



## Increasing Clinical Trial Forecasting & Budgeting Efficiency with Activity-based Costing

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# EXECUTIVESUMMARY

Clinical trial forecasting and budgeting, once a fairly straightforward process, has today become one of the key clinical development areas under heavy scrutiny as sponsors seek greater efficiencies from their processes and portfolios. As studies have become more complex and costly, trial sponsors recognize that gains in efficiency for planning their studies result in faster development cycle-times and reduced trial costs, while maintaining the achievability of studies.

Accurately planning the budget and resource needs for a complex clinical study or a program of clinical studies, however, requires a thorough understanding of the operational work required and the level of effort expended to perform the associated tasks. Unfortunately, this detailed level of information is often not readily available, or is difficult to calculate accurately. In addition, sponsors are moving into new therapeutic areas and geographic regions, and shifting more responsibilities to multiple service providers, adding further complexity to both internal and external trial forecasting and budgeting.

To meet these challenges and gain greater efficiency and accuracy in clinical trials, life sciences companies are implementing key best practices to:

- Shift from “number crunching” to strategic costing and rapid scenario planning
- Anticipate resource demand and cash flows more effectively and efficiently at the study, program, or portfolio level
- Gain greater transparency in outsourced studies and functional outsourcing approaches
- Reduce sponsor/service provider contract negotiation time and effort
- Obtain greater accuracy and consistency of budgeting results, regardless of the nature of the study

This white paper explores one of the central best practices enabling sponsors and services providers to accomplish the above goals: Activity-based costing. A methodology widely – and effectively – used in other industries for years, activity-based costing is being embraced by life sciences companies in increasing numbers.

## Comparison of Activity-based Costing and Traditional Costing in Clinical Trials

### 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

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

Activity-based costing offers benefits for the planning and outsourcing of clinical trials that traditional costing methods do not provide. The table below summarizes the differences between the methods, and the benefits of activity-based costing.

Traditional Costing	Activity-based Costing	Benefits of Activity-based Costing
Based on studies whose development strategies may differ greatly	Reflects internal development strategy; modifiable as strategies change	Better supports efficiency & cost-containment initiatives, by enabling quick assessment of multiple potential development strategies
Based on full-service clinical outsourcing	Can reflect virtually any type of outsourcing	Supports current outsourcing models (e.g. FSP, hybrid studies, sponsor-only studies, contract resources & full-service outsourcing)
Based on average costs in past service provider bids	Based on cost drivers and current assumptions, and work effort	Improves accuracy by considering unique aspects of the study
Starts with overall cost averages then backs into FTE estimates	Starts with required work effort, and then derives costs	More accurate estimates for internal as well as external resource/FTE requirements
Provides only high-level cost & information	Can generate costs, and key metrics, dates, timelines	More complete operational plan, driven from each study's unique assumptions
Data exists at study-cost level	Works at cost-driver level	Improves probability of study success by revealing conflicting assumptions
Applies only to external cost information	Applies to both internal and external costs and resources	Enables accurate calculation of internal as well as external costs and resources to conduct a study

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

*Research shows that less than 10 percent of all projects are delivered at their original cost and scheduling estimates.*

performing each activity (including indirect costs), add up all the costs, and arrive at the estimated total project cost.

## Key Criteria for Evaluating Traditional and Activity-based Costing Methods

### Accuracy

While the traditional method of costing *might* provide an accurate estimate of the cost and resource demand 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 changes in labor costs between different countries or over time. In contrast, the activity-based costing method is based on current hourly costs for each specific task. Starting the planning process with a work breakdown structure and by estimating the required hours to perform that work is a true “project management” approach and will yield a more accurate estimate. This method also allows the accurate forecasting and budgeting of internal costs and resource demands, as well as better management of cash flow and accruals.

### 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 there exists a comparison of apples to oranges, and the cost and resource estimates using the traditional method may not be applicable. The activity-based costing method defines tasks up front (e.g. study methodology), so cost estimates are based on the techniques, strategies, and unique characteristics of *each study*. Activity-based costing also provides more flexibility when “rolling up” studies into programs or portfolios – maintaining accuracy while allowing easier assessment of costs and resources across different dimensions such as therapeutic indication or geographic region.

### Reforecasting

Research shows that less than 10 percent of all projects are delivered at their original cost and scheduling estimates.<sup>1</sup> 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 reforecasting than an inflexible one. And the traditional costing method is relatively inflexible. Why? Because costs are not “calculated” as they are in the activity-based costing 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 activity-based costing 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 activity-based costing 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 activity-based costing approach can

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<sup>1</sup> McManus, J., Rushmore Professor in Management Sciences and Senior Research Fellow at the University of Lincoln, United Kingdom.

*Algorithms that drive the activity-based costing approach can be adjusted at any time to reflect changes in approach, so they can always be current with evolving industry conditions.*

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. Adaptive trials place a far greater burden on the initial trial design, ranging from understanding the potential for changes in resource allocations and demands in areas such as biostatistics and data monitoring, to the need for more accurate simulations of differing trial scenarios and their operational elements.

Clearly, traditional costing methods have no provisions for this type of change, but the activity-based costing 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 activity-based costing 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 models may not have been used at the time those data were gathered or will represent a smaller sample size. In addition, as outsourcing approaches are becoming increasingly complex, traditional costing methods are challenged to gather sufficient relevant data.

#### **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 activity-based costing 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 activity-based costing is a bottom-up approach, planners can more easily spot conflicts, make adjustments, and amend estimates to reflect the new reality.

#### **Forecasting FTEs**

The activity-based costing 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 activity-based costing method, which is a true project-management approach.

#### **Facilitating “What If” Analyses**

Because of its bottom-up, task-plus-time structure, activity-based costing 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 Activity-based Costing

While the preceding comparisons do appear to give a clear edge to the activity-based costing method of estimating costs versus traditional methods, activity-based costing 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 Activity-based Costing

- 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 an important aspect of effective planning, and the completeness of these cost drivers is a principal determinant of the accuracy of an activity-based costing system.

## Conclusion

The activity-based costing method of estimating cost and resource demand has many advantages over traditional 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 cost and resource forecasts help in the decision-making process. Because activity-based costing has built-in flexibility, study planners can experiment with various what-if scenarios before the project begins, change the study design after the study is underway, and even evaluate costs and resources at the program or portfolio level.

## About ClearTrial

ClearTrial provides Clinical Trial Operations (CTO) software that makes the planning, forecasting, and tracking of clinical project and financial performance faster and more accurate. The ClearTrial system creates dramatic internal and supplier efficiencies and cost savings for our biopharmaceutical customers by integrating their clinical operations from Plan to Payment™.

Top 20 biopharmaceutical companies, Clinical Research Organizations (CROs), medical device companies and small biotechs have all embraced ClearTrial software. These organizations have come to rely on ClearTrial's industry intelligence, embedded clinical knowledge, and activity-based planning approach to add speed, flexibility, accuracy, and consistency to their clinical operations. For more information please visit [www.cleartrial.com](http://www.cleartrial.com).