Overview of Basic Project Management

"Being busy does not always mean real work. The object of all work is production or accomplishment and to either of these ends there must be forethought, system, planning, intelligence, and honest purpose, as well as perspiration. Seeming to do is not doing'

– Thomas Alva Edison

Project management delivers the promise of an on-time, on-budget delivery of a unique deliverable according to specification. The concept was first introduced in the early 1950s by contractors for the US Department of Defense that found project management practices to be a useful means of accelerating the development of new weapons during the early days of the Cold War with the Soviet Union.

Why are project management concepts & practices useful to the concept of expediting drug and biologics development? Since project management promises on-time, on-budget delivery, the corollary of this idea implies that without project management we should not expect projects to complete on time and on budget. By using project management practices for the develop of new drugs, we are following a deliberate approach to predict, manage, and control a budget and schedule. With the given that human beings have not mastered the art of accurately predicting the future, it is also a given that our project predictions will be wrong. Even with the use of project management to assist with the prediction of the launch dates for new market entries, the best we can do is to improve our predictions. This is especially true for drug & biologics development projects that rely on several unpredictable factors that affect key performance indicators, such as schedule and budget:

- The inability to control patient registration for clinical trials
- Reliance upon the FDA (and similar regulatory agencies in other countries) for the review and approval of NDAs
- The unpredictability of clinical outcomes such as adverse events that can send present significant challenges to schedule predictions

Successful project management is supposed to ensure a more reliable means of successfully launching new compounds into the marketplace (i.e. on time, on budget and within the specifications of the label).

The balance of this chapter will try to provide a clear answer to the question:

"Why are project management concepts & practices useful to the concept of expediting drug and biologics development?"

The fast answer is that project management is useful to any business application that attempts to build a unique outcome that has never been done exactly this way before, i.e. a unique deliverable such as a new market entry in the pharma and biologics world.

Some examples include a new computer system for tracking customer orders, a 40 story building in the center of town, a new type of laundry detergent, and the development of a new drug. It's not that these things have never been done before, but more a matter that they typically have not been done in quite the same way each time. This challenge is the crux of the need for project management to provide business controls that guide the clinical development process.

Let's start with a deeper investigation of what a methodology is, what a project management methodology really is and how it is used on a typical clinical development project.

What is a Methodology?[i]

The definition of Methodology is an integrated, cohesive, and well-documented set of repeatable processes which provide for quality deliverables through the consistent execution of practices that have been proven to work.

Methodologies are usually developed in organizations that are tired of 'reinventing the wheel'. Processes that have been successful are documented and shared across the organization. Methodologies often include document templates, such as sample design reports; procedures, such as detailed approaches for producing a data model; forms, such as requests for system enhancements; and work plans, such as Microsoft Project work plan templates.

A Methodology:

- Defines repeatable processes
- Is often used to instill quality into service-based processes
- Removes creativity from processes that should not be creative
- Provides a floor—not a ceiling
- Organizes the project tasks for the work plan
- Forms the foundation for continuous improvement

How should a Project Manager Use Methodology?

Methodology is the project manager's primary means of ensuring quality in a project. It supplies the project manager and the entire project team with a 'cookbook' for performing the tasks in the project plan.

Project management is consistent from project to project, but methodologies tend to vary. The project manager needs to determine whether the organization has a methodology for the specific type of project they will manage.

Samples of Methodologies

Methodologies are used to develop the outputs of a project. Some examples of methodologies include:

- Construction of a single family home
- The commercialization of an newly approved drug
- Object-oriented application development
- Manufacture of a computer circuit board
- The design and construction of a new drug manufacturing facility in a 'green field'
- Project Management
- Development of a new drug
- Management of the process of publication and regulatory submissions to the FDA

The 'Horizontal' versus the 'Vertical' Methodologies Required to Successfully Develop & Deliver a New Drug to Market

Many clinical development organizations view the development of new drug as the embodiment of the scientific processes required to develop that drug. While it is true that these processes are extremely important to the success of the project, they are not project management. The Project Manager's responsibilities include both the on-time, on-budget delivery of the new product as well as the delivery of that product with specifications.

The Project Manager can rely on two distinct and separate process groups in order to define and manage the drug development effort:

- The 'Horizontal' Process: The Project Management methodology is the over-arching set of business controls that the Project Manager utilizes to define and control project outcomes according to schedule and budget.
- The 'Vertical' process: The Drug Development Methodology that defines the steps that need to be followed in order to order to achieve the desired outcomes of the project, i.e. "the label" or claims that the drug-maker will ultimately be required to prove in order to achieve FDA approval.

Figure 1 below shows a sample of the basic processes that define the foundation of a project management process flow.

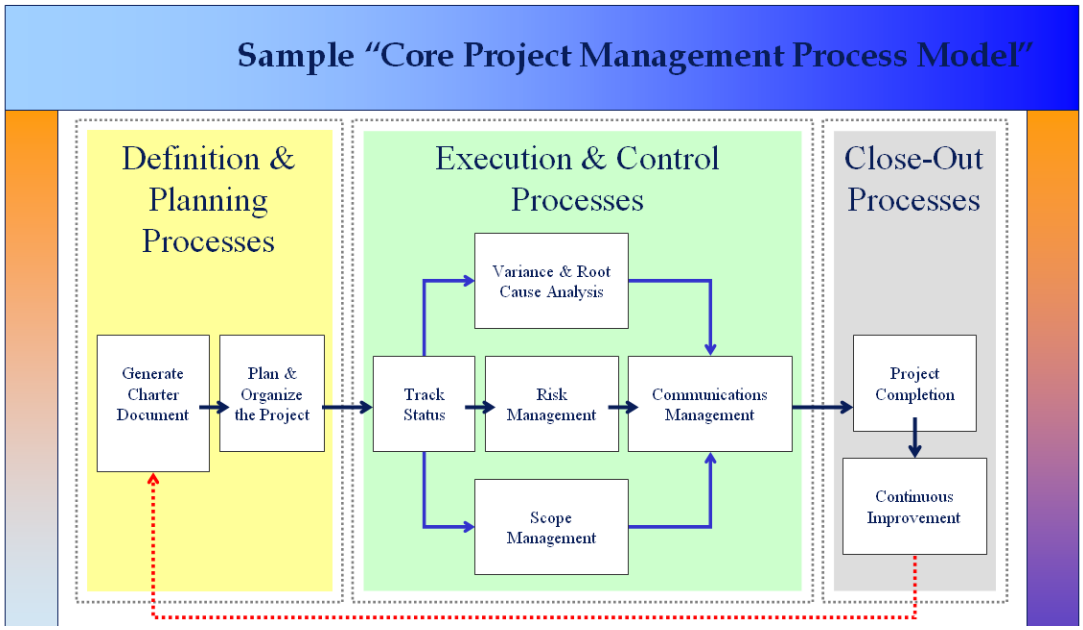


Figure 1. The "Horizontal Methodology" – Sample Core Project Management Processes

The project management process can be thought of in three distinct process groups:

Definition and Planning Processes: This stage of the project management process illustrates the steps that need to be followed before a project starts, to ensure that the proper definition and planning steps are completed to increase the chances that the project will be delivered on time and on budget.

Execution and Control Processes: This stage of the project management process illustrates the steps that need to be followed when the project is underway in order to understand if the project is going according to plan at each stage of the project.

Close-out Processes: This stage of the project management process illustrates the steps that need to be followed when the project is completed in order to ensure that the outputs of the project are properly transitioned to the teams that will be responsible for the life cycle of the product.

Figure 2 below shows a sample of the processes that define how a new drug is brought from 'concept to market' and details the scientific processes and regulatory processes that are followed to successfully research and develop a new drug.

