THE 3E PRINCIPLE OF OUTSOURCING

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Drivers of outsourcing and influencers of partner selection vary on the basis of the imperatives and strategy of the sponsor organization and what is desired to be outsourced.

Reasons for outsourcing go far beyond labor arbitrage, which is considered the core reason most companies choose to use an outsourcing "partner." There are unprecedented shifts in the way biopharmaceutical companies conduct their business today, partially forced by macroeconomics, politics, population growth and aging, and the "flattening" of the globe, all of which provide previously unknown opportunities and challenges.

There is enormous pressure on the management of these companies to perform the concurrent miracles of significant cost reductions with simultaneous productivity improvements in order to thrive in their business. Drug discovery and development are becoming more complex and more resource intensive, despite increased automation. There are daily headlines of massive layoffs and facility closures. No corner of the business, regardless of the geography, is immune from these pressures.

As a consequence, the amount of outsourcing/out-tasking/off-shoring that the biopharmaceutical industry has undertaken has increased. While this industry has been late out of the starting blocks, the lost time is being rapidly made up. Variations on the theme are diverse and include captive centers, joint ventures with global outsourcing companies, major expansion of use of clinical research organizations (CROs), use of diverse geographies, and any other creative aspects companies can envision.

We outline three key areas of consideration for outsourcing, specifically in the context of outsourcing knowledge-based functions in drug development and postmarketing in the areas of safety and risk management, statistics and programming, and scientific writing. We call it "The 3E Principle" which encompasses the "whys" of doing business together. Each company's priorities differ, and the relative importance of these three principles in partner selection decisions also differs by the function that is being outsourced. The 3Es are Effectiveness, Efficiency, and Economics. We describe below what we mean by each of these.

Effectiveness. Effectiveness encompasses delivering quality and regulatory compliance, consistently and reliably. Given the volume, magnitude and variety of the functions and tasks involved, and the need to adapt processes to evolving regulations, it is a significant challenge for the sponsor company to comply effectively. Niche partners who focus on specific areas and make it their business to continually learn, adopt, evolve and comply, day after day, help realize the desired effectiveness.

Efficiency. Efficiency is defined as the ability to manage "peaks and valleys" in workload with minimal impact on productivity and cost. Specialized outsourcing partners provide just-in-time resources in fully outsourced or hybrid models.

Economics. Labor arbitrage is an important reason for outsourcing and off-shoring. Cost reduction without compromising quality and compliance is the key principle. The goal is to select outsourcing partners who absorb employee overheads, nonproductive time, etc, in a seamless manner, while maintaining the economic advantage.

Let us now analyze how "The 3E Principle" applies to each of the following service areas:

- Safety and Risk Management (SRM)
- Scientific Writing
- Statistics and Programming

Safety and Risk Management

Patient safety is clearly of paramount importance in drug development and marketing. Regulatory reporting compliance is critical for each reportable adverse event and each aggregate safety report. Compliance with company SOPs is also extremely important. The pharmacovigilance function tends

to be most scrutinized by regulators, and any noncompliance is likely to lead to serious consequences. Changes in the drug development process, globalization, and the dynamics of collaboration in the biopharmaceutical industry lead to evolving regulations for safety reporting in many regions of the world. Hence, subject matter expertise and ability to be on top of changing regulations is a key requirement for sound pharmacovigilance operations. Hence the first "E," ie, effectiveness, is often a driver for outsourcing and thus is a mandatory requirement of any outsourcing partner.

For a mid-to-large-size pharmaceutical company with a sizable portfolio, the impact of volume fluctuations on resource needs is not high. Process and productivity improvements are expected on an ongoing basis given the nature of the business, and these are important. Overall, however, efficiency ranks lower than effectiveness as part of the decision to outsource and vendor selection.

In our experience, cost reduction is a major consideration for mid-to-large pharma companies when they decide to outsource safety operations, especially postmarketing spontaneous reporting. Though the entire SRM was considered to be a CORE function until a few years ago and hence was retained in-house, with the increasing pressure on R&D productivity and cost reduction, companies are now interested in outsourcing safety operations and retaining the strategy in-house. They find ways of minimizing the risk in outsourcing, for example, by outsourcing only the data entry part of single case processing while retaining triage and medical review with themselves, or outsourcing a subset of cases (eg, literature cases) where the risk and impact of failure are low.

