

Project Management in Biopharma: *A Necessary Evil or a Source of Competitive Advantage?*

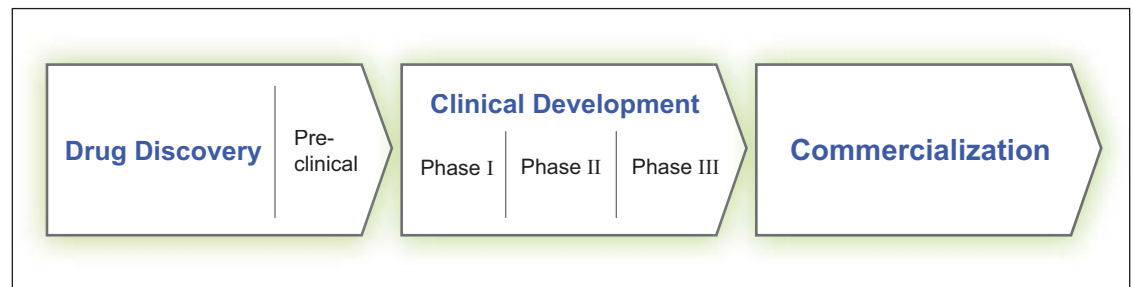
“...It takes over \$802 million to bring prescription drug from experimental research to use by patients...” (Thomson CenterWatch Report, 2001)

“...Biopharmaceutical organizations more than quadrupled their R&D expenditures since 1970 while new chemical entities approvals have only doubled.” (Tufts Center for the Drug Development, December 2001)

Everybody knows the statistics – they are in almost every industry publication. It is not as if companies are not trying to break out of the status quo to release more drug candidates into the development pipeline and turn those candidates into commercial products faster. Numerous avenues have been explored: accelerating drug development by acquiring promising compounds, investing in advanced information technology tools to faster process and analyze scientific data, outsourcing major parts of clinical development to CROs in order to reduce costs and increase speed. All these methods have shown improvements, but not to the extent needed: while blockbusters become more and more difficult to come upon, R&D costs continue to rise and development times are still too long.

This paper takes a fresh approach to the problem. It suggests that by reexamining the role of project management in various stages of the process and adopting new methods of project management, biopharmaceutical companies can substantially increase speed and productivity of R&D.

Figure 1

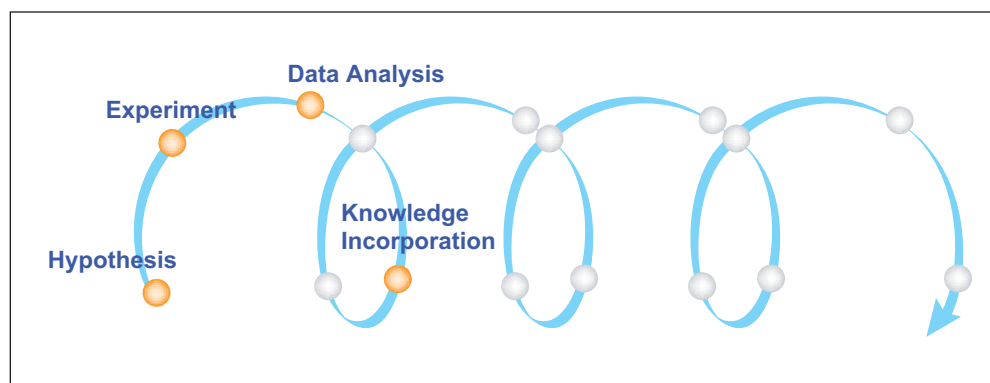


Project Management in Drug Discovery

Scientists are mostly skeptical about the value of project planning and control in drug discovery. They view it as a burden arguing that it is hardly possible to define and structure research activities – “how can you plan and control scientific breakthroughs”?

Yes, exploratory/early stage research is different from conventional business processes as it deals with the unknown, where even the output of the overall process is not known in advance. In its most elemental form, the drug discovery process consists of multiple “research loops” which can be summarized in the following steps: formulating hypothesis, conducting experiments, assessing data, incorporating knowledge and repeating the iteration with the benefit of expanded knowledge.

Figure 2



These loops involve multiple functions: genomics, bioinformatics, in vitro validation, high-throughput screening, etc. The path an overall project follows and the resource requirements keep changing; it's impossible to define a sequence of activities for the entire phase and to estimate how long an activity or a research loop will take. It becomes difficult to coordinate activities between different functions, and precious resources often get engulfed in firefighting and multitasking.

Instead of defining precise project networks for the entire phase and tracking progress against those plans, the goal of project management in drug discovery should be coordinating multiple experiments and providing clear priorities to the teams of scientists.

Better coordination will increase both throughput (number of experiments conducted) and speed (time taken to conduct one experiment), which in turn will improve the quality of information available to assess promising compounds, and also increase the number of drug candidates which go into clinical development.

It will also give scientists what they ultimately want: being able to focus on their work instead of constantly firefighting and multitasking.

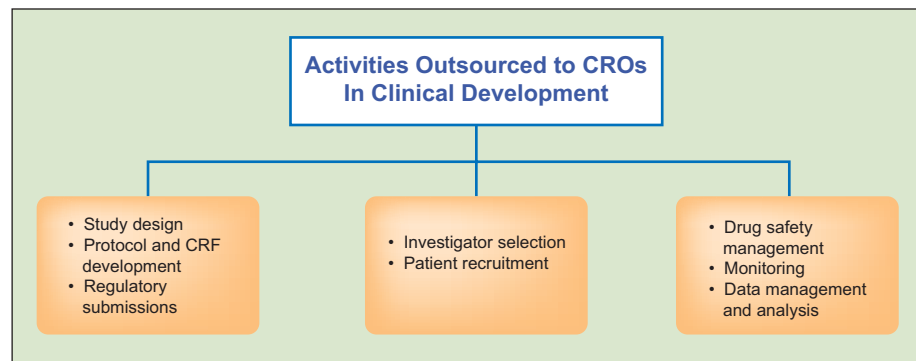
Project Management in Clinical Development

Unlike discovery, clinical development employs a set of better-defined steps to plan and execute projects: there are accepted standardized processes and protocols. However the problem is still there: while each day of delay in bringing a drug to market costs the proverbial “more than \$1 million” in lost revenue, more than 75% of clinical trials are completed 1 to 6 months behind schedule (Thomson CenterWatch Report, 2001).

