Project Management in Biopharma:

It's All About Managing Execution

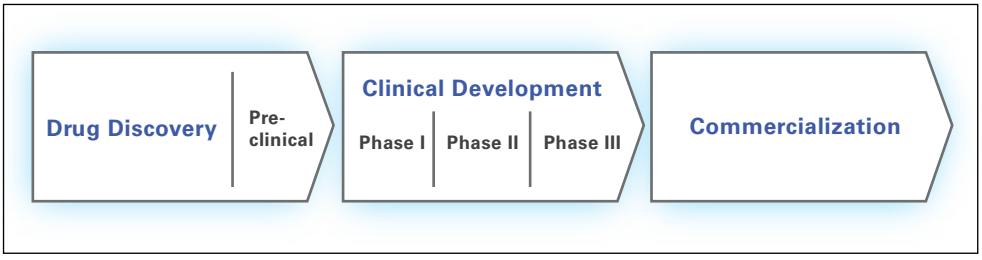
"…It takes over $802 million to bring a prescription drug from experimental research to use by patients…" (Thomson CenterWatch Report, 2001)

"…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 underlying goals of project management in various stages of the process and adopting Execution Management breakthroughs, biopharmaceutical companies can substantially increase the speed and productivity of R&D.

Figure 1

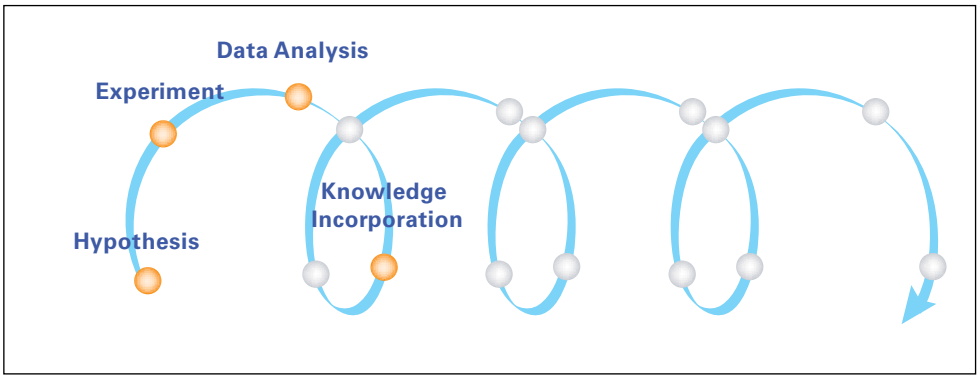


Managing Execution in Drug Discovery

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, et cetera. 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. This in turn will increase the number of drug candidates which go into clinical development.

It will also give scientists what they ultimately want - the ability to focus on their work instead of constantly firefighting and multitasking.

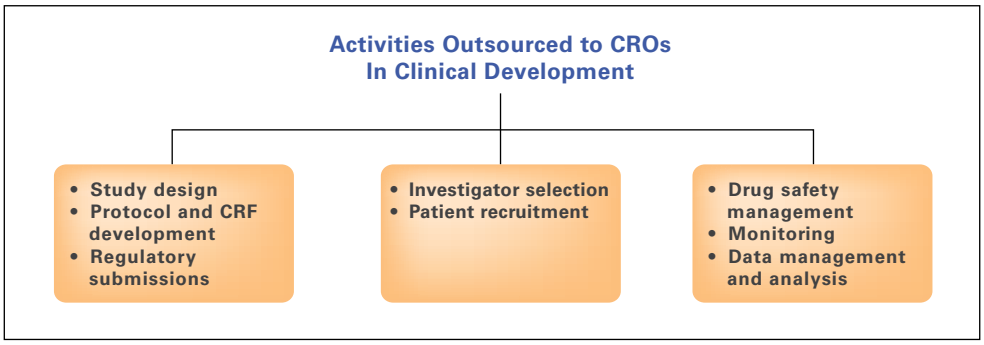
Managing Execution in Clinical Development

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 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, 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.

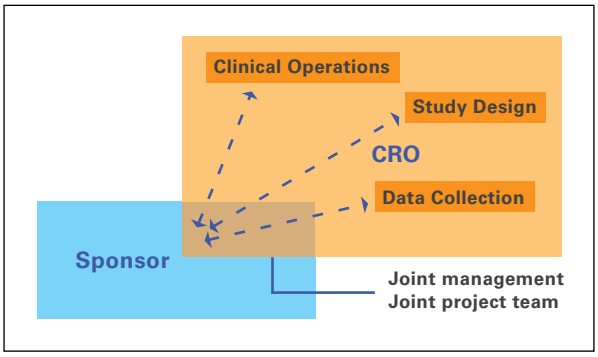
Figure 3



Project managers often wonder whether they are just hapless administrators and reporters of progress, or if they can 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.

