

COSTING METHODS FOR CLINICAL TRIALS: A COMPARISON OF ACTIVITY BASED COSTING (ABC) AND TRADITIONAL COSTING

INTRODUCTION

Today, more than ever before, manufacturers of pharmaceuticals and medical devices must reduce cost and time in bringing new products to market. Since 1992, both the total cost of bringing drugs to market and the length of time devoted to testing and review – which effectively reduces the life of a product's patent protection – have more than doubled. The process now averages more than 12 years.¹

Furthermore, far more products fail than succeed. The Federal Trade Commission estimates that pharma companies market about one of a hundred products for which they have developed patents, and two thirds or more of new drugs that do reach the market do not recover their full costs.²

The costs are extraordinary: A Tufts University study in 2003 estimated that manufacturers now must invest nearly \$900 million to develop a new drug. And once a life sciences product does reach the market, current governmental policy – as well as economic factors – may impact pricing. At present, there is pressure from some lawmakers at both the federal and state levels and from consumer groups to reduce drug prices. Changes in compliance procedures, which add time and cost to the drug-approval cycle, and rising labor costs also have their effects. With all these factors in play, estimates suggest that, in order to maintain profit margins at 1998 levels, today pharma companies must develop *three times* the number of new products.

The goal in the life sciences industry is to bring new products to market as quickly and inexpensively as possible. Yet the industry spends more than \$1 billion annually in the planning, budgeting, Request for Proposal (RFP) process, and contract management of clinical trials alone. Unfortunately, as much as \$700 million of these funds may be wasted on inefficiencies that plague the clinical budgeting, project planning, and outsourcing processes. Since planning and estimating costs for clinical trials are so critical to the successful launch of a new product, it behooves pharma companies to choose the best method of cost estimation. The aim of this paper is to describe and compare two methods of estimating costs: the traditional method employed by the industry, and *activity-based costing* (ABC), a method that while newer to the biopharmaceutical industry, has been standard in other industries for years.

TRADITIONAL COSTING

Traditional costing is based on the premise that the costs of a previous similar project will be a good measure for the costs of the current project, possibly with some adjustments. In the case of clinical trials, estimates are usually based on the *average bid costs* of similar studies in the past.

This approach starts with a sample set of data points. For example, a company might derive estimated costs for a planned phase III clinical study by querying their database for previous phase III clinical studies that had similar characteristics, such as number of subjects, therapeutic indications, and so forth. This method typically produces a range of costs for all the studies in the sample set. The company could then use the average of these costs to estimate costs for the current study. The salient features of the traditional approach are that it is based on *previously known costs* and it is a top-down method.

ACTIVITY-BASED COSTING (ABC)

Activity-based costing uses a different approach. Sometimes referred to as a “project-management approach” or a “bottom-up approach,” ABC starts by determining the level of effort for a specific

¹ Bandow, D. Report from the Cato Institute, July 2000.

² Ward, M., staff economist, Federal Trade Commission

resource (person) to perform a given task (activity). This level of effort is typically calculated using an algorithm derived from experience and analysis of the *cost* and *time drivers* that affect each activity. After calculating the effort (in work hours), one can derive costs for that specific task by factoring in the hourly cost of the person(s) who perform that task. The compilation of costs for all tasks in the project is the total project cost.

So, in the example of the phase III clinical trial, planners would begin by compiling a list of tasks required for the study. Then they would determine the time and cost for the persons performing each activity (including indirect costs), add up all the costs, and arrive at the estimated total project cost.

COMPARISON OF TRADITIONAL AND ABC METHODS

Accuracy

While the traditional method of costing *might* provide an accurate estimate of the cost of a current project, that would be likely only if all factors remain relatively constant from one project to the next. Many experts cite using historically inaccurate or outmoded data as one of the principal causes for misestimating costs. Costs of previous studies, for example, might not accurately reflect current labor costs. In contrast, the ABC method is *based* on current hourly costs for each specific task. Starting with “hours” provides a more accurate reflection of actual costs.

Flexibility

Furthermore, traditional costing is often based on average bid costs of *similar* studies. What if the current study is *similar*, yet *different*, perhaps in study methodology? Now we have a comparison of apples to oranges, and the cost estimates using the traditional method may not be applicable. The ABC method defines tasks upfront (e.g., study methodology), so costing should be more accurate.

Research shows that less than 10 percent of all projects are delivered at their original cost and scheduling estimates.³ This statistic implies either unrealistic initial expectations or changes in the parameters as the project unfolds, or both. A *flexible* costing method provides a better tool for recalculation than an inflexible one. And the traditional costing method is relatively inflexible. Why? Because costs are not “calculated” as they are in the ABC method; they are averages of costs in the sample sets of previous studies. The traditional approach therefore may not show the resulting impact of changes in your assumptions or parameters of the project.

Targeting Unsupported Costs

Another important aspect of the ABC method: Because individual tasks are identified and costed by person hours, it is much easier to determine costs that cannot be justified. With traditional costing methods, planners may realize that costs are out of line, but they do not have the *visibility* to determine why they are out of line, and the subsequent *ability* to negotiate proper adjustments in the manner that ABC provides.

