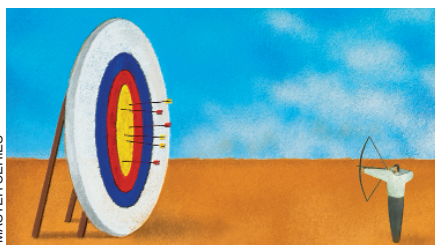


Using Earned-Value Analysis for Better Project Management

EVA allows project managers to refer to tangible numbers, not just a gut feeling, in determining whether a project is advancing on time and within budget

From the outset, all managers expect their projects to come in on schedule and within budget. Unfortunately, according to the Standish Group (www.pm2go.com), only one in five (20%) of all major projects actually meets one or both of those goals. In the pharmaceutical industry, this kind of failure can have enormous consequences: For example, development resources are wasted when a drug candidate is not eliminated soon enough, and foregone profits can result from a delayed launch.

At least 12 factors can derail projects, says John Gioia, president of Robbins-Gioia (www.robbinsgioia.com), a leading project management firm. These include the underestimation of program complexity, requirement creep, a lack of leadership commitment and sponsorship, and the absence of measurable controls. Thanks to the use of a project management tool known as earned-value analysis (EVA), many of these problematic factors can be caught and corrected before failure becomes inevitable.



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EVA is the analysis of a project's actual performance compared with a detailed plan and is performed at various points in the project schedule. Its greatest benefit is risk mitigation. Because EVA takes into account the project scope, schedule, and budget, a project manager can refer to tangible numbers — rather than just a gut feeling — to determine whether the project is advancing on time and within budget.

Like many project management methodologies, including management by objective, EVA is performance centered. However, it supplies an indicator of true cost performance that usually isn't found with other project management techniques. With EVA, project managers have an early warning system that provides the information they need to identify risks and do something about them while there's still time.

"In the past, people monitored their costs by looking at what they budgeted and what was actually spent, then calculating a variance and determining whether or not they were over or under cost," explains Paula Spinner, senior cost and economic analyst for Robbins-Gioia. "Well, that's fine, but it winds up giving you a skewed picture because it doesn't relate to the project schedule, and the schedule is absolutely critical. With EVA, you get the entire picture."

Getting Back to Simple

The Department of Defense began using EVA about 40 years ago, but through the years it created a methodology so complex that other industries viewed the tool as too difficult and costly to use. In the past five years, however, a major push to make the

methodology simpler and more accessible has inspired industries from aerospace to fashion to begin investigating EVA and incorporating it into major projects. EVA's methodology now involves these six steps: Scope the project using a work breakdown schedule, plan and schedule the project estimate and budget available resources, form a baseline, monitor performance against the baseline, and forecast progress and the final costs and schedule.

"**Scoping**" the project involves separating the project into measurable tasks, each of which has an estimated value, and then assigning staff to monitor the performance of each task. On the basis of this first step, a schedule is determined and a budget is estimated.

After the initial setup, managers using EVA can perform frequent and regular analyses to measure any cost or schedule variances and to assess any potential risks that could throw off the project. Of course, EVA is only as perfect as the project itself, but it does provide enough flexibility to give a manager options when variances are too great to overcome. For example, if a project is time sensitive and falls behind schedule but is still within its budget, the project manager can choose to spend more money to align the project to the schedule.

Taking Hold

The pharmaceutical industry is using EVA already, although only sparingly. Merck (www.merck.com) is perhaps the highest-profile proponent, having implemented the methodology as part of its drug development process for years. A few other companies

Outlook

Doomsday, in the form of reduced revenues and profits resulting from blockbuster products going off patent, has finally arrived for major pharmaceutical companies. A number of majors, including Merck (www.merck.com), Eli Lilly (www.lilly.com), Bristol-Myers Squibb (www.bms.com), and Schering-Plough (www.schering-plough.com), have warned that 2002 results will be flat or down relative to 2001 as a result of new generic competition. Compounding that problem is the increasing downward pressure on drug prices from state governments, buying groups, and third-party payers, which are forcing drug companies to offer large discounts and rebates.