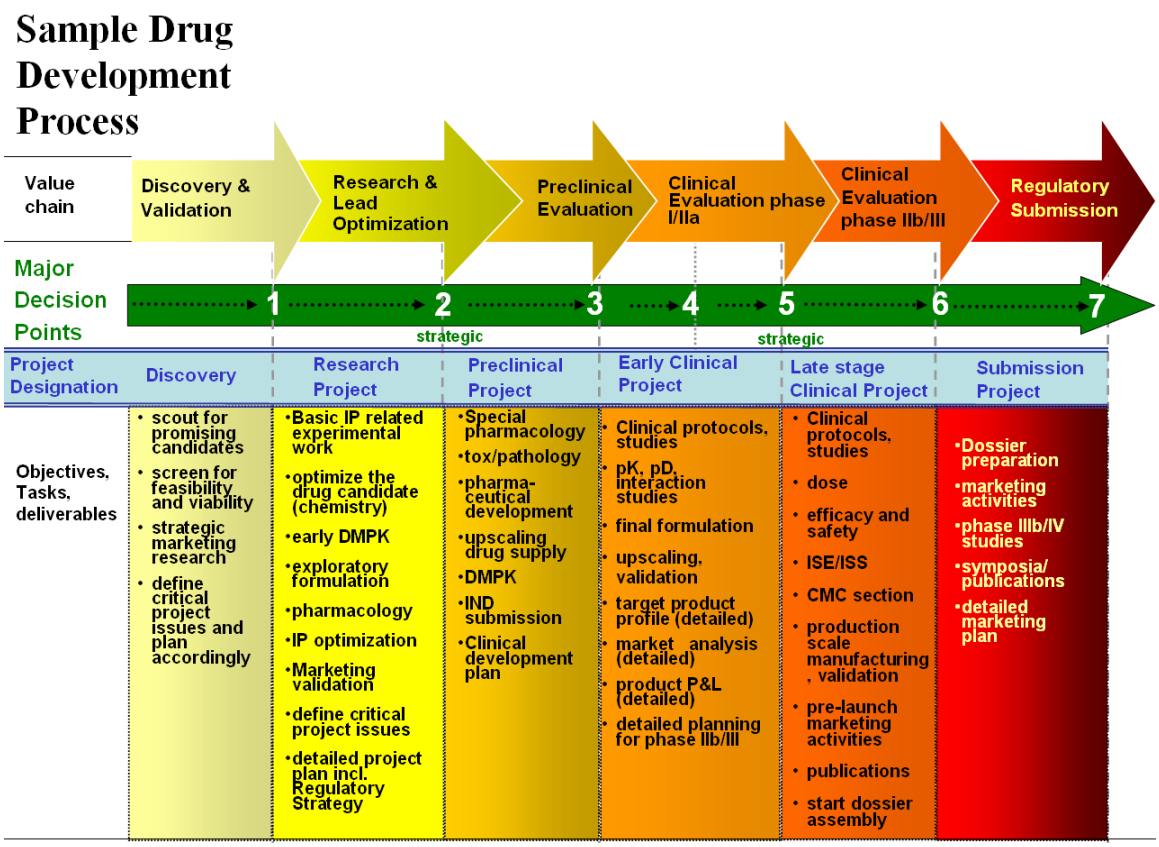


Figure 2. The "Vertical Methodology" – Sample Drug Development Processes

The "Vertical" methodology illustrated above is a sample of a generic methodology for drug development. Many of the chapters in the balance of this book will take a deeper look at the finer details involved in a drug development methodology.

So how does the Project Manager combine the vertical and horizontal processes into a success approach to managing the project?

In order to answer this question, let's take a closer look at each of the three stages of project management.

The Definition and Planning Stage of Project Management

Generate the Project Charter

A Project Charter is a document that is intended to formally define the initial project concept in specific terms that makes the 'scope' of the project clear to all involved. So if we understand the definition of scope, we are well on our way to understanding what basic elements need to go into a Project Charter.

Think of project scope as a series of questions about a project with a series of answers to those questions, as best as they can be known before a project begins. In order for a project to achieve an on-time and on-budget completion according to specifications, the elements of scope are defined to direct a project towards a successful outcome. If we anticipate the types of questions that any business will want answered about a project, we can begin to see the major sections that a project charter document should cover:

- The question of "Why" – If we ask the question, "Why are we doing this project?" the answer will typically found in a section called Goals and Objectives. These goals and objectives should encapsulate the measurable outcomes that will define the success of the project. Any survey regarding stakeholder satisfaction at the end of the project should reference these statements.
- The question of "How" – If we ask the question, "How will we do this project?" the answer will typically found in the section called Approach. The approach will be based on the "vertical methodology" to be followed in order to produce the project deliverables. In the case of drug and biologics development methodology, the approach will be a summary of the project plan, similar to the one shown in Figure 2.
- The question of "What" – If we ask the question, "What are the expected deliverable(s) from this project?" the answer will typically found in the section called Deliverables Guidelines. A more specific approach to defining deliverables from a drug development are covered later in this section of the chapter (see Targeted Product Information)
- The question of "When" – If we ask the question, "When will the project start and finish?" the answer will typically found in the section called Estimated Schedule, which is typically a summary level view of the project schedule.
- The question of "How Much" – If we ask the question, "What will it cost to perform this project?" the answer will typically found in section called Estimated Business Investment. Most pharmaceutical companies have a Portfolio Management organization that deals with establishing the initial business case for a new product, based on estimated development cost, timelines, and expected sales over the product lifetime of the drug.
- The question of "What can go wrong" – If we ask the question, "Can anything go wrong to threaten the success of this project?" the answer will typically found in the section called Risk Management. This topic will be covered in greater detail later in this chapter.
- The question of "What don't we know" – If we ask the question, "Are there unknowns in this project that need to be addressed?" the answer will typically found in the section called Assumptions. Most projects are started with unknowns, so assumptions to document the best guesses that have to be made before the project gets started.

Targeted Product Information (TPI) Section of the Project Charter

In the world of drug development, the project charter is typically referred to by the more specific name of "Target Product Profile" document or "Targeted Product Information" document. This section of the Project Charter document is important because the US Food and Drug Administration has specific regulations that must be followed for drug labeling. The "Target Product Profile" or simply 'the label' states the scope or 'claims' that will ultimately be approved by regulatory agencies such as the FDA.

These regulations are found in 21 CFR 201.56 and 201.57 which describe the specific regulatory requirements for the content and format of labeling for human prescription drugs, such as:

(a) Description
(b) Clinical Pharmacology
(c) Indications and Usage
(d) Contraindications
(e) Warnings
(f) Precautions
(g) Adverse Reactions
(h) Drug Abuse and Dependence
(i) Overdosage
(j) Dosage and Administration
(k) How Supplied
(l) Animal Pharmacology and/or Animal Toxicology (if necessary)
(m) Clinical Studies/References (if necessary)

The TPI should be treated as a supplement to the other sections of the Project Charter that are covered earlier in this chapter. The TPI is not a substitute for this other pertinent project scoping information.

Chapter 6 will address the TPI requirements in greater detail.

Plan and Organize the Project

The Project Management Institute defines the detailed steps of project planning as follows:[ii]

- Activity Definition—identifying the specific activities that must be per-formed to produce the various project deliverables.
- Activity Sequencing—identifying and documenting interactivity dependencies.
- Activity Duration Estimating—estimating the number of work periods that will be needed to complete individual activities.
- Schedule Development—analyzing activity sequences, activity durations, and resource requirements to create the project schedule.
- Resource Planning—determining what resources (people, equipment, materials) and what quantities of each should be used to perform project activities.
- Cost Estimating—developing an approximation (estimate) of the costs of the resources needed to complete project activities.
- Cost Budgeting—allocating the overall cost estimate to individual work items.
- Project Plan Development—taking the results of other planning processes and putting them into a consistent, coherent document.

Another way to look at project planning is a series of connected logical questions that can be used to develop the initial project schedule and budget.

- Review ‘What’ is to be built – The project deliverables (or TPI) in the Project Charter should provide a clear roadmap of the outputs of the project. It is these outputs that ultimately will drive the “vertical methodology” that should be used to develop the tasks that are required to perform the project and build the deliverables.