A key challenge in managing clinical development is loss of control because most of the work is performed by “independent agencies” such as hospitals, and timelines for drug administration and patient monitoring are set by regulatory agencies.

This “loss of control” is getting only more pronounced as clinical trials are outsourced to CROs (according to CenterWatch, 60% of all drug development expenditures in 2004 will be committed to outsourcing; that compared with only 4% in the early 1990s). Managing outsourced work is much more difficult than managing internal work. Meanwhile the expectation that CROs would provide increased speed and predictability by virtue of specialization has not been met.

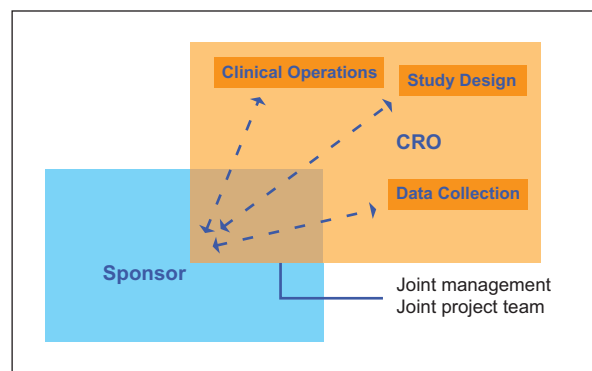
Figure 3



Project managers often wonder whether they are just hapless administrators and reporters of progress. Or can they do more to prevent projects from falling behind?

It is important to remember that even with the current outsourcing volumes, 40% of the work is still done in-house. Effectively coordinating internal activities and resources, making sure that clinical supplies do not become a bottleneck and providing quick turnaround of data gathered from the field can accelerate and increase on-time completion of clinical trials.

Figure 4



Project Management in Commercialization

During commercialization, majority of the work is focused on coordinating operational elements such as manufacturing scale-up, packaging design, supply chain development and marketing.

Figure 5



While technical risk diminishes, execution risk increases because the project team grows in both numbers and functions: now many different departments outside of R&D are also involved. Effectively coordinating a cross-functional team is not easy, especially when resources are not dedicated to just commercialization or to just one commercialization project: resources are spread across multiple endeavors.

Delays in this stage are costly and unforgivable: all that stands in the way of commercial success (the proverbial \$1 million per day is now very real) are internal delays and bottlenecks. Effective multi-project management should be able to solve these problems by assigning resources to the right activities at the right time and providing adequate control to project managers so that they can find and fix problems before it is too late.

Table 1 *New Model of Project Management in Different Stages of Biopharmaceutical R&D*

	Drug Discovery	Clinical Development	Commercialization
Key Challenge	Unknowns: how to plan and control scientific breakthroughs?	Lack of control: most work is controlled by outside agencies such as hospitals and CROs.	Cross-functional coordination: many functions are involved, and resources are shared across multiple projects.
New Model	Treat each research loop as a mini-project, and coordinate work and resources across multiple mini-projects.	Carve out and manage only internal sub-projects such as study design, clinical supplies packaging, data analysis and submission.	Instead of managing each project and each function separately, manage multiple projects and resources as an integrated whole.

Method of Project Management

The nature of projects, structure of teams and the value of project management change as you go from one stage of biopharmaceutical drug development to the next. However, the following characteristics of projects remain the same:

- **Uncertainties.** Drug development involves numerous uncertainties: from high technical risk in early stages to more mundane risks such as vendors not delivering on time in the late stages. Work is rarely completed as planned; managers spend time re-creating and updating plans, timelines keep getting pushed out and projects are consistently delivered late.
- **Shared resources.** All projects involve multiple functions, and same people can work on a number of different projects simultaneously. Due to the uncertain nature of projects, resource planning also becomes difficult. In execution, uncertainties multiply: delays on one project cascade to other projects through shared resources; same resource being needed on two projects at once induces multitasking; and projects get more de-synchronized because resources are not available as planned.

What is therefore needed is a method of managing multiple projects and resources that:

- ☑ Helps managers make planning decisions that are immune to uncertainties.
- ☑ Contains uncertainties from multiplying in execution.
- ☑ Keeps work and resources tightly coordinated even as uncertainties strike.
- ☑ Helps managers control deviations from the plan proactively, not after the fact.
- ☑ Provides focus for improving management and technical processes.

Such a method is now available; it is based on the theory of constraints/ critical chain, and has been adopted by leading companies in the biopharmaceutical as well as other industries. It is called Multi-Project Flow, and proven to increase project throughput and speed by 20 to 30% and help attain 90%+ due-date performance.

In summary, if biopharmaceutical organizations redefine the model and methods of project management, they can reap substantial benefits.

About Realization Technologies:

Realization is the leading provider of multi-project flow solutions used by major pharmaceutical companies. Realization offers complimentary consultation to assess the potential for streamlining and increasing the flow of projects in your organization.

To request a “flow analysis” or for more information, please call 1.408.271.1712, or send e-mail to biopharma@realization.com

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