

# VIEW ON Clinical Services

A SUPPORTING PUBLICATION TO PHARMAVOICE

## Outsourcing: A Vital Clinical Strategy

**A large, unmet need exists for improved research and development productivity within pharmaceutical and biotechnology companies.**

**Outsourcing discovery research, clinical trials, and formulation manufacturing offers companies the opportunity to benefit from**

**improved productivity, increased growth, and higher quality.**

**Pharmaceutical companies are outsourcing in response to**

**pressure for consistent, high-growth financial returns.**

by  
**Denise Myshko**  
and  
**Taren Grom**

**O**utsourcing relationships between companies are complex and require a vigilant management approach to optimize outsourcing activities for ultimate project success.

By 2010, Clarkston Consulting predicts that 50% of big pharma R&D will be outsourced to capable organizations to maintain a strong and vital pipeline of new blockbuster drugs. But researchers from Clarkston say the service-supplier companies that will lead the new pharmaceutical model for the 21st century will be those that have invested in the development of their internal and external business practices and can then successfully port that discipline to their development partners.

### WORKING WITH SERVICE PROVIDERS: PROS AND CONS

*According to sponsors, outsourcing, like any other functional area, requires management, experience, and proficiency.*

**CHARLES.** Some of the hardest challenges to tackle with our service suppliers include staffing inadequacies — turnover and lack of experienced/qualified individuals in certain regions or functions. Although this is an issue within big pharmaceutical companies as well. During a meeting this year, an organization was handing out stickers with “I (heart) my CRO.” Noticing that I was wearing one of these stickers, one of my colleagues from a CRO partner joked, “Well, what if you are not with the CRO you love the most?” and I quick-

ly retorted “Love the one you’re with!” I think there are always going to be problems that arise in supplier relationships, but the important thing is how one handles them. Working through the problems, as painful as it may be at times, with a partner CRO is much like the way the strongest marriages work: you don’t discard the relationship when problems arise. You work through them to improve the relationship.

**MILLER.** One of the biggest hurdles is receiving a standardized data structure from multiple vendors. When working with several different vendors, we want to get information in a standardized format or structure. This way we can combine the information to evaluate it. If we are running several studies on the same compound with different vendors, we can look at all of our study information across all of those studies no matter which vendor the data are coming from. This allows us to know that compound much better.

**BLANKSTEIN.** One challenge that sometimes occurs when projects are winding down is getting the attention and focus necessary from the service supplier to bring tasks to closure. When we’re finalizing reports, there’s a tendency for things that may impact the timeline not to be brought up in a timely fashion; whereas in other stages of the program the supplier has been very proactive.

**LIPSET.** People tend to come to a project from many dif-

**THOUGHT LEADERS**

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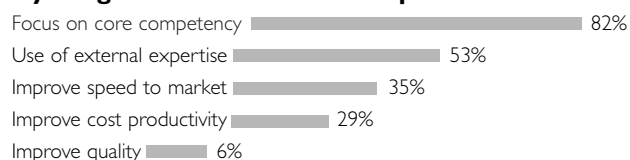
**RICK MILLER.** Director, Clinical Information Management, Solvay Pharmaceuticals Inc., Marietta, Ga.; Solvay, a subsidiary of Solvay Group, Brussels, Belgium, is a research-driven pharmaceutical company that seeks to fulfill unmet medical needs in the therapeutic areas of cardiology, gastroenterology, mental health, women's health, and a select group of specialized markets including, men's health. For more information, visit [solvaypharmaceuticals-us.com](http://solvaypharmaceuticals-us.com).

