A business model for sustainable, strategic relationships

Historically relationships between CROs and pharmaceutical and biotech companies, and the results of these relationships, have not met shared expectations for strategic value exchange. This article presents a business model for achieving a sustainable relationship that is attractive for both biotech and large pharma.

By Dr Douglas J. Squires and Dr James E. McClurg

Increasingly, businesses around the world are turning to strategic relationships – including alliances, joint ventures, outsourcing arrangements, networks and other partnerships – as a way to gain a competitive edge in today's global business environment. In fact, business alliances have become so prevalent that an entire cottage industry has sprung up around the whole relationship management issue. Businesses of all types seek valuable, committed relationships to extend their global reach, build value, enhance products, reduce costs and fill gaps in their capabilities. This trend is certain to continue alongside the growing pressure for companies to succeed on a global scale. As companies begin to work more interdependently with former suppliers and even competitors, their goal is to establish longer-term, more deeply inter-reliant alliances.

This growing reliance reflects a trend across the entire business community that extends to the pharmaceutical, biotech and related industries. Traditionally, pharmaceutical companies licensed or even purchased strategic technologies from biotech firms, universities and other research institutions. Today, the relationship is more likely to involve those same research institutions in joint research and development efforts with the pharmaceutical companies that offer the best prospects for collaboration[1].

From 1997 to 2002, the number of collaborative agreements signed within the pharmaceutical industry nearly doubled to more than 700 (source: PharmaDeals® Agreements), with pharmaceutical and biotech companies joining forces to:

- Enjoy complementary technologies and expertise while minimising dilution.
- Share the innate risk of the discovery process.
- Expand their product portfolios or development pipelines.

However, of the collaborative R&D relationships initiated in 1997, only 50% were still in effect at the end of 2001, with a third of the relationships termed 'unsuccessful'[2].

The same is apparently true for alliances across all business groups, as a three-year study of more than 130 organisations by Vantage Partners, an offshoot of the Harvard Negotiation Project, found that as many as 70% of business alliances fail or only achieve their initial goals. Further, these failures occur despite brilliant business plans and technology, well-negotiated financial and legal agreements and the obvious potential of the individual

		Table 1		
SITUATION	**SCENARIO #1** Need to outsource more, but wisely	**SCENARIO #2** Wants a 'better deal' with CROs	**SCENARIO #3** Dissatisfied with CROs	**SCENARIO #4** Wants to be more strategic with CROs
REACTION	Task force initiates Request for Information (RFI) process to select a few approved providers	Negotiates a discount in return for increased volume/first right of proposal on all studies	Pull more work inside; increase headcount and infrastructure	Define, create and deliver value for both parties. Merge processes and accountability
VALUE EXCHANGE	Increased CRO sales; fewer vendors for sponsor; 1st step towards partnering	Same as Scenario 1, but now solely a price relationship	None to CRO; sponsor gains increased feeling of control, but with higher costs, more management duties	Efficient relationships and processes that eliminate redundant work
RESULT	Some resistance at Pharma company; more studies to fewer CROs; could concentrate the dissatisfaction on fewer CROs	Same as Scenario 1, with broader sponsor awareness of CRO's role	Company risks worsening of 'bottom line' and increasing fixed costs vs developing compounds	Initial resistance on both sides; growing efficiency and satisfaction; decreased costs and increased speed; trusting relationship develops and joint planning begins

alliances. Vantage Partners found that the leading causes of alliance failure were such relationship issues as lack of trust, poorly handled conflict resolution, inadequate communication and 'an inability to work well with a different culture'[3].

The relationships between contract research organisations (CROs) and pharmaceutical and biotechnology companies have not met either party's shared expectations for strategic value exchange. While these relationships have succeeded at achieving tactical and operational value exchange – in the form of price, speed, quality and consistency – they have not accomplished long-term, strategic value.

Alliances offer great potential benefit for the CRO industry as well as its pharmaceutical and biotech partners, since its current business relationships are largely fee-for-service, project-by-project transactions. Relationships are also often discontinuous, leaving gaps between projects. This problem is exacerbated further by the fact that customer relationships are likely to be with each business unit, versus across a number of business units within the same CRO or pharmaceutical company.

Although these partners have undertaken numerous attempts to modify their business relationships, such as establishing preferred provider relationships, offering volume discounts, conducting web auctions and creating fee-based models, all focus on price savings versus real value exchange. Exchanging value must achieve more than a lowered price, making it possible to enhance shared services and programmes and expand mutual capabilities through a long-term relationship.

Table 1 outlines a number of pharmaceutical company scenarios that demonstrate the need for sustainable, strategic relationships and explain why standard, project-by-project relationships do not build value.

What do pharmaceutical and biotechnology companies value in their CRO alliance partners? A review of pharmaceutical companies' Requests for Information (RFIs) and numerous industry surveys identifies the following attributes:

- Quality.
- Indication or protocol experience.
- Speed.
- Cost.
- Differentiating characteristics and services.
- Core competencies.
- Core values.
- Stability/profitability.
- Previous experience of quality work.
- CROs that want to succeed in developing meaningful, strategic relationships will take the appropriate steps to bring such attributes to the fore when courting alliances.

Strategic relationships with pharmaceutical and biotechnology companies that can provide real impact for CROs should: provide increased revenue, be longer term, connect across business units within both companies, be global in nature, sell at a higher level within the client, produce proprietary infrastructure support, offer transformational simplification of the relationship and, most of all, deliver value to both partners.