Small companies that have only a select set of products, on the other hand, tend to be highly risk averse since they have so much at stake with just one or two molecules that they are developing. However, they also don't have the wherewithal to set up safety operations in-house. Thus, they are forced to outsource, but they tend to outsource to established near-shore providers rather than selecting the option of offshore delivery. Cost reduction isn't as important a consideration for such companies.

For the risk management part of SRM and for other safety activities that are resource intensive but also require significant domain expertise (eg, writing periodic safety update reports and performing signal identification and analysis, running patient registries as part of Risk Management Plans), effectiveness and efficiency feature higher than economics when outsourcing decisions are made.

The 3E Matrix (Hierarchy of Relevance of the 3 Principles)

	Mid-to-Large-Size Companies	Small Companies
Safety Operations	Effectiveness	Effectiveness
	Economics	Efficiency
	Efficiency	Economics
Risk Management, Other Safety	Effectiveness/Efficiency	Effectiveness
	Economics	Efficiency
		Economics
Scientific Writing	Efficiency	Effectiveness
	Economics	Efficiency/Economics
	Effectiveness	
Statistics and Efficacy Programming	Efficiency	Effectiveness
	Effectiveness	Efficiency
	Economics	Economics
Safety Programming, Mapping	Economics	Effectiveness
	Efficiency	Efficiency
	Effectiveness	Economics

Scientific Writing

We define scientific writing as comprising safety writing (aggregate reports, etc), clinical writing (clinical study reports, protocols, IBs etc), regulatory writing (sections of CTD involving clinical/nonclinical overviews and CMC manufacturing changes, as well as Integrated Summaries of Safety and Efficacy) and preparation of medico-marketing literature (such as product toolkits, product-specific and therapeutic area-specific training for sales and marketing personnel and manuscripts for publications).

Although there are some differences across different categories of writing, for scientific writing as a whole, the primary driver for outsourcing work is the need to have adequate resources available when required (in order to deliver on regulatory reporting compliance or any other deadlines). Achieving compliance is challenging, primarily from a resourcing consideration rather than due to evolving regulations. Thus, efficiency is the main driver for outsourcing of scientific writing work and is a major criterion for partner selection. In today's environment, economics comes in second ,and effectiveness is the third principle that plays a role.

Statistics and Programming

Though it is natural to combine statistics and programming, the drivers for outsourcing statistics tend to be quite different from the drivers for outsourcing programming work. We define statistical services as comprising statistical contribution to study design, planning, oversight, and conduct of the statistical analysis of clinical trial and any other related data. For the purpose of this discussion on outsourcing, we could segregate programming into safety programming and mapping on one hand and efficacy programming on the other hand.

Due to the increased focus on making trial designs more efficient, the requirement for statistical resources has increased significantly. At the same time, due to acquisitions and portfolio rationalization, both the peaks and valleys get accentuated in the context of statistical services. The regulators come out with new guidance documents in order to provide some direction to the industry about new statistical methodology required to make design and analysis more efficient. This implies that the statisticians performing the outsourced work have to keep abreast of all new guidelines on an ongoing basis and need to have good subject matter expertise. The volume, and hence budgets, for outsourcing statistical work are quite low, so cost reduction doesn't feature as a major driver for outsourcing these activities. Thus, we believe that efficiency is very important, with effectiveness coming in at a close second and economics trailing behind the other two principles.

The primary consideration for outsourcing domain-intensive efficacy programming work is similar to that for outsourcing statistics work, so efficiency is the most important principle that is applied when decision to outsource such work is made and vendors are selected. However, the outsourcing budget for programming tends to be higher than for statistics, since the volume of work and number of resources required are much higher. Thus, effectiveness and economics are about equally important.

The volume of work involved in safety analysis and mapping data between standards is higher for mid- to large-size companies than for small companies. At the same time, large companies tend to have established libraries of programs and macros that can be used repeatedly. Hence, economics tends to be the primary driver for the selection of a provider for outsourcing. Efficiency is the second most important consideration, since the peaks and valleys apply equally to safety programming and efficacy programming and statistics. Effectiveness would rank third among the 3E principles.

For small biopharmaceutical companies that typically don't have statistics and programming capability in-house, effectiveness ranks at the top for outsourcing decisions, with efficiency coming second, and economics in the third position. There is no differentiation across statistics, efficacy programming, and safety programming in the case of these companies. ■

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