



MAKE LIFE SIMPLER

THE COST CONSIDERATIONS OF OUTSOURCING VS. INTERNAL DEPLOYMENT

Outsourcing as a business practice has been around for centuries and some economists would argue it has been around since man first started providing services to one another. The concept is based on the premise that a specialist company that focuses on a specific functional area can do a better job faster, and at less cost, than a generalist approach whereby you employ all functional areas needed internally. The practice has become entrenched in many areas of industry including the Pharmaceutical and Biotech industry and has fuelled a boom in companies carrying the acronym CRO (Contract Research Organization).

Outsourcing in the clinical development area accelerated rapidly in the last 25 years fuelled mainly by five main factors:

1. Difficulty in aligning the varied clinical functional needs with multiproduct and multi-phased developmental pipelines
2. Increasing domestic internal costs
3. Globalization to reduce overall development costs
4. Harmonization efforts to facilitate globalization
5. Technology advancements.

The impact of technology in gathering and disseminating information is a primary driver of this expansion, which allows low-cost labor providers in developing countries to do the work cheaper than domestic workers.

However, the cost gains from outsourcing can be lost if you don't have a strategic plan addressing critical deployment issues. Let's take a look at the main cost factors companies need to assess to make an informed decision on whether to outsource or to do the services internally.



Fixed Versus Variable Costs

One of the drivers of clinical services outsourcing is the ability to convert normal fixed costs that absorb available capital to variable costs. This tactic adds significant economic value to the company. Instead of using scarce capital to employ potentially underutilized resources (and the facilities needed to support them as a fixed asset), you can employ a variable cost for the functional service when you need it. The impact on your burn rate if you are a biotech company can be significant and for pharmaceutical companies the economic value is boosted.

Employment Costs

A reduction in labor costs is another leading driver for choosing outsourcing clinical development services. It is important to analyze the true cost of the outsourced service compared to your internal cost. The overall cost of the labor is made up of several components. To evaluate the true wage cost between internal resources and the CRO, the following items must be considered:

1. Hourly wage
2. Benefit Cost
3. Federal income taxes
4. State or Provincial income taxes
5. Local or City income taxes

CROs will typically roll all of these items into their hourly wage cost in their rate cards to come up with a fully loaded wage rate. Pharmaceutical and biotech companies typically look at only the hourly rate without the employment costs, which run around 34% in the United States (see Table A). Therefore, many internal cost analyses are understated by 34%. When considering the employment costs in developing countries, the difference can be significant. The difference between the United States and developing countries like India (16.75%) and China (20%) can be as much as 17%. The hourly wage rates in developing countries (Table B) are much lower than the developed countries, and this presents one of the major cost advantages for off-shoring labor in addition to less employment benefit taxes and facility costs.



Table A. Breakout of Employer costs for employee compensation, September 2009. US Dept of Labor.

	Civilian	Private ind.	State & local Govt
Wages and salaries	69.7%	70.7%	65.9%
Benefits	30.3	29.3	34.1
Paid leave	6.9	6.8	7.6
Supplemental pay	2.6	3.0	0.9
Insurance	8.6	7.8	11.5
Health benefits	8.1	7.3	11.1
Retirement	4.4	3.4	8.1
Defined benefit	2.7	1.5	7.3
Defined contribution	1.7	1.9	0.8
Legally required	7.8	8.2	6.0

Table B. Comparison of Hourly compensation costs in U.S. dollars. US Dept of Labor, 2009

Country or Area	1996	1998	2000	2002	2004	2005	2006	2007
United States	22.11	23.12	24.63	27.01	28.94	29.74	29.98	30.56
Argentina	7.32	7.87	8.05	2.98	4.47	5.45	6.57	7.98
Brazil	7.12	6.69	4.31	3.07	3.81	5.01	5.99	7.13
Canada	19.01	18.08	18.68	18.78	24.20	26.73	29.27	31.91
Mexico	2.32	2.37	2.89	3.44	3.34	3.57	3.72	3.91

Overhead (General & Administration) Costs

A critical analysis of the true cost of a service for internal consumption requires you to look into your internal overhead costs. CROs will add overhead costs to their labor costs, which internal analyses rarely consider. The CRO overhead costs can range from 10% to 27%. Pharmaceutical companies' G&A costs often run between 20% and 60%. Once you have your company's G&A costs, you can apply this to your available labor costs. So, if your hourly wage for a full time principal statistician is \$56 an hour, you would add 55% to that cost to come up with your fully loaded cost of \$86.80. In some instances, the G&A cost difference may be small if choosing between a global full-service CRO or doing it internally.



