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Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

R&D Management REPORT

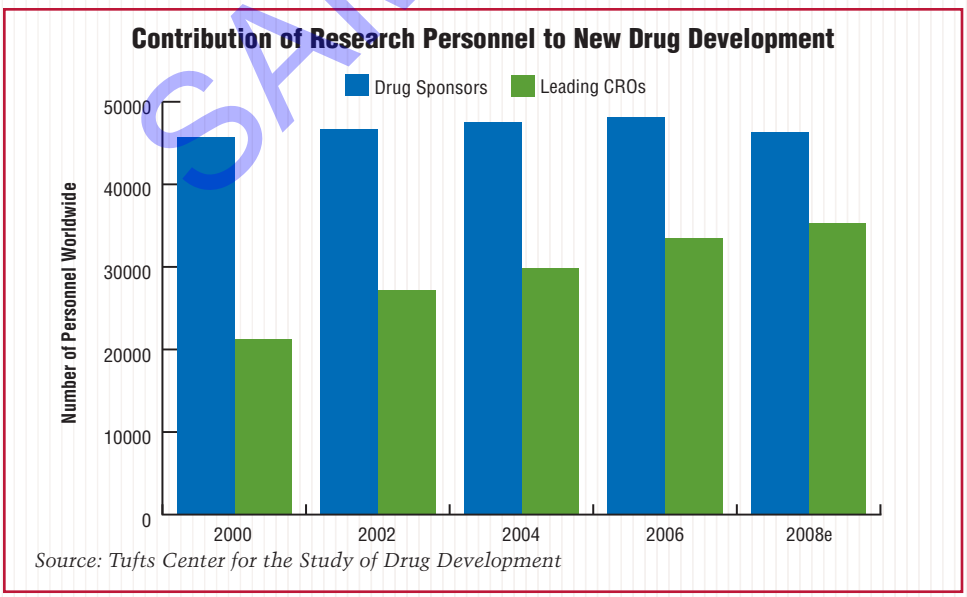
Moving Drug Development Outsourcing to a Higher Level

Outsourcing one or more of the many complex steps in the drug development process is shifting into higher gear, driven by drug sponsors' need to improve R&D productivity and get more products to market faster. The historical, transactional approach to outsourcing, where sponsors manage the entire development process, but engage contract research organizations (CROs) and other service providers to handle specific tasks, is giving way to more integrated partnerships. In this new approach, both parties interact more as equals, drawing on their respective experiences and knowledge, enabling them to leverage capabilities and create greater efficiency and flexibility to solve problems jointly.

The need for sponsors to improve relationships with external partners is paramount: for the first time R&D budgets, in addition to sales and administrative costs, are being cut, partially in response to the current global economic slowdown.

In May 2009, Tufts CSDD convened a roundtable of senior managers from pharmaceutical and biopharmaceutical companies and CROs to share insights on this changing landscape. All agreed that the research-based drug industry is shifting its approach to R&D, but they acknowledged that the pace of change has to proceed much more rapidly if sponsors are to remain competitive. Speeding up R&D is the order of the day, but so, too, is maintaining an absolute commitment to quality. This report summarizes major points made by roundtable participants.

Demand for outsourced clinical services continues to grow



Source: Tufts Center for the Study of Drug Development

Stronger, deeper partnerships between drug sponsors and CROs may be the key to reducing cycle time and lowering development costs. Although the number of companies with active clinical projects worldwide increased by 80%—from 1,167 in 2000 to about 2,100 in 2008—sponsors have kept their R&D headcount even, as shown at left. CROs made up the difference by increasing their headcount by 65%. Both parties, under pressure to improve R&D efficiency, expect to work ever more closely, moving from traditional transactional relationships to alliances.

Challenges in current approaches to outsourcing

The traditional approach to outsourcing, in which the sponsor essentially views the external service provider, frequently a CRO, as providing a way to quickly staff up for specific tasks, continues to work. Outsourcing lets sponsors reduce internal headcount while still executing critical tasks. In fact, a Tufts CSDD study found that high CRO usage projects tend to be completed faster compared to projects involving low-CRO usage. Also, median time to final database lock was found to occur significantly faster—by two weeks on average—for projects in which a majority of the work was managed by contract service providers.

However, prevailing outsourcing practices bring distinct challenges. Among them are the following:

- Redundancy of personnel between sponsors and external service providers, due often to a high level of project oversight on both sides
- Substantial out-of-scope costs
- Sponsor difficulty in managing a large, fragmented group of niche and full-service providers
- Minimal to no integration of operating processes and systems between sponsors and external service providers

In addition, many sponsors continue to grapple with developing a full understanding of their internal costs—to decide whether to outsource, and, later, to assess how much was saved. This is an industry-wide issue that is compounded by the lack of historical, activity-based costing models.

Moving from FIPCo to FIPNet

Value-added outsourcing that more fully integrates sponsors with external service providers is about moving from vendor relationships, that emphasize an oversight function on the part of the drug sponsor, to partner relationships, in which success depends on the sponsor's developing insight into the way external partners operate and leveraging those partners to provide non-core capabilities.