The profit squeeze will have several implications for the outsourcing industry. CROs are counting on sponsors to maintain or increase their product development efforts to fill the revenue gaps and maintain historic growth rates. This was an explicit assumption in the recent revenue forecasts of several publicly traded CROs, and sponsor behavior seems to be bearing this out. Bristol-Myers Squibb, for instance, announced that its R&D budget would grow by at least 10% in 2002, and Merck projected a 16% increase in its R&D spending, despite both companies' revenue losses.

That commitment to product development spending should bode well for contractors, but there are some caveats. Cost-conscious sponsors will want to make sure that in-house resources are used fully before going to a CRO, so expect them to look even harder at the justification for each outsourced project contract. Also, sponsors will use their muscle to get the best possible prices from their contractors, so look for more work going to preferred providers as well as tough price negotiations.

Mergers. One response to lower profits that has a downside for contractors would be another wave of mergers among major pharmaceutical companies. Such mergers in recent years (for example Pfizer with Warner-Lambert and Glaxo Wellcome with SmithKline Beecham) have meant project cancellations and program delays until the merged entities sorted out organizational and portfolio issues. Those delays and cancellations played havoc with CRO financial performances two years ago, and with Lilly, Bristol-Myers Squibb, American Home Products (www.ahp.com), and Pharmacia (www.pharmacia.com), among others, still viewed as likely merger candidates, CROs could find themselves replaying 2000 all over again.

Partnering. Ultimately, sustained pressure on sponsor revenues and profits could lead to restructuring that could push certain CROs and contract manufacturers into becoming true strategic partners to their clients. Chronic financial performance problems eventually force companies to take drastic measures to fix underlying issues. Even a \$90 billion colossus such as IBM (www.ibm.com) could not absorb losses forever in its personal computer business; it recently signed a \$5 billion deal to outsource much of its PC manufacturing.

Cutting costs. High profit margins have allowed Big Pharma to ignore many of the tough resource allocation decisions that companies in other industries have had to face. In a more difficult environment, their management's first reaction will be to keep as much activity as possible in-house to cover fixed costs. In the end, however, corporate executives will focus on seriously reducing those fixed costs to maintain profitability while freeing resources for new product development. When that happens, outsourcing may get senior management attention as it never has before.

Contractors Versus Smallpox

Two contract manufacturers scored big in the government's latest award of a smallpox vaccine contract. Both BioReliance (www.bioreliance.com) and Chesapeake Biological Laboratories (CBL, www.cbllinc.com, a subsidiary of Cangene, www.cangene.com) are subcontractors to Acambis (www.acambis.com), which was awarded the \$428 million contract by the Centers for Disease Control and Prevention (CDC). The contract calls for the production of 155 million doses of a smallpox vaccine within 12 months and includes funding of an accelerated clinical development plan. BioReliance will support Acambis with testing and development services for the smallpox vaccine, and CBL will perform the final fill and finish, including lyophilization.

CBL said the contract was the largest in its history, and it recently built a manufacturing suite specifically for handling live-virus vaccines. Capacity that is not used for the CDC contract will be available to the industry.

BioReliance president and CEO Capers McDonald indicated that the company's work with Acambis, on top of preexisting commitments, will use most of BioReliance's available manufacturing and analytical testing capacity through the end of 2002. In a recent interview, McDonald said that BioReliance is moving ahead with plans to expand both its manufacturing and analytical testing capacity. Build-out of the viral manufacturing facility, which will increase manufacturing capacity eightfold, will be completed in the next three years, while expansion of the cell-culture facility in Stirling, Scotland, is under way. The company will add a 37,000-ft² expansion of its analytical laboratory space.

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are incorporating EVA during the marketing phase of new products.

EVA potential. However, the industry has yet to fully recognize EVA's potential for curing some of its more prevalent ills, according to Steve Lines, development program manager for AstraZeneca Pharmaceuticals (www.astrazeneca.com). He believes the tool should be used in both

research and development and marketing — from the beginning of a drug program, through its life cycle, and even when it is rolled up into a single portfolio planning document. This way, EVA can be applied to all products at once, and risk mitigation can be conducted comprehensively on the basis of the performance of every drug in development.