- Define what actions need to happen to build the deliverables: The Work Breakdown Structure (WBS) is a logical grouping of high level tasks, activity groups, detailed tasks, tasks, and sub-tasks that define the overall approach to completing the project.

  Many methodologies are accompanied by suggested work plans that have been built based upon the WBS used on previous successful projects that used that work plan. These work plan templates are a valuable source of information that can be used by the project manager in building an initial project work plan.

  A word of caution: the work plan templates that accompany methodologies can sometimes contain hundreds, or even thousands, of pre-defined tasks. It is important that you validate these work plan templates since it is tempting to think that a plan with that much detail already loaded must be right.

  Every project is unique so it is important that the Project Manager involve the project early in determining which tasks are right for your particular project. These details are best worked out in facilitated session with the key members of the project team who has the requisite knowledge to ensure that the right WBS is built to start the project.

  In addition to the WBS from previous projects, the body of FDA regulations provides significant guidance regarding what needs to happen for a new drug to be successfully launched into the US market.

  Once the basic tasks of the 'vertical methodology' are added (drug development activities), the plan is completed by adding 'horizontal methodology', the project management activities as well as any key milestones that will be used to report on the highest viability events that are of interest to the stakeholders. These milestones will be the key to simplifying management reporting and will be covered in the section on Communications Management, later in this chapter.

- **1.1 Project Planning and Definition Stage**
  - **1.1.1 Develop Project Scope Definition Document**
    - 1.1.1.1 Develop solution approach with description and completion criteria
    - **1.1.1.2 Initiate Work Plan Development**
      - 1.1.1.2.1 Develop draft project approach and supporting work plan/schedule
      - 1.1.1.2.2 Develop proposed work hours estimates by resource type
    - 1.1.1.3 Assist with draft scope of work (SOW) document
    - 1.1.1.4 Conduct initial risk assessment
    - 1.1.1.5 Secure commitment/approval/funding
  - **1.1.2 Complete project work plan**
    - 1.1.2.1 Refine the project statement of work (charter, business plan, product description, etc.)
    - 1.1.2.2 Review final proposed: investment/estimated labor/resource requirements/deliverables
    - 1.1.2.3 Review and document project objectives with project stakeholders/investors
    - 1.1.2.4 Refine initial work plan & proposed approach
    - 1.1.2.5 Conduct or review risk assessment
    - 1.1.2.6 Review work estimates with project team
    - 1.1.2.7 Setup issue tracking and reporting plan
    - **1.1.2.8 Communicate project plan to stakeholders/sponsors**
      - 1.1.2.8.1 Verify assignment of sponsor's project administrator
      - 1.1.2.8.2 Review work plan and schedule
      - 1.1.2.8.3 Review change control plan
      - 1.1.2.8.4 Review deliverables acceptance process
      - 1.1.2.8.5 Review sponsor satisfaction survey and verify project objectives
  - **1.1.3 Verify all elements of project plan**
    - 1.1.3.1 Verify resource commitments
    - 1.1.3.2 Complete and communicate change control (scope management) plan
    - 1.1.3.3 Verfiy and communicate actuals collection plan

- **2 Project Execution Stage**
  - **2.1 Execute project work plan**
    - 2.1.1 Capture baseline project plan
    - 2.1.2 Define approach for time and cost collection
    - 2.1.3 Conduct project team orientation
    - 2.1.4 Conduct Stakeholder Project Kick-off
    - **2.1.5 Collect weekly actual work and cost from team (recurring task)**
      - 2.1.5.1 Conduct project status meetings (recurring task)
      - 2.1.5.2 Review actual hours/costs and release to Financial System (recurring task)
    - 2.1.6 Analyze the impact of requests for scope change (recurring task)
    - 2.1.7 Perform work plan variance analysis (recurring task)
  - **2.2 Project Communications**
    - 2.2.1 Conduct Weekly Project Team Metings
    - 2.2.2 Conduct Monthlhy Stakeholder Steering Committee Meetings
    - 2.2.3 Report Quarterly Portfolio key performance indicators
    - **2.2.4 Complete monthly project status reports**
      - 2.2.4.1 Submit stakeholder status report (recurring task)
      - 2.2.4.2 Submit internal management status report (recurring task)
  - **2.3 Complete the project**
    - **2.3.1 Project Close-out and Transition**
      - 2.3.1.1 Submited Project Completion Report
      - 2.3.1.2 Capture final actuals for work plan database
      - 2.3.1.3 Communicte SOW completion/acceptance with stakeholders
      - 2.3.1.4 Administer satisfaction survey and verify that project objectives were met
      - 2.3.1.5 Provide feedback to methodology support group
      - 2.3.1.6 Transition to project support (product support/scale up)

Figure 3. Sample Project Management WBS

- Decide 'who' will staff the project: Once the WBS is defined, it is possible to develop a resource assignment plan based upon the skills that are needed to perform

the tasks. In many organizations, the Project Manager does not have the authority to provide the exact names of the people resources that will be required to perform the work. The initial work plan may contain generic skill types such as 'clinical data analyst' or 'medical writer' that will have named resources assigned by the manager in each of the skill centers.

In addition to the 'internal' people resources that are usually needed to perform the work in the WBS, there are often external organizations that need to be assigned such as Clinical Research Organizations (CROs), venture partners, and other sub-contractors, such as manufacturing sites that may provide clinical batches to trials. These organizations can often provide a sample WBS for the type of work that they typically perform.

Finally, a project may require material resources in order to provide a complete picture of what will be needed to complete the project and how much it may cost. It is a good idea to think about scarce or difficult to schedule resources that may be needed to perform some of the tasks, as they often present a challenge that cause delays. Examples include facilities such as laboratories and manufacturing lines that need to be reserved for clinical batches. Materials may also be limited, especially pre-clinical supplies such as lab animals.

- Estimate 'how long' - Work estimates

Before you start estimating the labor for each task in the plan, the next step is to decide if the WBS contains enough detail (or too little detail). How do you know? A plan with 3 phases that contain 1,000 hours each is not enough detail. However, if you loaded every step in a procedure into your work plan, that would probably be too much detail (for example, a plan that contains 3,000 tasks, each one hour of effort).

So what's the difference between a methodology procedure step and a task? Tasks are estimated, scheduled, and have resources assigned. You wouldn't want to go through all that effort for a procedure step. It's not worth it. What we need are some estimating rules of thumb for determining the right amount of detail.

The 'Rule of 80' is one way to test whether the WBS contains enough detail. In the book Productivity Management, Donald Plummer states the Rule of 80 as follows, "The 80-hour rule stipulates that you break a project into tasks of 80 hours or less, each of which must result in a tangible product or deliverable."

This rule is just a guideline. You have to decide what the right level of detail is for your project. A small project that occurs over a three week period might contain 50 tasks that are each 30-60 minutes of effort. Some organizations use a guideline that tasks should be greater than 4 hours of effort and less than 40 hours of effort.

When you think you have enough detail, you should refer to the list of deliverables to be certain that tasks exist to build each of the deliverables. This is a good test of completeness.

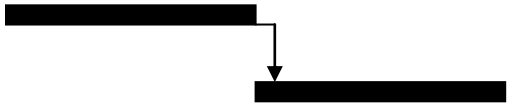
Once you have enough detail in your WBS and have an idea of the types of resources required to estimate those resources, you can start to assign labor estimated to each of the resources assigned to the tasks in hour plan. Some methodology templates assign averages to use as a guideline. Subject matter experts from the project team are also another good source of estimating labor. Referring to the actual work required on previous projects that are similar to the one that you are building can also be a reliable source of labor estimates.

- Decide 'in which order' – In order get an idea of the overall project schedule, it is vitally important to have a grasp of the order in which tasks must be performed. A clinical study must be designed before a study can start. This type of dependency between tasks is often referred to a predecessor-successor relationship.