So what are the steps to achieving sustainable, strategic value? Stuart Kliman of Vantage Partners says that the most successful alliance partners have determined that relationship management is dependent on institutionalised capabilities that constantly foster and monitor the relationship. He cites 10 'best practices' that lead to the most successful alliances:

- Establish an internal system that identifies key decisions and issues, knows who the stakeholders are and keeps them involved.
- When considering potential partners, formally evaluate and consider differences in corporate culture, operating style and business practices.
- During negotiations, focus separately and equally on the substance of the negotiations and on the future working relationship.
- Develop a relationship launch process for defining how the partners will work together, resolve conflict and jointly manage the relationship.
- Employ a dedicated 'alliance manager' who is responsible for implementing the relationship methodology.
- Teach collaboration, so that employees focused on the alliance will work together fairly and effectively.
- Focus on joint goals and think in terms of the overall good of the alliance.
- Manage a corporate-wide method of identifying, discussing and tracking all of the complex interactions among competitors, vendors, suppliers and customers that also have relationships with one another.
- Formally monitor the health and trust of the working relationship through a mutually defined audit process.
- Anticipate changes in the relationship[3].

While effective relationship management is essential, in order for pharmaceutical companies and CROs to succeed in establishing meaningful, sustainable and strategic alliances that build real value, they must find new ways to do business with existing and potential partners. Partners must focus on relationships built around capacity or programmes rather than individual projects, moving beyond a project-by-project arrangement to share their science, facilities, people and systems – to address the sponsor's clinical development needs over a long period of time. Also, focusing on long-term, versus today's 'one size fits all' mentality, allows customisation and increased efficiency.

Information technology is the fastest growing area of strategic outsourcing today, with a global market totalling $56 billion in 2001 and expected annual growth of 11-14%. IBM is the clear industry leader, possessing more than half of the market share[4]. The primary objectives of IT outsourcing partnerships are to:

- Gain access to the next generation of IT infrastructure and applications.
- Reduce IT costs.
- Allow companies to focus on core competencies.
- Improve service.

In our industry, similar next-generation business models include MDS Pharma Services and Sankyo Pharma, which have partnered to build and manage a dedicated clinical pharmacology unit in Neptune, New Jersey, USA, and the 1999 agreement between Quintiles Transnational Corp and Aventis which led to the formation of a major regional pharmaceutical product development hub at the site of the former Hoerchst Marion Roussel facility in Kansas City, Kansas, USA.

The Sankyo Clinical Pharmacology Unit conducts clinical pharmacology and Phase I studies, with initial emphasis on the evaluation of novel treatments for diabetes and lipid disorders. The unit's staff, comprised primarily of MDS Pharma Services personnel dedicated exclusively to Sankyo projects, operates under the direction of an advisory board consisting of senior officers from the two companies.

Those CROs in a position to succeed via strategic alliances have increased their capacity to manage client projects across the drug development continuum, while investing the time and money to develop an integrated team of individuals who are technically and scientifically proficient and have a strong business sense. A CRO with the capability and expertise to both customise and execute research and development programmes offers outstanding value in the quest for accelerated drug development.

CROs forming strategic alliances with pharmaceutical and biotechnology companies represents a natural progression of the CRO business model from order taking through tactical outsourcing to strategic outsourcing and ultimately, insourcing, which is characterised by a 'one company' mentality and a high level of integration between CRO and sponsor.

The real benefits of strategic alliances may lie in an increased level of trust between the two companies that results from working together closely with shared objectives. CROs in such alliances must deliver outstanding service to achieve this type of trust.

The current fee-for-service business model does not lend itself to either CROs or pharmaceutical or biotechnology companies investing in their relationships. Establishing high level, strategic relationships allows both parties to invest specifically in a given relationship, to take ownership of the goals, objectives and management of their shared business plan.

Those of us in the CRO industry often talk about how we have to change, but in today's environment, change is a two-way street. Our pharmaceutical and biotechnology partners must also change how they conduct their relationships, if we are to build value together. Our industries face the same challenges: cost control, efficiency, globalisation, etc, and need to work in concert to maximise opportunities for strategic value exchange. But in order for a relationship to be truly strategic, it must cause both parties to act differently – to effect change from within that will benefit a long-term, mutual relationship. Transcending tactical, operational relationships requires both CROs and their pharmaceutical partners to possess a vision and a passion for achieving real value exchange.

Millennium Pharmaceuticals, Inc is known for its success in sizeable strategic partnerships. Michael Christianio, Associate Director of Business Development, said: "We believe a successful alliance should cause value-creating structural changes in each partner."

Significantly more alliances fail than not, due to the fact that companies have historically relied upon the skills and personalities of a few key individuals to drive the success of even the most complex business relationships. As with any business, the success of a strategic alliance between a CRO and a pharmaceutical or biotech company is the responsibility of a number of individuals at all levels on both sides of the relationship. It also requires common understanding of the goals for the relationship, common methods for managing it and a plan for working together. With these characteristics, alliances and other partnerships are well positioned to carry out the complex, interdependent strategies of today's competitive, global business environment[1].

There is no question CROs will play an essential role in the drug development process as they mature from subcontracting providers to outsourcing partners, capitalising on the very real need of the pharmaceutical industry for fast, efficient and reliable drug development services. What is uncertain is how many will have the vision to integrate their services to offer unique and innovative solutions via programme development; the foresight to identify and pursue strategic business relationships and models to unlock the value of their drug discovery and development capabilities; and the business sense to add the new technologies, services and geographic presence that will differentiate their CRO from the others. DDW

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