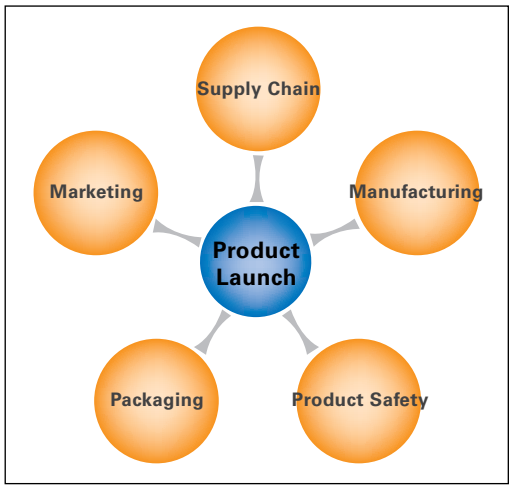
Figure 4



Managing Execution in Commercialization

During commercialization, the majority of 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 dedicated to more than just commercialization or more than 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 they can find and fix problems before it is too late.

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

	Drug Discovery	Clinical Development	Commercialization
Key Challenge	Unknown: 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.

New Method of Execution Management

The nature of projects, structure of teams and goals change as you go from one stage of 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 the same people can work on a number of different projects simultaneously. In execution, uncertainties multiply- delays on one project cascade to other projects through shared resources, the same resource needed on multiple induces multitasking, and projects become less synchronized due to resources not being available as planned.

Therefore, what is needed is a method of managing execution that:

☑ 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.

Such a method is now available - it is based on Critical Chain principles, and has been adopted by leading companies in the biopharmaceutical and other industries.

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

EXECUTION MANAGEMENT RESULTS

	BEFORE	AFTER
Electrical Power Transmission, Engineer-to-Order ABB AG, Power Technologies Division	Throughput was 300 bays per year.	Throughput increased to 430 bays per year.
Transformer Repair and Overhaul ABB, Halle	42 projects completed January-December 2007. On-time delivery of 68%.	54 projects completed January-December 2008. On-time delivery of 83% .
Theme Park Design, Install and Commissioning Action Park Multiforma Grupo	121 projects completed in 2004.	142 projects completed in 2005. 153 projects completed in 2006.
Telecomm Switches Design, Development & Upgrades Alcatel-Lucent	300-400 active projects with 30+ deliveries a month. Lead times were long. On-time delivery was poor.	Throughput was higher by 45% per person. Lead times are 10-25% shorter. 90+% on-time delivery.
Customer Experience Systems – Customized SW Development for Telecommunications Amdocs	8 projects in crisis requiring CEO level attention in 2007. Market pressures to reduce cost and cycle time of projects.	0 projects in crisis in 2008. Project cycle time decreased by 20%. Increase of 14% in revenue/man-month across 4,000 people.
Iron Ore Asset Development Projects BHP Billiton	25,800 man-hours of engineering design work had to be completed in 8 months. Historical delays of 2 weeks and man-hour overruns of 20%.	Project finished 3 weeks early. Productivity increased by 25% with only 19,500 man-hours needed.
Satellite Design and Assembly Boeing Space & Intelligence Systems	Antenna Assembly and Test was the constraint in Satellite delivery.	Antenna Assembly and Test was no longer the constraint in Satellite delivery. Productivity increased by 64% on the next Satellite and a further 26% on the subsequent Satellite.
Nuclear Power Engineering Central Nuclear Almaraz Trillo	19 design evaluation and modification projects were completed per month.	Throughput increased by 25% to 24-30 projects per month.
Nuclear Power Engineering C.N. Cofrentes (Iberdrola)	Due date performance was 60%.	Due date performance increased to 95%. Throughput increased by 30%.
Oil & Gas Platform Design & Manufacturing LeTourneau Technologies, Inc.	Design Engineering took 15 months. Production Engineering took 9 months. Fabrication and Assembly took 8 months.	Design Engineering takes 9 months. Production Engineering takes 5 months. Fabrication and Assembly takes 5 months with 22% improvement in labor productivity.
Advertising Product Development Marketing Architects	Completed 7 projects in 2006.	Completed 7 projects in 8 months of 2007.
Steel Plant Maintenance TATA Steel	Boiler Conversion projects took 300-500 days. Routine maintenance and upgrade took too long.	Boiler Conversion projects took 120-160 days. In 2007, 1st year of Critical Chain, reduced maintenance and upgrade cycle times by 10-33%–saving of $13.4 million. In 2008, achieved a further 5-33% reduction in cycle time.
Defense Products Design and Manufacturing TECNOBIT	Difficult to synchronize Design and Manufacturing. Long project cycle times with frequent delays.	Project cycle times were reduced by 20%.
Automotive Assembly Systems, Engineer-to-Order ThyssenKrupp (Johann A. Krause, Inc.)	70% of projects were late. High overtime and outsourcing.	Lateness reduced by 50%. 63% productivity gain. 15% more projects completed.
Custom Furniture Design and Manufacturing Valley Cabinet Works	Struggled to complete 200 custom furniture projects per year. Revenues were flat, business was just breaking even. A lot of firefighting in execution.	Completed 334 projects in 9 months. Revenues increased 88% and profits increased by 300% in the first year. Firefighting and thrashing eliminated.
Equipment for Manufacturing Solar Panels, Engineer-to-Order Von Ardenne	Revenues of €130 M. Profits of €13 M. Cycle time 17 weeks. On-time delivery of 80%.	Revenues of €170 M. Profits of €22 M. Cycle time 14 weeks. On-time delivery of 90%.