  There are different ways that tasks can depend on one another. There are four different kinds of task dependencies possible:

  Finish-to-Start Dependencies:

  The most common type of dependency is the finish-to-start relationship (FS). This relationship is set up such that the first task, the predecessor, must be finished before the next task, the successor, can start. On the Gantt chart it is usually represented as follows:



  Start-to-Start Dependencies

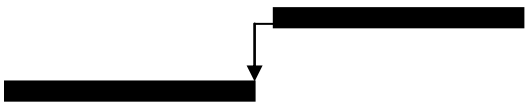
  The next type of dependency is the start-to-start relationship (SS). This relationship is set up such that the successor task cannot start until the predecessor task starts. On the Gantt chart it is usually represented as follows:

  Finish-to-Finish Dependencies

  The third type of dependency is the finish-to-finish relationship (FF). This relationship is set up such that the successor task cannot finish until the predecessor task finishes. On the Gantt chart it is usually represented as follows:

  Start-to-Finish Dependencies

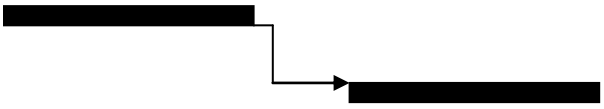
  The start-to-finish relationship (SF) is a less common task relationship and is set up such that the successor cannot finish until the predecessor starts. On the Gantt chart it is usually represented as follows:



  Variations of Task Dependency Types

  Tasks that have overlap are considered to have lead (or lead time), and tasks with a delay inserted between them have lag (or lag time).

Task with Lead



Task with Lag

Once the WBS is defined and the tasks have been sequenced, it is possible to depict the initial project schedule in what is known as a Gant Chart, which gives a visual representation of the tasks, how they are scheduled and how they depend upon one another. Most project management tools will provide a view that contains this visual representation of project schedule information.

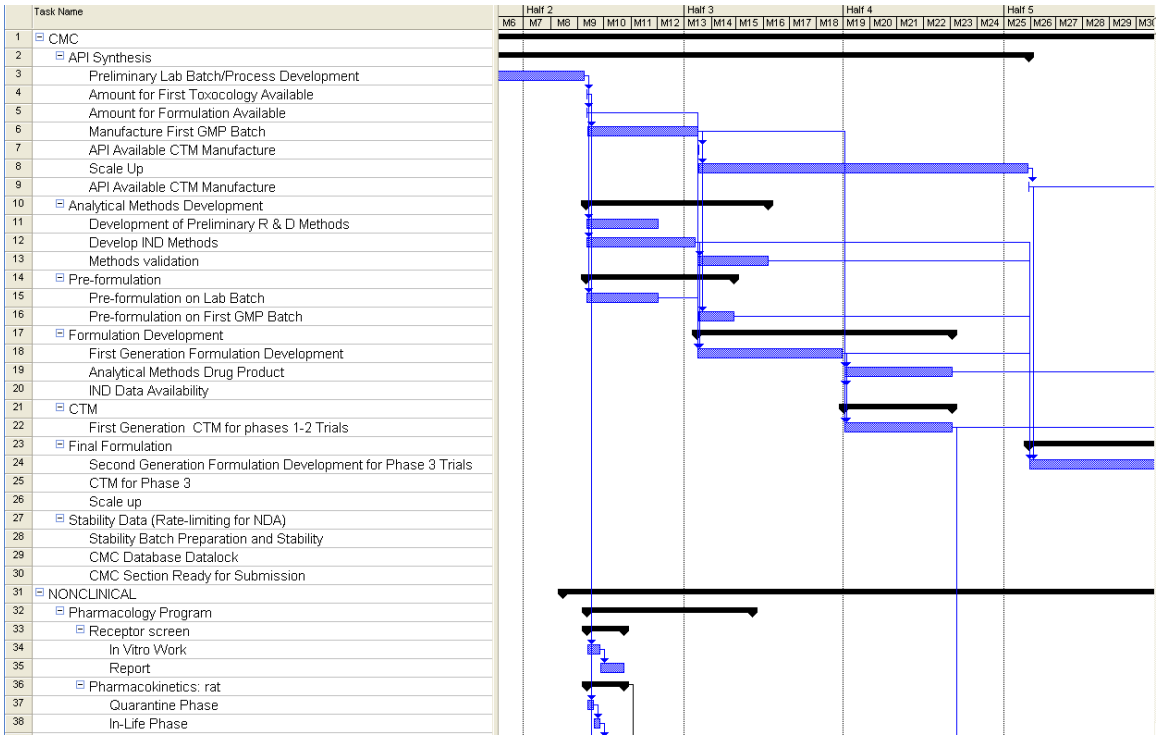


Figure 4. Sample Gantt from Microsoft Project

The Network Activity Diagram can also be drawn at this point in the project planning process. This diagram is a means of visually depicting the sequence of events that

results from defining the WBS, then assigning successor predecessor relationship between the tasks in the WBS.

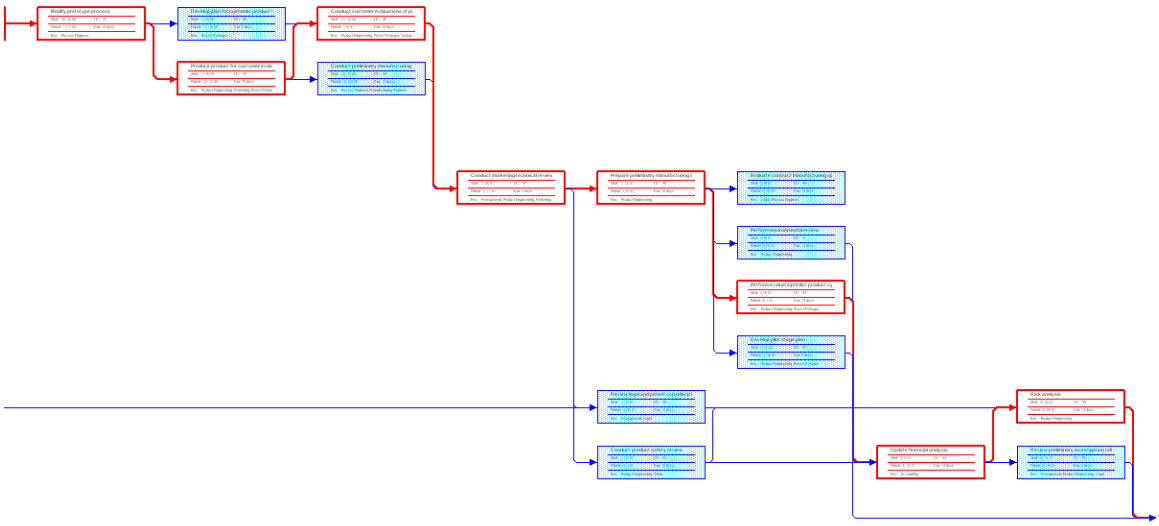


Figure 5. Sample Network Activity Diagram

The network activity diagram is the foundation of determining how long the project will take from start to finish, known as "the critical path."

Just as the longest pole in the tent defines the overall height of the tent, the critical path is the longest path through the network, based upon task duration, which defines the shortest amount of time in which the project can be completed

Slack is defined as the amount of time that a task can be delayed without impacting the project end date. A task that is not on the critical path will have slack. Tasks that are on the critical path have zero slack, since any delay in a 'critical' task will delay. A critical task with a one day delay will delay the end of a project by one day, just as adding six inches to the longest pole of tent will raise the tent another six inches in height.

This technique of determining how long a project will take is also referred to as the Critical Path Method or CPM. This technique is sometimes coupled with a technique called PERT (Program Evaluation, and Review Technique), a project management planning process in the probable schedule is evaluated based on three scenarios: a best-case, expected-case, and worst-case scenario. The probably schedule may be stated in terms of scenarios that are design to determine the duration of a task, its start date, or its finish date.