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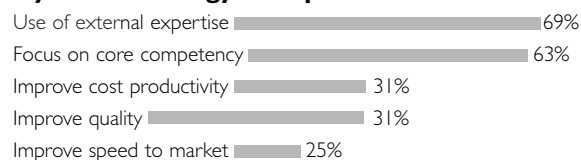
**Outsourcing Market Overview**

- Large, unmet need for improved R&D productivity
- NCE introduction more important than reduced R&D spend
- Pressure for consistent, high-growth financial returns drives need to improve NCE introduction rate and reduce cost of new drug discovery and development
- Companies continue to expand investment in new discovery and development technologies: combinatorial synthesis, genomics, proteomics
- R&D objectivity offered by an independent expert allows thorough review and due diligence of drug portfolio, enabling companies to focus on their most valuable potential NCEs
- Access to technological advancement is enabled through outsourcing
  - Allows continual progress with advancing technology
  - Midsize biotechs to large pharma companies are dedicating resources to evaluate emerging technologies and companies
- Outsourcing facilitates portfolio management and prioritization of compounds in preclinical and clinical stages
- Outsourcing enables effective resource allocation to most promising therapies
- High level of fragmentation within outsourced segments — electronic trial software, large-scale manufacturing — provides competition for services, downward price pressure
- Outsourcing is expanding from regulated activities (clinical development, toxicology) to all areas of a pharmaceutical company
- Large pharma companies rely on outsourcing for successful R&D to:
  - Focus on specific therapeutic areas, IRB approval, marketing/selling other core competencies
  - Access emerging technology for drug discovery and research
  - Fulfill the mandate to "own or access" emerging platforms that deliver major impact to discovery
  - Improve return on capital
  - Leverage in-licensing of compounds to avoid over-reliance on in-house research and discovery
  - Rationalize redundant individual labs or facilities postmerger
  - Use excess manufacturing capacity to produce third-party therapies

**Why Large Pharmaceutical Companies Outsource**



**Why Biotechnology Companies Outsource**



Note: Survey respondents ranked their company's rationale for outsourcing its business activities and replied with a No. 1 or No. 2 ranking in each category. Source: Cambridge HealthTech Advisors, Waltham, Mass., Pharmaceutical R&D Outsourcing Survey, July 2004. For more information, visit [chadvisors.com](http://chadvisors.com).

We outsource based on our internal resource needs. **If we want to move forward with a project** and we do not have the available resources internally, **then we will outsource part of the work or all of the work.**



**Larry Blankstein**

Genzyme

ferent perspectives and make a lot of assumptions about what the other parties — the vendor, the sponsor — are expecting. Simply achieving what one person thinks is the goal does not make for a successful project. People need to make sure expectations are clear and that they've communicated those expectations. A pharmaceutical sponsor can sit back and say, "Well yet another CRO has failed me." But maybe it's not necessarily that the CRO has failed, rather things were not clear-

ly communicated by the sponsor up front in terms of expectations.

**MILLER.** When partnering with vendors to run clinical trials, timeliness is a big hurdle as well. One challenge is how fast the data can be collected from the site and how soon the CRO can get the information into its system and then how fast the data can be transferred from the CRO's system to our system.

## Contract Manufacturing Is Growing

**N**OT so long ago, big pharmaceutical companies turned to contract manufacturing organizations (CMOs) solely to achieve efficiencies in cost, capacity, and time-to-market or to obtain a specific expertise not available in house. Today, these factors still play a role, but the most dynamic driver behind the use of CMOs is rapidly becoming the unique, innovative, and state-of-the-art processes and production technologies these companies offer. More and more pharma companies are leaning toward outsourcing so that they can spend less time in drug discovery and manufacturing and, instead, concentrate on marketing their products. This applies to those virtual companies that exist by the simple fact that they can rely on the contract manufacturers and researchers.

The global revenue for contract manufacturing and research for the pharmaceutical industry was estimated at just more than \$100 billion in 2004 and is expected to rise at an average annual growth rate (AAGR) of 10.8% to \$168 billion in 2009.

CMOs manufacture chemical or biosynthetic bulk pharmaceutical chemicals or intermediates for clinical testing or commercial use, or they may produce dosage forms such as tablets or injections.

