilities. The RASCI communications model in Figure 4 is a simple and effective tool for determining roles and responsibilities.

A well-planned and documented structure and process to support effective study communications are required. Biopharma companies may have effective methods for communicating with employees about human resource and corporate matters, but not for communications within, from and to project teams. Project

**Figure 4: RASCI Communications Model**

- **Responsible:** Owns the project
- **Accountable:** Must sign off and approve the project
- **Supportive:** Can provide resources and support for implementation
- **Consultative:** Has information and/or expertise to help complete the project
- **Informed:** Must be notified of results, but need not be consulted

leaders are rarely trained in developing effective communications on the team level. One approach is to develop the communications plan as part of a team charter.

### **Team Mission and Charter**

The team mission is a high-level statement of goals and objectives. It should be specific enough so the team can get started in the right direction, but not so limiting as to dictate the process and outcomes. The team will establish more specific goals and objectives when it creates the project plan.

The team charter defines authority and accountability for the project leader and team members. It should be created in a collaborative process, so that each member of the team is a stakeholder and understands and agrees to his or her role in the project. In developing the charter, the project manager is the facilitator who fosters an environment of collaboration, rather than acting as a dictator who forces his or her own view. The team charter should include: definition of success, team norms, constraints and assumptions, resources and schedule, roles and responsibilities, and a formal communication plan.

Any confusion or disagreements about the mission or charter among the team and other stakeholders should be resolved at the outset of the project. They may be revised during the project to reflect changes in staff, assumptions or prioritization.

During execution of the project, the charter serves as an agreement on how the team will function internally and with the project sponsors — the external stakeholders with primary responsibility for the project — providing common objectives shared by all team members. The charter also helps to maintain the scope of the team's efforts and serves as a vehicle to identify, understand and communicate any changes during the project.

### **Conclusion**

A good project plan greatly increases the likelihood of a successful project. Organizations that fail to include the right people early in the planning process will inevitably encounter unforeseen problems during the project that waste time and money. Project planning entails much more than just putting together a Gantt chart. The art of project planning is combining measurable processes with the intangibles of leadership and communication skills, and mixing them into a cocktail of success.

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