- Is the project schedule realistic? In order to build a project that will meet its stated objectives, it is important to ensure that the resources required to staff the project are available during the time frames that their tasks will be scheduled. This exercise is often referred to as "load-leveling". The process requires that the labor demands sated in the project plan can be staffed from the limited resource capacity of the organization. This exercise often requires that a project plan be considered in light of all other projects that are placing demands upon a common pool of shared resources.

Resource Name	Work	Details	4th Quarter				
			Month 1	Month 2	Month 3	Month 4	Month 5
Unassigned	0 hrs	Work					
Sr Medical Comm Scientist	83.55 hrs	Work	83.55h				
Sr Dir - Clinical Research	120 hrs	Work	60h	60h			
Sourcing Operations Manager	300 hrs	Work	180h				50.67h
Sourcing Operations Associate	391.63 hrs	Work	270.7h	61h	18.03h	16.47h	17.25h
Senior Clinical Data Analyst	300 hrs	Work	180h				50.67h
Scientist - HEOR	2,640 hrs	Work	240h				43.33h
Safety Operations Manager / Team Ldr	2,280 hrs	Work	320h	40h			83.17h
Project Mgmt and Capacity Planning AC	480 hrs	Work	293.33h	112h	74.67h		
Medical Submissions	1,200 hrs	Work					21.67h
Medical Publishing	196 hrs	Work	156h	40h			
Medical Comm Specialist	176 hrs	Work			16h	160h	
Medical Comm Scientist	12 hrs	Work			0.4h	11.6h	
IIT Associate	440 hrs	Work			21.23h	356.47h	62.3h
IIT Specialist	24 hrs	Work			24h		
Epidemiologist	180 hrs	Work	140h	40h			
Dir Preclinical Sciences	284 hrs	Work	220h	40h	24h		
Dir Exp Medicine/Clin Science	180 hrs	Work	140h	40h			
CTM - Clinical Research Scientist	120 hrs	Work	60h	60h			
Clinical Research Manager	90 hrs	Work	80h	2h	8h		
Clinical Research Associate	524 hrs	Work	412h	112h			
Clinical Research Assistant	490 hrs	Work	248h	74h	8h		
Clin Pharmacokineticist	170 hrs	Work		2h	8h		
Clin Data Mngmt Programmer	2,196.8 hrs	Work	860h	433.25h	212h	432h	176h
Assoc Dir - HEOR	1,068 hrs	Work	416h	2h	32h	8h	104h
Assoc Dir - Clinical Research	492 hrs	Work	400h		0.4h	11.6h	

Figure 6. View of an over-loaded resource pool

A project plan that does not consider the availability of the resources required to perform the project is a project planned that is destined to miss its deadline.

- How much will the project cost – Once the project is scheduled and the resources needed to perform the work are known, it is possible to derive a time-phased project budget, primarily based on the cost of internal resources, external resources, and material resources.

"The cost of clearing a single drug past today's legal, regulatory and marketplace hurdles has risen to $1.7 billion, according to a recent study by consultants Bain & Co."[iii]

Scope, Quality, Risk and Communication Management Plans

In addition to the basic project schedule and budget, it is important that the Project Manager develop specific written plans for how scope will be managed, how risk will be managed, how quality will be assured, and how and when communications will be disseminated.

The Execution and Control Stage of Project Management

Once the Project Charter is completed and the project plans are developed, the project is typically ready to start. Most projects start of with a project kick-off meeting to introduce key players, review the Project Charter, and communicate the project plans.

Once the project starts, the Project Manager primary responsibility is to establish and maintain control of the project. The attributes of an effective Project Manager are covered later in this chapter, but let's first look at what it means to be in control.

Project control means that the project manager is actively spending time managing the project using the plan. As a result, the project manager always knows where the overall project stands during the execution of the project. A project manager who is actively managing the plan will always know where he/she stands in relation to the original approved project plan.

Track Status -

Before the Project Manager starts to track progress, it is important that there be snapshot of the original project plan. This concept is often referred to as 'the baseline.' The baseline is captured so that the project manager has a stake in the ground by which to measure progress as the project begins. It is one of the final steps before the project starts. The baseline is the foundation for reporting the 'plan vs. actual' that is so fundamental to gauging whether a project is on course or not.

The Project Manager may be forced to consider base lining only the earlier phases of a project. For a long, multi-phase project, there may be so much uncertainty in the later phases of the project that the baseline is only valid for the earlier parts of the schedule. For this type of project, the project manager should set the expectation that the baseline is only reliable for the parts of the plan for which there can be any reasonable level of certainty.

Tracking project progress is often referred to as 'collecting actuals.' As the name implies, it is simply the process of gathering progress information from all project resources on a regular basis.

Tracking progress presents the project manager with the first step towards validating the estimated work effort for the planned tasks. As a result, the project manager has a vehicle for continuing to keep accountability to the plan with the entire team. If the team knows that you intend to measure their progress against their estimates, the entire team will share a commitment to the estimates.

Some team members may not be comfortable with tracking at first. The project manger needs to be sensitive to any concerns that the team may have with motivations for tracking and make sure that the importance of tracking and reporting progress are well understood.

Many organizations are not culturally prepared for the requirements posed by the project manager who wants to track progress on a regular basis. Since the project manager is often not the personnel manager for all of the resources, resistance to the idea of tracking may present a problem. The project manager needs to consider how realistic it is to institute a tracking process in an organization that is not ready for it.

Perform Risk Management

A risk is any potential threat to the overall success of the project. The subject of risk is first brought up during the definition process, since this stage of the project presents a good opportunity to decide how you will deal with threats to success.

What can you do about risk?

The approach to dealing with risk is generally broken down into five major processes:

- Identifying risk: Determining where potential threats will originate.
- Assigning probability factors: Assessing the odds of realizing any particular threat
- Determining the impact: Predicting what will happen if a particular point of risk really happens
- Selecting Unacceptable Risks: Choosing which risks warrant an action plan to deal with the possibility that they could happen.
- Development of contingency plans: Putting together plans to avoid, mitigate, eliminate, or neutralize the risk.

Methodologies help the risk manager by providing the project manager with a check list to help assess risk. Some examples of items you might find on a risk checklist are as follows:

- Loss of key resources
- Key resources are inexperienced, such as the project manager
- Tasks on the critical path
- New or untested technology or development approaches
- Scarce skills
- Tight budgets
- Failure to employ 'stage-limited' commitment
- Lack of user/sponsor participation
- Objectives that are not measurable
- Geographically dispersed team
- No lag between major project milestones

Conduct Variance and Root Cause Analysis

"Those who say they can perform project control without comparing project performance to a baseline do not fully understand the meaning of project control" – Harvey Levine

Once a project manager collects the actual progress on a project, it's time to compare the original plan to current progress to see if any variances to plan are occurring. Variance analysis is the process of identifying and understanding differences between current progress against the initial baseline estimates for a project work plan. Variance analysis is an important aspect of project control because the process highlights potential trouble spots in a work plan.

One of the key questions resulting from variance analysis is: "will the project still finish on time?" One of the key indicators is the total remaining work for the entire project.

Consider this example: There are ten months left on the project, ten people assigned full-time, and 18,000 hours of remaining work; will the project complete on time? One person can comfortably consume about 130 hours in a month, so 10 people can consume 1,300 hours in a month and 13,000 hours in ten months. In this example, it looks like the 18,000 remaining hours will not be consumed by the target end date.

Questions that variances analysis should be able to answer:

- Can the remaining work be consumed by the end date?
- Do estimates need to be adjusted based on current variance trends?
- Are resources arriving as scheduled?
- Are schedule bottlenecks preventing tasks from starting and completing as planned?
- Which tasks or resources require additional attention to get back on course?

Project Managers should expect variances and be prepared to explain both the causes of those variances and the actions required to get the project back on course. The project variances form the foundation of the measurable key performance indicator indicators that are typically reported in the project status report.

