*Original Research*

# Taking the Pulse of Strategic Outsourcing Relationships

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## ABSTRACT

**Purpose:** Articles in peer-reviewed journals and the trade press presuppose that strategic outsourcing relationships have been formed to replace preexisting collaborative approaches with contract research organizations. They do not consider that large, fragmented pharmaceutical and biotechnology companies may be supporting competing and conflicting relationship models simultaneously. A recent Tufts Center for the Study of Drug Development study quantifies actual strategic outsourcing practices among drug development companies and sheds new light on why these relationships may be failing.

**Methods:** Tufts Center for the Study of Drug Development conducted an in-depth assessment of 43 Phase II and III clinical studies completed since 2012 to examine the outsourcing relationships used by 9 major pharmaceutical and biotechnology companies to support key functional areas. Descriptive statistics were assessed and *t* tests were performed to characterize outsourcing practices by function and to determine differences in study performance between transactional and strategic outsourcing relationships.

**Findings:** The results indicate that sponsor companies are using a variety of outsourcing relationship models to support their studies, mixing and matching the use of internal staff, and using traditional transactional and strategic outsourcing relationships simultaneously. Specifically, despite the fact that each sponsor company had entered into several strategic outsourcing relationships, in no instance did a single contract research organization manage all functional areas supporting an individual Phase II or III study. In addition, sponsor companies vary the types of outsourcing relationship models that they use on a study-by-study basis.

**Implications:** The inability of pharmaceutical and biotechnology companies to consistently embrace and coordinate sourcing strategies is creating internal friction and inefficiency. As a result, the expected impact of strategic outsourcing relationships on drug development performance, quality, and cost remains elusive. (*Clin Ther*. 2014;36:1349–1355) © 2014 Published by Elsevier HS Journals, Inc.

**Key words:** contract research organizations, functional relationships, outsourcing, pharmaceutical company, research and development, strategic alliances, transactional relationships.

## INTRODUCTION

In 2014, half of every pharmaceutical research and development (R&D) dollar was spent on contract service providers. Moreover, the level of R&D spending apportioned to outsourcing will likely continue to rise.[1] The current operating environment demands more variable infrastructure from an integrated and coordinated collective of internal and external sources to support complex, global R&D programs.

During the past 20 years, the decision to hire contract service providers was driven in large part by the need to employ a variable head count to support peak periods of drug development activity. Sponsor companies also looked to their contract service providers to gain access to scientific expertise and for assistance in expanding into unfamiliar emerging global regions.[2]

More recently, pharmaceutical and biotechnology companies have experienced massive downsizing and consolidation, in part due to global economic conditions. According to Challenger, Gray & Christmas, Inc

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(Chicago, Illinois), since 2003, >325,000 biopharmaceutical positions have been eliminated, with an estimated 35% of the total coming from R&D divisions.[3] As a result of downsizing and other cost-saving measures, pharmaceutical and biotechnology companies are turning to outsourcing to supplement or replace critical functional support that is no longer available internally.

At the same time that the receptivity to and use of outsourcing are increasing, a growing number of pharmaceutical and biotechnology companies have implemented more integrated and coordinated engagements with partnered contract research organizations (CROs). In contrast to traditional outsourcing relationships, where sponsor companies contract with service providers to deliver single or multiple tasks on a per-project basis, these newer strategic relationships involve CRO companies providing single functional or multifunctional support for entire programs across large portions of sponsor company portfolios.

Strategic relationships hold the promise of offering higher levels of efficiency at lower cost to the sponsor organization through the use of advanced planning, dedicated staffing, shared governance, and shared data and management control systems and procedures, with fewer sponsor staff overseeing CRO execution. These relationships are typically established under preferred pricing arrangements, offering cost savings to the sponsor.

All of the top 30 largest pharmaceutical and biotechnology companies have now entered into ≥1 strategic outsourcing relationship.[4] Major sponsor companies establish a mean of 3 strategic relationships to support their portfolios. However, although strategic outsourcing relationships have been widely adopted during the past 7 years, there is little evidence to suggest that they are contributing to faster and more efficient R&D activity on a consistent basis.

Research by the Tufts Center for the Study of Drug Development (CSDD) indicates that drug development remains a highly risky activity. Only 16% of drugs entering clinical testing today are approved by the Food and Drug Administration, down from 21.5% in the 1990s.[5] Tufts CSDD research has also shown that clinical phase durations are 15% longer than they were in the early 1990s and that sponsor companies must typically double the planned enrollment period to give investigative sites enough time to recruit study volunteers and complete a given clinical trial. In addition, between 2003 and 2013, the pharmaceutical industry spent a cumulative $1.3 trillion (US$) on R&D, resulting in 296 new drug and biologic approvals. This translates into $4.4 billion (US$) mean annual cost per approved molecule. In that 10-year period alone, the mean development cost per new chemical and biologic entity increased 30% from the first half of the decade to the second half.[6]

Initial reports in 2010 from 2 early adopters—Pfizer, Inc (New York, New York) and Eli Lilly & Co (Indianapolis, Indiana)—suggested that strategic, integrated relationships resulted in cost savings, largely through reductions in the level of oversight required and in the number of vendors bidding on project work. Eli Lilly, for example, reported 20% cost savings on data management and monitoring and a 93% improvement in monthly patient enrollment volume. Pfizer reported saving $20 million annually through consolidated management of its vendors, from 150 to 17; a 26% reduction in enrollment cycle time; and an 80% reduction in the number of contracts delayed by >120 days.[7]

But recent assessments from a variety of sources, based on much larger numbers of sponsor companies, present a more mixed picture. For example, a study of 89 sponsor companies conducted by the Avoca Group (Princeton, NJ) in 2012 found that 1 of 5 sponsors had terminated a strategic relationship with a CRO. That same study noted that approximately one third of sponsors surveyed were not satisfied with the performance of their strategic relationships, and nearly half did not believe that their strategic relationships would ever achieve the intended outcome.[8]

A 2013 study conducted by Vantage Partners (Boston, Massachusetts) of 81 sponsor company representatives and 88 CRO company representatives found that a large percentage of strategic relationships were unable to establish a collaborative working style and failed to align expectations and capabilities. In addition, one third of the sponsor organizations reported that their strategic alliances had not delivered expected cost and time savings, and 56% said that their relationships were not delivering innovative solutions.[9]

In 2012, as part of a broader study, Tufts CSDD assessed the frequency of change orders in studies for which most of its budget was allocated to contract service providers. Change orders are defined as formal, written changes to the original scope of work agreement. Tufts CSDD hypothesized that strategic relationships would result in fewer change orders because the parties share planning and governance, and the CRO partner is given more autonomy to manage the study. However, the findings revealed no