“One of the reasons why pharmaceuticals are so expensive is that only one in 1,000 drugs makes it to market,” he explains. “That’s a pretty lousy success rate. Having the EVA tool available will allow you to kill products that are not worth developing a lot earlier in the cycle. Clearly that would be a great help to the industry.”

Implementing EVA. Yet implementing EVA is not necessarily an easy course. “The devil is in the details,” admits Lines, who adds that even with his advocacy, EVA is incorporated only on a limited basis at AstraZeneca. The tool is not yet applied at the project level, but Lines does use EVA as a kind of scorecard that absorbs critical information — dollars, timing, and resources — about the development of drugs bundled for use in therapeutic areas such as cardiovascular medicine and oncology. The information then is put into an equation, which creates a risk score that can be balanced against a variety of other projects.

Richard Musselman, president and CEO of AvAmed Consulting Group (Lincolnshire, IL), and an experienced

manager of clinical research programs at G.D. Searle (Pharmacia, www.pharmacia.com) and several other CROs, says EVA offers value for any type of project a pharmaceutical company might want to apply it to, including clinical studies. To make the process easier, his firm has developed a project tracking and planning application called P2T2 that incorporates EVA and helps companies better plan and manage their clinical studies during phases 2–4. The program uses an algorithm to study project timelines, resources, associated costs, and deliverables; it even processes as many as 350 associated tasks and 11 different CRO billing rates.

“Plenty of planning tools are out there, but this is the first one that is specific to the

pharmaceutical industry and the intricacies of these types of clinical trials,” notes Musselman. “So it really becomes a powerful planning and project management tool for people who don’t necessarily understand all of the technical components of project management. This tool demystifies all of that.” His firm also can customize the tool to specific sponsor requirements.

Managing Effectively

Whether a manager uses a software application that includes the methodology or simply goes through the steps with or without the help of a project management specialist, EVA can provide a new and successful way to manage projects more efficiently and more effectively (see the “How EVA Works” box). “What you want to do is make better decisions using better tools and data, and that’s where EVA really leverages you,” says Lines.

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How EVA Works

Because EVA can be difficult to grasp, consider its usefulness in this generic example provided by Paula Spinner, senior cost and economic analyst at Robbins-Gioia, a project management firm.

After a project was “scoped” using a work breakdown schedule, it was found to have 10 units that needed to be developed and tested, and each unit required about the same amount of resources. After the broad schedule was determined, the team responsible for each unit developed more detailed schedules, all of which were then put together to form a master project schedule.

The project manager then concluded that the entire project would take 12 months to complete. Each unit would require \$100,000, for a total project cost of \$1 million. After three months, the project’s initial performance review produced these results:

- Three units were scheduled for completion, but only two had been completed.
- The team had forecasted expenditures of \$300,000, and \$300,000 had been spent.

Typically, project managers would conclude that the project is slightly behind schedule but on target with its budget. They might decide to work a little harder to get back on schedule. A different

conclusion, however, would be reached if the team used EVA, which would measure the following seven points of data.

Q: How much work was scheduled for completion at the point of measurement?

A: three units

Q: What is the budgeted value of the work scheduled?

A: \$300,000

Q: How much of the scheduled work is actually completed?

A: two units

Q: What is the budgeted value of the work actually performed?

A: \$200,000

Q: How much has actually been spent?

A: \$300,000

Q: What is the schedule variance?

A: \$100,000

Q: What is the cost variance?

A: Spent \$300,000 to accomplish \$200,000 worth of work.

Thus, at the end of the first quarter, the project has met only 67% of the planned work schedule and is overrunning its costs by 50%. This will result in a significant overrun. The risk mitigation effort can now take effect, enabling management to consider such solutions as adding more people to accomplish the work, hiring less-skilled workers, or taking other steps that will bring the numbers back in line with the planned schedule and budget.