There are two primary ways to make sure your plan remains dynamic and up-to-date: rescheduling unstarted, late tasks and rescheduling remaining work on in-progress tasks. These rescheduling processes help you avoid stagnant work plans, a common problem for late and over-budget projects.

Before the project manager can revise the plan, there are often project stakeholders that must approve your revision strategy. This is a situation where a project manager is often forced to make trade-offs:

- A cheaper resource can help stay within budget, but the work estimates may increase due to lack of experience of the cheaper resource.
- A scope reduction may help, but you are probably sacrificing some of your objectives to stay within schedule and budget.
- Adding lead (overlapping tasks) increases the risk of missing the schedule.

The unfortunate reality is that serious oversights in the Project Charter, or plan, can significantly reduce the chances of completing the plan according to all of its original expectations.

Control and Manage Scope

Effective Scope Management makes two important assumptions:

1. The project manager has made it clear what the scope is:

   A sound approach to change control highlights the importance of the definition document, specifically completion criteria.

2. Strict scope management also requires adherence to the deliverables acceptance procedure.

   Change requestors acknowledge that their request is out of scope:

This second important assumption relies on the communication and acceptance of the change control procedure at the start of the project, based upon a clear Project Charter.

Even when these two assumptions are valid, scope management requires a tenacious attitude on the part of the project manager. Project managers sometimes become overly concerned with client satisfaction when they are asked to make 'free' scope changes.

Effective project managers manage scope well by knowing how to say "no" with a smile.

A scope control procedure should be develop as part of the initial project plan and communicated during the project kick-off. An example of a scope management procedure might look like the following:

1. Change request completed by team member or user and submitted to project manager for evaluation.
2. The project manager and primary client contact approve change for impact analysis.
3. Project manager records time spent on analysis and reports impact (price/schedule/scope) and recommendation for approval or disapproval to client.
4. Out of scope changes are recorded & deferred, if possible.
5. In scope changes may have to be added to work plan immediately.
6. In or out of scope changes may be disputed & sent for arbitration in extreme cases.
7. Approved changes are recorded and signed by project manager and client to indicate approval

Manage Communications

Project communications are a key component of the Project Manager's role. The constant setting, re-setting, and managing of expectations is critical with both the project team members as well as the project stakeholders.

The initial project communications plan should define the types of communications and frequency of those communications. For example, the project communications plan might include:

- Monthly management meetings with project stakeholders. These meetings should follow a pre-defined agenda, a regular schedule, and invitees.
- Weekly project team meetings with team members to review project status, update and resolve issues, develop strategies to deal with unfavorable variances, and develop project communications.
- Weekly status reports (see example later in this section).
- Quarterly steering committee meetings with portfolio management organization. These meetings should follow a pre-defined agenda, a regular schedule, and invitees.

The project status report is a regular project management deliverable, as such, its structure should be communicated as outlined in the initial project communications plan.

- Summary
    - Review project objectives
    - Brief statement of project highpoints
    - High visibility issues & risks

  - Key performance indicators (scope/schedule/budget)
- Planned accomplishments for this period
- Actual accomplishments for this period
- Explanation of differences
- Major tasks planned for next period
- Issues / Concerns / Recommendations
- Summary of Risk Analysis
- Project work plan trend analysis
  - Cumulative task summary
  - Work variances (Estimated Work higher than Baseline)
  - Start variances (Actual Start later than Baseline)
  - Finish variances (Actual Finish later than Baseline)
- Week-to-week trends (gaining or losing ground on unfavorable variances)
- Scope Change Summary
- Financial summary / Cost variances

Besides the regular 'push' of project communications, there are many tools on the market today that can assist the Project Manager with publishing information to a central database to make information available 'on demand' from web-based applications.

For example, drug development projects can be grouped by therapeutic area in order to show a summary of all clinical trials within each therapeutic area.

Figure 7. Summary of project by therapeutic area

Project information can also be summarized to show how key skill areas are being demanded across the organization. By summarizing all project plans against a central resource pool, it is possible to develop a roll-up of resource skill areas into a resource breakdown structure (RBS).

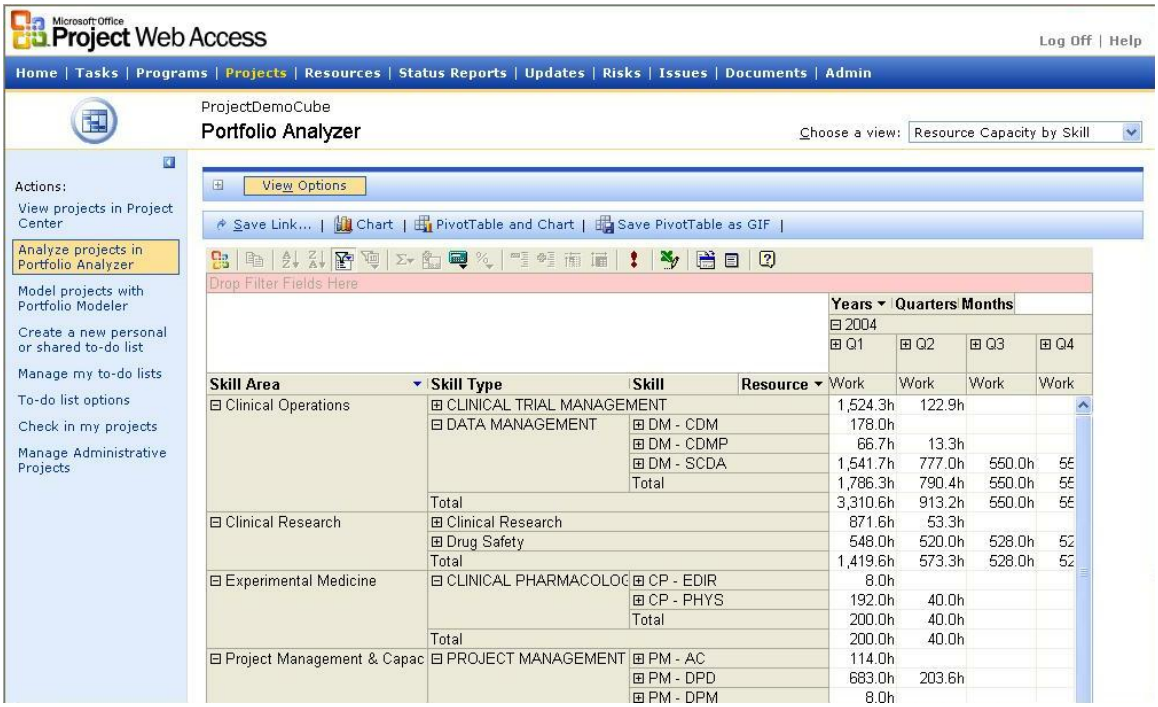


Figure 8. Summary of resource demands by RBS

It is also common practice to summarize a group of projects to view a few key milestones from each project to enable a brief summary of the key events within each project.