EXECUTION MANAGEMENT RESULTS

	BEFORE	AFTER
Next Generation Wireless Technology Product Development Airgo Networks	Cycle time from first silicon to production for 1st generation was 19 months.	Cycle time from first silicon to production for 2nd generation was 8 months.
Customized Software Development Alna Software	Growth was stagnating, becoming insufficient to secure market position.	Throughput increased by 14% in first 6 months. Cycle time reduced by 25% and project completions increased 17% with over 90% on-time delivery.
IT Projects Celsa Group	15 SAP functionality projects were completed per month.	SAP functionality project completions increased by 30% to 20 projects a month.
Automotive Product Development Chrysler	Cycle time for prototype builds was 10 weeks.	Cycle time for prototype builds is 8 weeks.
Biotechnology Plant Engineering Danisco (Genencor International)	20% projects on time.	87% projects on time. 15% immediate increase in throughput.
Pharmaceutical Product Development Dr. Reddy's Laboratories	In 12 weeks prior to Critical Chain 6 projects were completed; 20% were on-time.	In 12 weeks since Critical Chain was implemented, 11 projects completed; 80% on-time.
Telecommunications Network Design & Installation eircom	On-time delivery was less than 75%. Average cycle time was 70 days.	Increased on-time delivery to 98+%. Average cycle time dropped to 30 days.
Semiconductor Design and Manufacturing e2v Semiconductors	Actual cycle time of projects 38 months; 25% of projects were on-time.	Actual cycle time reduced to 23 months; almost all projects are within the committed cycle time of 24 months.
Home Appliances New Product Development Hamilton Beach Brands, Inc.	34 new products per year. 74% projects on time.	Increased throughput to 52 new products in 1st year, and to 70+ in 2nd year, with no increase in head count. 88% projects on time.
Digital Camera Product Development HP Digital Camera Group	6 cameras launched in 2004. 1 camera launched in spring window. 1 out of 6 cameras launched on time.	15 cameras launched in 2005. 7 cameras launched in spring window. All 15 cameras launched on time.
ASIC Design Technology Development LSI Logic	74% projects on time for small projects. Major tool releases were always late.	85% of small projects on time. Major tools released on time for three years in a row.
High Tech Medical Product Development Medtronic	1 software release every 6-9 months. Predictability was poor on device programs.	1 software release every 2 months. Schedule slips on device programs cut by 50%.
High Tech Medical Product Development Medtronic, Europe	Device projects took 18 months on average and were unpredictable.	Development cycle time reduced to 9 months. On-time delivery increased to 90%.
Food Preparation & Packaging Oregon Freeze Dry	72 sales projects completed per year.	171 sales projects completed per year. 52% increase in throughput dollars.
Pharmaceutical Product Development Procter & Gamble Pharmaceuticals	In 2005 completion rate of 5 projects/Quarter; 55% of projects delivered on time.	In 2008, completing 12 projects/Quarter; 90% of the projects on time, with the same number of resources.
Marketing/Publishing Support Rapid Solutions Group	Projects were always late. Lead times were not acceptable.	On-time delivery improved by 30%. Lead times were reduced by 25%.
Garment Design Skye Group	Product ranges were late to market.	100% due-date performance. 30% reduction in lead times and sampling costs.