Currency

Costing based on past studies – the traditional method – fails to consider that industry practices have changed dramatically in recent years. Estimates taken from previous data do not factor in changes in study conduct. Algorithms that drive the ABC approach can be adjusted at any time to reflect changes in approach, so they can always be current with evolving industry conditions.

The need for currency is particularly important if planners wish to employ any of the newer development strategies. For example, adaptive clinical trials are aimed at allowing clinical research professionals to monitor the progress of a clinical study and change its design after it is under way. Most of the focus at

³ McManus, J., Rushmore Professor in Management Sciences and Senior Research Fellow at the University of Lincoln. Article written in June, 2006.

present is on dynamic recruitment of study subjects based on the way that certain groups of subjects respond early in a study, but the approach can also be applied to other aspects of the study.

Clearly, traditional costing methods have no provisions for this type of change, but the ABC methodology can easily adapt.

Outsourcing

With traditional methods, outsourcing estimates are usually based on a full-service outsourcing strategy – because that is how outsourcing was *traditionally* done. In contrast, because ABC works at the task and resources level, it can project costs for virtually any outsourcing model, such as Functional Service Providers (FSPs), hybrid studies, sponsor’s internally conducted studies, and contract resources, as well as conventional full-service outsourcing. Since traditional costing is based on older data, these newer models may not have been available at the time those data were gathered.

Efficiency and Cost Containment

Another possible pitfall in using traditional costing methods for current clinical studies is that previous studies were, in all likelihood, conducted by different people, so estimates are based on someone else’s strategy. This could make a little difference or a lot, depending on how much their methodologies differed. The ABC method allows one to modify clinical assumptions at a very basic level, so planners can quickly assess multiple development strategies and select the one that best meets current business goals, whether driven by deadline, budget, or resource constraints. Traditional costing does not consider changes in development strategy or cost-driven assumptions.

Study Achievability

Traditional costing methods are top-down: they operate at the top “cost” level. They are not structured to “see” that underlying assumptions or tasks may conflict with one another and therefore result in a plan that may be difficult to achieve. Because ABC is a bottom-up approach, planners can more easily spot conflicts, make adjustments, and amend estimates to reflect the new reality.

Forecasting FTEs

The ABC method begins with the resource requirements (often called Full Time Equivalents or FTEs) and derives the corresponding cost based on the hours and the level of person required to complete the task. Some traditional costing methods aim to forecast FTE/resource requirements, but they back into their estimates by starting with the cost and then extrapolating the hours required to accomplish the task. This is neither as efficient nor as accurate as the ABC method, which is a true project-management approach.

Facilitating “What If” Analyses

Because of its bottom-up, task-plus-time structure, ABC is well suited for relatively rapid calculation of various what-if scenarios. Planners can easily see the impact of changing multiple clinical assumptions. With traditional methods, this would be a much more laborious – and less accurate – procedure.

CAVEATS

Limitations of ABC

While the preceding comparisons do appear to give a clear edge to the ABC method of estimating costs versus traditional methods, ABC does have some limitations. Since costs are determined by person hours needed to complete individual tasks, how does one allocate costs for “business sustaining” activities that cannot be assigned to individual tasks or even to one project alone? There is no meaningful method, so these costs must be distributed proportionally as nearly as possible. Traditional costing procedures cannot sensibly allocate these activities either, so this issue exists for both methods and is not a reason to employ one method over another.

Another problem is inherent in the very nature of making estimations. Estimation is more art than science in most cases. Will the task take 10 people 12 days to perform? Is one 50 percent certain that the task can be completed by that many people in that amount of time? Sixty percent certain? Experts say one should achieve 80 percent accuracy in order to be able to make reliable cost estimates. Planners must bear in mind that effort, cost, and schedule are all interrelated, so a change in one will affect the other two.

Again, the “certainty” issue hampers both planning methods, but it highlights the importance of being able to create multiple scenarios of a plan very quickly: for example a “best case” and “worst case” scenario that might reflect the uncertainty factor. This *contingency planning* frequently gets brushed aside in an industry where planners – already burdened by long hours and heavy workloads – are lucky to develop one comprehensive operational plan, much less two or three scenarios.

Ingredients for Success Using ABC

- Planners have a working knowledge of the tasks required to complete the project.
- Planners are aware of the indirect cost associated with these activities.
- Planners understand how indirect costs relate to cost drivers.
- Planners can successfully identify cost drivers.
- Planners have the ability to quickly generate multiple scenarios.

The ability to address all of the major cost drivers is a very important aspect of effective planning, and the completeness of these cost drivers is a principal determinant of the accuracy of an ABC costing system.

CONCLUSION

The ABC method of estimating costs has many advantages over traditional costing methods. More costs can be accurately traced to the product under study, which results in the ability to achieve more relevant pricing. In addition, more accurate costs help in the decision-making process. Because ABC has built-in flexibility, study planners can experiment with various what-if scenarios before the project begins and even change the study design – use the adaptive clinical trial strategy – after the study is underway.