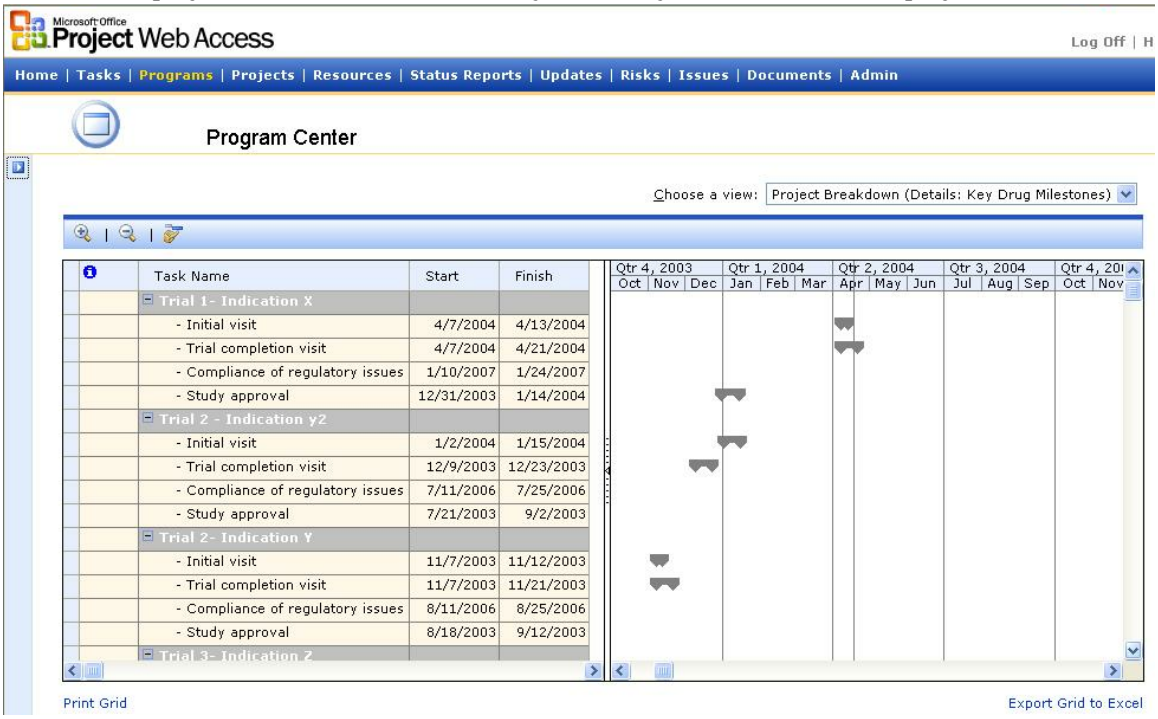


Figure 9. Summary of key milestones across multiple projects

The three summary views above give a very brief overview of what is possible with EPM technology.

The Close-out Stage of Project Management

Complete Project Transition

Once the project has completed all of the tasks that were scheduled and the product is approved, the Project Manager should perform an orderly close-out of the project.

The project close out activities should really be the final tasks in the project plans and may include activities such as:

- Archiving of project documents
- Collection of final project key performance indicators (budget & schedule)
- Final status report(s)
- Final steering committee meeting
- Transition of all product information to the commercial organization (sales, marketing, manufacturing)

Ensure Continuous Improvement

To ensure that the organization get the benefit of learning from mistakes and building on new ideas for how to do thing better next time, it is a good idea to capture this information. The

most common means of accomplishing this final task is often called the Lessons learned check list, is basically a brief walk through the project management process to

Project Scope

- What went well during scoping?
- What could have been done better?
- What information or processes were documented that should be captured for use on future projects?
- Were project objectives met?

Project Planning and Initiation

- What went well during project planning and initiation?
- What could have been done better?
- What information or processes were documented that should be captured for use on future projects?
- Did the initial baseline plan document the scope of the project in sufficient detail?

Project Tracking

- What went well during project progress tracking?
- What could have been done better?
- What information or processes were documented that should be captured for use on future projects?
- Was project progress tracked on a regular schedule?

Project Variance and Root Cause Analysis

- What went well during project analysis?
- What could have been done better?
- What information or processes were documented that should be captured for use on future projects?
- Were the projects key performance indicator well-defined and regularly captured and reported?

Project Communications

- What went well with project communications?
- What could have been done better?
- What information or processes were documented that should be captured for use on future projects?
- Were project communications well planned and regularly updated?

A Sample Project Management Methodology

In order for an organization to standardize its approach to project management, it is a good idea to have a roadmap of what a Project Manager will need in order to perform all of the required steps to manage a project to a successful conclusion.

The example below shows an illustration of the types of project management "horizontal methodology" that are commercially available to be purchased 'off the shelf' and modified to an organization's needs:

Stage	Document	No.	Class	Audience	Signoff By
Initiation	Handover form	32	C2	Deliverer manager	None
	Project binder	51	C1	PM	None
	Classification worksheet	53	C1	PM, deliverer manager	None, but reviewed by deliverer manager
	Scope definition checklist	54	C1	PM, customer approver, CPM, deliverer manager	None
	Project charter	01	C2	Customer approver, CPM, deliverer manager	PM, customer approver, deliverer manager
	Satisfaction criteria	04	Policy	PM, customer approver, deliverer manager	PM, customer approver
Planning	Work breakdown structure	07	C1	PM	None
	Activity definition	10	C5	PM, executing team member	None directly. Approval with Proj. Plan
	Assumptions checklist	03	C2	PM	None directly. Approval with Proj. Plan
	Constraints checklist	02	C2	PM	None directly. Approval with Proj. Plan
	Cost estimate worksheet	12	C2	PM, deliverer manager	PM, deliverer manager
	Cost management plan	13	C4	PM, deliverer manager, customer approver (T&M)	PM, deliverer manager, customer approver (T&M)
	Schedule management plan	11	C4	PM, customer approver, CPM, deliverer manager	PM, customer approver, deliverer manager
	Staffing requirements form	56	C2	Deliverer manager	None
	Scope management plan	05	C3	Customer approver, deliverer manager	PM, customer approver, deliverer manager
	Risk assessment checklist	16	C1	PM, deliverer manager	None directly. Approval with Proj. Plan
	Risk management plan	17	C4	PM, customer approver, deliverer manager	PM, customer approver, deliverer manager
	Communications management plan	15	C5	PM, CPM, team members	PM, customer approver
	Quality management plan	55	C4	PM, CPM, project team	PM, customer approver, deliverer manager
	Project plan	14	C1	PM, deliverer manager, customer approver, CPM	PM, deliverer manager, customer approver
Execution	Time sheet	24	Policy	PM	None
	Corrective actions checklist	23	C1	PM, team members	None
	Scope change request form	19	C1	Customer approver, PM	Customer approver
	Deliverable review form	52	C3	PM, team members	Team members
	Formal acceptance signoff form	21	C2	Customer approver, PM. (Deliverer mgr.–project)	Customer approver, PM
	Status report	25	C1	Customer approver, CPM, deliverer manager	None
Close-out	Handover form	32	C2	Deliverer manager	None
	Satisfaction criteria	04	Policy	PM, customer approver, deliverer manager	PM, customer approver
	Lessons learned checklist	26	Policy	All future project participants in the organization	None
	Performance appraisal form	20	Policy	Team members, team members' supervisors	PM, team member
	Archives index	27	C2	Future PMs and deliverer manager	None
All stages	Issues log	31	C1	PM, CPM, customer team, project team	None
	Meeting agenda	28	C1	Meeting participants	None
	Meeting minutes	30	C1	Meeting participants	None

Figure 10. Sample components of a project management methodology[iv]

Attributes of the Successful Project Manager

Now that we have explored the activities involved in project management, it is equally important to staff our project management positions with the types of people that are needed for a project to succeed.

The list of attributes that define a successful Project Manager can be somewhat daunting and intimidating. Since project management is really the process of managing a series of business controls, the skills required to ensure the success of these business controls is really quite broad. The Project Manager that has a good balance of the attributes we are about to explore has really attained a set of skills that are of great value and applicability to many part of a business organization.

The Take Charge Attitude

Many organizations do not have a project management process that is so clearly defined that a Project Manager knows exactly what he or she is and is not supposed to do when they are appointed Project Manager. We've all heard the phrase "it's easier to ask for forgiveness than it is to ask for permission." Many Project Managers find that this attitude is necessary in order to establish their leadership on a project.

It is the Project Manager that understands how to take leadership instead of waiting to be told what to do who is most likely to find the best approach for achieving the desired project outcomes. As Donald H. McGannon once said, "Leadership is action, not position."

Leadership is not only taken, but also requires some basic qualities in order to ensure support from the project team and stakeholders: character, competency, commitment, creativity, and compassion.

"As of now, I am in control here at the White House", after the assassination attempt of U.S. President Ronald Reagan

Figure 11. Alexander Haig, U.S. Secretary of State March 30, 1981

Ability to make effective trade-offs

In order to achieve the expected project outcomes, the Project Manager is often faced with the realization that things are not always going to go according to plan.