A growing number of large biopharmaceutical companies are making efforts to transform themselves from a Fully Integrated Pharmaceutical Company (FIPCo) to a Fully Integrated Pharmaceutical Network (FIPNet). The intent is to improve capacity to create better patient outcomes and attain portfolio goals. A FIPNet strategy typically moves through specific levels of engagement, as follows:

- **Level 1** – Sponsor outsources specific functions
- **Level 2** – Sponsor shares R&D costs and risks with external partners
- **Level 3** – Sponsor and external partner make equity investments in new products

A successful FIPNet strategy will likely lead to decreased operational expenses, increased R&D flexibility that allows shifting of investments to meet strategic goals, shorter cycle times, and greater opportunity to develop new capabilities between partners.

Sponsors looking to transition to FIPNet—that is, to move from a traditional, transactional-oriented to a functional-outsourced model—need to answer the following questions:

- What functional areas and support services will be needed to account for all previously outsourced tasks?
- How does the internal study management organization need to change to adapt to a functional servicing management orientation?
- What tools/processes are needed to support and facilitate this change?

At its core, FIPNet creates a strategic partnership that defines new relationships, *illustrated below.*

Pharmaceutical and biotech senior executives expect that alliances with external service providers, a defining element of FIPNet, will yield important benefits. In interviews with Tufts CSDD, one said, "FSP and alliance relationships do away with the 'beauty contest' aspects of outsourcing. They focus on extending and supplementing functional capabilities and shortening initialization times." Another noted, "Transactional relationships are all about cutting cost. Alliances will likely be more expensive initially, but long-term we expect to be able to manage our costs more effectively and reduce redundancy."

Making the transition work—while ensuring quality of existing projects and avoiding site or program disruptions—involves several steps. Among them: identifying critical paths and minimizing overlap between service providers, and developing critical communication pathways for existing CROs, internal stakeholders, and investigational sites. One chief operating officer at a global drug developer helps increase the likelihood of success when working with a CRO by holding his internal team responsible for program results. That is, the internal team can't blame shortcomings on the CRO; it has to figure out how to make the relationship work.

Governance is key

Governance is key to making FIPNet relationships deliver value. It starts with both parties obtaining full support and ongoing participation of their senior executives. Agreeing on mutual expectations and success measures is as important as clearly defining roles, responsibilities, operational processes, and systems. Flexibility and adaptability, supported by open and frequent communication, enable the high level of collaboration needed to quickly solve problems that typically emerge in clinical development.

A biopharmaceutical sponsor with nearly 2,000 employees worldwide employs a two-tiered governance strategy, with responsibilities assigned as follows:

Operational Management Team (OMT)	Executive Oversight Committee (EOC)
Key managers from both organizations are jointly responsible for: • Ensuring successful day-to-day interactions • Managing and delivering resources as needed • Reviewing operational performance	Senior managers from both organizations together are responsible for: • Establishing a joint vision, values, and culture • Ensuring that the collaboration remains forward focused • Deciding issues that get escalated from OMT

The path toward becoming development partners

Sponsors and CROs expect their use of transaction-based outsourcing to diminish—but not disappear—over the next five years. This approach will be augmented increasingly by portfolio-based relationships. R&D success will require sponsors and CROs to operate under a number of models, ranging from insourcing to alliance partnerships and full service outsourcing.

Full service outsourcing , in which a CRO conducts all studies for a particular compound, offers distinct advantages, and may emerge as an important path forward, especially for smaller, research-based companies with limited resources. However, this approach also poses important challenges for sponsors and outsourcing partners, as follows:

Full Service Outsourcing

Advantages	Challenges
• CRO develops expertise in a certain class of drug and offers strategic development insight • CRO and client teams form strong relationship with fully dedicated resources • Sponsor takes advantage of a CRO's entire service offering and associated efficiencies • CRO provides strategic insight and functions as a development partner • Fosters innovation, cooperation, and operational efficiencies • Streamlines contracting and invoicing processes	• Project holds or cancellations make it difficult for CROs to staff-up and plan • Experience of the CRO program team must be of very high caliber • Sponsor shadow team can derail efficiencies • Mixed outsourcing models can lead to confusion

Upcoming Tufts CSDD Executive Forum Roundtables in Boston:

The Tufts CSDD Executive Forum provides a unique opportunity for senior pharmaceutical and biopharmaceutical leaders to engage in frank and open discussion on R&D strategies and practices, and share ideas with industry peers in a neutral setting. The next Roundtables in 2009 will be held on:

September 10, 2009 **Best R&D Practices of Top Pharma/Biotech Performers**
November 12, 2009 **Comparative Approaches to Capacity Forecasting**

For more information, call 617-636-2170, email csdd@tufts.edu, or visit http://csdd.tufts.edu.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums.

Tufts Center for the Study of Drug Development
Tufts University
75 Kneeland Street, Suite 1100
Boston, MA 02111 USA

Tel 617-636-2170
Fax 617-636-2425
Email csdd@tufts.edu
Web http://csdd.tufts.edu