The following are some overhead costs that impact total cost:

1. Legal services
2. Accounting services
3. Marketing services
4. Sales services
5. Executive management
6. Facility costs
7. IT costs
8. R&D costs
9. Training
10. HR
11. Quality Assurance
12. Finance
13. Purchasing

CROs are typically lower priced (compared to your internal costs) due to their low overhead and labor and employment costs (depending on where they are located). The important criteria for a full service approach employed by a sponsor company require that the overhead cost for each functional area of expertise needs to be rolled up into the overall G&A cost. In the case of a full-service, global CRO, the difference could be less pronounced since they have similar organizational structures to the manufacturer, with the exception of R&D costs. The difference between the CRO and manufacturer's costs could be as high as 40%.

Time Estimation

When determining outsourcing costs, you also need to estimate the amount of time needed to complete the task. To do so, you need a well written protocol that limits the interpretation of what is needed and how long it will take. The sponsor and CRO must be in agreement on the outcome to be achieved and the time associated with meeting that outcome. Once this agreement is reached, a true comparative cost can be attained.

If your company has a detailed time reporting system or sophisticated financial/CTMS operating software based on clinical trial tasks, then you can determine the time associated with that general task as a starting point. However utilizing benchmarking as a tool to estimate costs has some inherent problems associated with its use. For instance, since it is based on historical data, it does not take into consideration new approaches and technology, or seasoned project managers who may be able to get the project running and finished faster.

Professional negotiators reducing initial estimates through reverse bid options, benchmarking, and the internal pressure to underestimate the project scope to get funding, all present a challenge to develop a true cost estimate of a particular task.



Scale of Management

The amount of time required to manage resources – especially when quality issues arise – also needs to be quantified. When a sponsor decides to develop a particular functional service they will need to employ a project manager and/or an alliance manager to work with the selected CRO. Depending on the scale of the project and the service required, this could include a team of individuals to ensure quality. Typically the scale of management within CROs is larger (meaning more people and projects are managed per person) than in pharmaceutical and biotech companies, which reduces the cost. It is not unusual for a CRO to have one project manager for multiple projects, whereas the sponsor will typically have one project manager for each project and will have layers within each supporting department reporting into them.

When evaluating the cost of management on whether to outsource or not, you also need to assess the internal management costs associated with each department that affects the project. Typically this area of cost is undervalued in the internal development assessment. And don't forget to consider any resulting quality and time delays if the scale of management is too large

Support Services

The fourth cost-related issue relates to the support services you will have to increase to bring additional resources on board: mainly the IT and facility requirements to employ the needed resources. If you consider the option of employing SAS programmers, for instance, you will have to provide a desk, computer, software, email, internet access, and IT support. You may even have to rent additional space. Typically CROs build into their cost models the support needed and offer different choices on where and how they interact with your assigned project manager. Conversely if you are not at full capacity with your facility and have more efficient IT support services than the CRO, then this cost difference could be minimal.

Recruitment Time

When comparing outsourcing to internal resources, many sponsors often overlook what it costs to recruit and hire personnel. To fill an open internal position typically can take up to six months. A CRO with recruitment staffing can typically employ and train a person in one to three months. Many CROs keep a pool of readily available candidates to fill positions as they come up.

The shorter the recruitment time, the faster you can get a product to market. Depending on the drug developed and the size of the market, saving one to three months can equate to millions of dollars, which easily can justify outsourcing a particular service.



Utilization Cost

Another issue to consider is the utilization cost associated with carrying essential employees who are underemployed. Timing the utilization of the needed resource amongst all of your trials can be daunting, especially when you consider the number and different phases that have to be aligned with functional needs.

Having enough critical clinical staff on hand for when you need them is the main driving factor why many companies chose to outsource in the first place. Conversely, keeping certain clinical support staff around when you have only a few products in the pipeline will result in underutilization of the employee and drive up your costs. For instance, timing exactly when you will need a statistician among multiple clinical trials is challenging due to the feast and famine nature of their role during the trial. A lot of work is done up front creating the format of the tables to be used. Then, they have to wait for the data to come in to analyze it. Medical writing also follows much the same routine in regard to the clinical development process, but can be utilized in other areas like publications to maximize utilization. CROs offer the opportunity to smooth out these utilization gaps when they occur.

At first, their service may appear more costly when compared on an hourly basis. However, if you consider the utilization cost of that internal person, the cost can be substantially less. To calculate the utilization rate of internal staff you need an accurate time reporting system and/or a CTMS system which identifies actual tasks associated with that position. The counterbalance to underutilization of resources is the reduced training time it takes to get new resources up to speed. So when analyzing this cost, both areas need to be assessed.

Summary

Several important cost factors need to be considered to determine whether or not to outsource some or all of your clinical development and operational needs. Once you have calculated all of the cost factors, you are ready to evaluate the different outsourcing approaches and the strategies to maintain control of your trials. After evaluating all of these areas you will be ready to make an informed decision on whether to internally develop or outsource your needs.

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