"I wanted a perfect ending. Now I've learned, the hard way, that some poems don't rhyme, and some stories don't have a clear beginning, middle, and end. Life

is about not knowing, having to change, taking the moment and making the best of it, without knowing what's going to happen next. Delicious Ambiguity." – Gilda Radner

In real life project, the most common trade-offs that must be made are often referred to as the "Iron Triangle" because of its inflexibility.

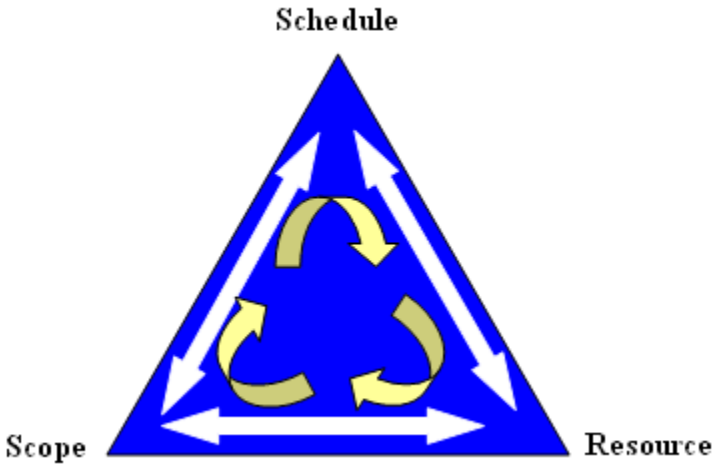


Figure 12. The "Iron Triangle"

The Project Manager is constantly wrestling with the iron triangle. Change one of the corners of the triangle and something else has to give:

- If it looks like the schedule will be extended, we need to cut scope or add resources (people or money).
- If it looks like the scope will be expanded, we will need to add resources or extend the schedule (people or money).
- If it looks like the resources will not be available, we'll need to extend the schedule or cut the scope.

These realities usually thrust the Project Manager into a position needing to pull off some tough negotiations. There never seems to be enough time or money to finish the project in the timelines and budgets that were initially approved. It is important that the Project Manager try to negotiate win/win outcomes for all parties involved. A successful negotiator will ensure that all parties get to an outcome in which all involved gain something they perceive as valuable. If you are in a situation that requires input from stakeholder, always negotiate with our own project team first. Make sure you have considered all angles before escalating to stakeholders. The more options you have, the better your chances of achieving the desired outcome.

"Prepare by knowing your walk away [conditions] and by building the number of variables you can work with during the negotiation... you need to have a walk

away... a combination of price, terms, and deliverables that represents the least you will accept. Without one, you have no negotiating road map." – Keiser

Comfortable operating in the 'gray area'

Because of the uncertainty that is project management, the Project Manager is often faced with problems that have never been encountered, may not have been anticipated and do not have clear cut solutions. These situations are often compounded by lines of authority that may not be clear, organizational policies that do not support an expeditious resolution, and stakeholders that expect these problems to go away quickly. The alternatives are usually not black and white. Thus an ability to operate in the gray area is critical.

As a Project Manager, it can be pretty tough to get what you can without compromising your principles.

"People talk about the middle of the road as though it were unacceptable. Actually, all human problems, excepting morals, come into the gray areas. Things are not all black and white. There have to be compromises. The middle of the road is all of the usable surface. The extremes, right and left, are in the gutters." – Dwight D. Eisenhower

Not Afraid to be the Lone Dissenter and Point out Unpopular Risks

Project management can be lonely for the Project Manager. The Project Manager knows all too well that the project team members and stakeholders may not understand how project management is supposed to work. Since Project management deals in a world of uncertainty, things do not always go according to plan and there is almost always a risk of failure: spending that is too far over budget to justify continuing the project, adverse events in clinical trials that can threaten the viability of the label, and schedules that were underestimated or incomplete.

No one like bad news and it is the Project Manager who must be the bearer of this bad news. The Project Manager is often reminded of the phrase "Don't shoot the messenger" and it can be tempting to downplay or avoid delivering bad news. It is so much more pleasant to share good news and the Project Manager is usually the first to know when it looks like the news will not be good. It takes courage to deliver the facts as they are. It also takes time to investigate alternatives and present options for mitigating the unpleasant effects of bad news.

Many organizations have a winning culture that drives an attitude that says failure is not an option. A winning culture is an important attribute of a profitable company, but not all projects can be winners. Project Managers can't be afraid to point where things may go wrong and should expect that they will feel pretty lonely while going through this exercise.

"Progress always involves risk; you can't steal second base and keep your foot on first." – Author: Frederick Wilcox

Communicate Effectively, with an Understanding of the Biases of the Audience

Because many Project Managers have what is known as a "Type A" personality, communications are too often thought of as transmission of information. While it is important that a Project Manager effectively transmit the key performance indicators of the project on a regular basis, it is equally important that the right information be transmitted. This information can only be learned by turning off the transmitter long enough to receive the information required to build effective project communications.

There are three keys to effective communications: Listen, listen, listen. People will tell you what they need, if you take the time to hear what they are trying to say. Poor listening skills often come from most people are so focused on their own agenda that they do not listen long enough to hear what others are trying to say.

> *"A good listener is not only popular everywhere, but after a while, he knows something." – Wilson Mizner*

Once the Project Manager has gathered all of the facts, it is then important to playback those facts with an understanding of the audience. The biases of a stakeholder audience will be different than the biases of the project team. Project communications should be designed with an understanding of what each receiver wants and needs to hear about the project.

People-oriented Interpersonal Skills

The effective Project Manager understands that successful projects outcomes depend on the individual actions of the people on the team and those who support and manage the team. A Project Manager that instills the team with a "two heads are better than one" attitude will get a lot farther than an attitude that there are "two ways to do it, my way or the wrong way."

This concept is often referred to as "people skills". These skills include fairness, openness, effective conflict resolution, handling difficult people, respect, honesty, coaching and support for your team.

> *"The best index to a person's character is (a) how he treats people who can't do him any good, and (b) how he treats people who can't fight back." – Abigail Van Buren*

Commitment to Quality

The Project Manager owns responsibility for the success of the project. If the project does not produce a quality product, it has failed. It is the Project Manager's commitment to quality that will drive the team to deliver what's expected. Since it is the "vertical" methodology (see Figure 2) that describes how the project will produce a quality outcome, it is the Project Manager who must ensure that the processes are followed and that each task in the project is completed by following the correct approach at each step of the process

> *"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives." – William A Foster.*

Has ability to think analytically

Project Managers are frequently faced with unanticipated changes: schedules change, market conditions change, team members change jobs, commitments to funding change, and pipeline priorities change. Responding to change requires solid problem-solving skills that depend on the ability to think analytically.

In order to think analytically, you must have a good grasp of the details and not take things for granted. Before a problem can be solved the root cause must be understood. Analysis of the available information leads to knowledge. An understanding of that knowledge is gained by applying good judgment. Generating reasonable alternative requires understanding the current situation so that the selection of future actions is built upon a good prediction of likely outcomes.

A repeatable and measured approach to problem-solving will leads to a rich set of alternatives that leads to selection of the best options.

> *"If you do not ask the right questions, you do not get the right answers. A question asked in the right way often points to its own answer. Asking questions is the A-B-C of diagnosis. Only the inquiring mind solves problems.' – Edward Hodnett*

A Word of Implementing Project Management Discipline in an Organization

In order for an organization to successfully embrace project management and implement a standard approach for project management, there needs to a plan that the organization can use to ensure that the proper foundation is established to 'make it stick'.

In order to build this foundation, a roadmap must be built to ensure that the five critical success factors for implementing a project management disincline into any organization:

(a) Executive support

(b) Cultural change management

(c) Methodology & processes

(d) Project Manager expertise

(e) Technology infrastructure[v]

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