EXECUTION MANAGEMENT RESULTS

	BEFORE	AFTER
Engine Repair & Overhaul Delta Air Lines, Inc.	Produced 40 engines per month. 4 weeks piece part cycle time.	Increased production to 50+ engines per month, 16%-26% reduction in engine turnaround time. 2.5 weeks piece part cycle time, 25% increase in piece part throughput.
Helicopter Manufacturing and Maintenance Erickson Air-Crane	Only 33% projects completed on time.	Projects completed on time increased to 83%.
Aircraft Upgrade and Repair French Air Force, SIAé Clermont Ferrand Transall Production Line	5 aircrafts on station. Cycle time of 165 days.	3 aircrafts on station, 2 aircrafts returned to Air Force, replacement value of €300 M. 15% cycle time reduction, 15% increase in output with 13% fewer resources; 22% reduction in support shops' cycle time.
Warfighter Systems Testing US Air Force Operational Test & Evaluation Center	Long cycle times. Low utilization of resources. Poor visibility of project slips.	30% reduction in cycle time measured over 900 projects. 30% improvement in resource utilization. 88% on-time delivery performance.
Aircraft Repair & Overhaul US Air Force, Ogden Air Logistics Center, C130 Production Line	21-24 aircrafts on station.	Reduced to 18 aircrafts on station. 25 out of 26 aircrafts delivered on-time or early. (Accumulated 191 days of early delivery in 6 months total).
Aircraft Repair & Overhaul US Air Force, Oklahoma City Air Logistics Center, B-1 Bomber Line	Turnaround time 162 days. 7 aircrafts in repair cycle.	Turnaround time reduced to 115 days. 4 aircrafts in repair cycle (3 returned to customer). Production output increased from 185 hours/day to 273. 1 1/2 dock spaces freed up.
Aircraft Upgrade and Repair US Air Force, Oklahoma City Air Logistics Center, B52 Production Line	Produced 11 aircrafts a year. Cycle time of 225 days.	Produced 17 aircrafts a year. Cycle time of 195 days.
Aircraft Upgrade and Repair US Air Force, Oklahoma City Air Logistics Center, E3 Production Line	4 aircrafts on base. Cycle time of 183 days.	On average 2.6 aircrafts on base. Cycle time of 155 days. 11% capacity released for additional workload.
Aircraft Repair & Overhaul US Air Force, Warner Robins Air Logistics Center, C5 Production Line	Turnaround time 240 days. 13 aircrafts in repair cycle.	Turnaround time 160 days. 7 aircrafts in repair cycle. 75% fewer defects.
Aircraft Upgrade & Repair US Air Force, Warner Robins Air Logistics Center, C17 Production Line	Throughput of 178 hours per aircraft per day. Turnaround time 46-180 days. Mechanic output was 3.6 hours per day.	25% increase in throughput. Turnaround time reduced to 37-121 days. Mechanic output increased to 4.75 hours per day. 40% overtime reduction.
Army Vehicles Maintenance & Repair US Marine Corps Logistics Base, Barstow	Repair cycle time for MK48 was 168 days. Repair cycle time for LAV25 was 180 days. Repair cycle time for MK14 was 152 days. Repair cycle time for LAVAT was 182 days.	Repair cycle time for MK48 is 82 days. Repair cycle time for LAV25 is 124 days. Repair cycle time for MK14 is 59 days. Repair cycle time for LAVAT is 122 days.
Aircraft Repair & Overhaul US Naval Aviation Depot, Cherry Point	Average turnaround time for H-46 aircrafts was 225 days. Average turnaround time for H-53 aircrafts was 310 days. Throughput was 23 per year.	Reduced H-46 turnaround time to 167 days, while work scope was increasing. Reduced H-53 turnaround time to 180 days. Delivered 23 aircrafts in 6 months. Throughput increased to 46 per year.
Submarine Maintenance & Repair US Naval Shipyard, Pearl Harbor	Job completion rate was 94%. On-time delivery was less than 60%. Cost per job was $5,043.	Job completion rate increased to 98%. Increased on-time delivery to 95+%. Reduced cost per job to $3,355, a 33% reduction. Overtime dropped by 49%, a $9M saving in the 1st year.

The Votes Are Also in

Attendees at the 2004 Project World held in October in Washington, voted, by an impressive majority of 92 percent, not to continue to throw more software at project management software problems. The consensus was that whether it's called 'project portfolio management,' 'enterprise project management' or 'collaborative project management,' they simply get more reports, more graphs, and more useless data. Yet, their projects are still delivered late, over budget and under scope.

"Execution Management is an extraordinarily powerful method which aligns business priorities and product pipeline execution," affirms Medtronic's Steve Schwister. "It provides us with improved pipeline velocity and increased productivity."

Like Schwister, today's executives know that their organizations have to deliver more projects faster, sometimes with fewer resources. Now they no longer need to feel stymied by the limitations of traditional project management, and increase project flow to meet the needs of business.

Is Execution Management right for your organization?

- Is your organization project-driven? Does increasing project speed or throughput translate into higher sales, competitive advantage and customer satisfaction?
- Do your projects require coordination of more than a handful of people and a few tasks? Are resources shared among multiple projects and contention for resources frequent?
- Are your project teams constantly rewriting project plans? Is project administration consuming excessive overhead?

If your answers to the above questions are "yes", contact us at info@realization.com.