Of the three market segments, the market for contract manufacturing of prescription drugs for 2004 was estimated at \$26.2 billion, which is expected to rise to \$43.9 billion by end of 2009. Contract manufacturing of OTC and nutritional products is the largest and fastest growing segment, expected to rise at an AAGR of 11.3% to \$102 billion by 2009. The contract research market is expected to reach \$21.9 billion by 2009, rising at an AAGR of 8.6% from \$14.5 billion in 2004.

Within the contract manufacturing segment, cardiovascular drugs are the largest category among all other application categories with worldwide revenue of about \$2.56 billion in 2004, and this is rising at an AAGR of 8.7% through the forecast period. Analgesics seem to be rising at the highest pace in the contract manufacturing business, with the expected AAGR of 11.9% over the five-year period.

Source: Business Communications Co., Norwalk, Conn. For more information, visit [bccresearch.com](http://bccresearch.com).

### Worldwide Revenue of Contract Manufacturing and Contract Research Organizations through 2009

#### CONTRACT MANUFACTURING OF BULK DRUGS AND DOSAGE FORMS

| 2002   | 2003   | 2004   | 2009   | AAGR % (2004-2009) |
|--------|--------|--------|--------|--------------------|
| \$21.4 | \$23.8 | \$26.2 | \$43.9 | 10.8%              |

#### CONTRACT MANUFACTURING OF OTC DRUGS AND NUTRITIONALS

| 2002   | 2003   | 2004   | 2009    | AAGR % (2004-2009) |
|--------|--------|--------|---------|--------------------|
| \$48.6 | \$54.2 | \$59.8 | \$102.0 | 11.3%              |

#### CONTRACT RESEARCH

| 2002   | 2003   | 2004   | 2009   | AAGR % (2004-2009) |
|--------|--------|--------|--------|--------------------|
| \$12.5 | \$13.2 | \$14.5 | \$21.9 | 8.6%               |

#### TOTAL

| 2002   | 2003   | 2004    | 2009    | AAGR % (2004-2009) |
|--------|--------|---------|---------|--------------------|
| \$82.5 | \$91.2 | \$100.5 | \$167.8 | 10.8%              |

(\$ Billions)



**Dr. Mark Ahn**

Hana Biosciences

We look for vendors that have a relevant track record of success, great references, and are candid about capabilities and limitations. **I appreciate enthusiasm, but overpromising and underdelivering are my biggest worries because investors rightly expect us to meet our timelines.**

**REUTER.** The challenges of working with service suppliers include differences in corporate cultures, which can lead to different communication styles. Each organization may have differing priorities, leading to frustration and conflict unless the groups are properly aligned and goals of each organization — pharmaceutical sponsor and service provider — are discussed honestly and clearly.

**LIPSET.** It's important that sponsors don't make assumptions. We have kick-off meetings when a project is awarded. We get the whole team to sit together, and we clearly lay out a straightforward plan in terms of the scope of work, project management, communications, and risk management. Ultimately, every project has challenges. What sets one supplier apart from another is how it defines those

## Successful Outsourcing of Pharmaceutical R&D: Trends and Strategies

- Outsourcing discovery research, clinical trials, and formulation manufacturing offers companies the opportunity to benefit from improved productivity, increased growth, and higher quality. Pharmaceutical companies are outsourcing in response to pressure for consistent, high-growth financial returns.
  - Given a significant decrease in new chemical entity introduction and increasing R&D expense, an increased focus on delivering valuable therapeutics is crucial to the long-term growth of pharmaceutical and biotechnology companies. Ultimately, NCE introduction is more important than reduced R&D spend.
  - Midsize biotechnology to large pharmaceutical companies are dedicating resources to evaluating emerging technologies and companies. Outsourcing enables improved access to technological advancement.
  - Large pharmaceutical companies rely on outsourcing for access to emerging technologies for drug discovery and research, improved return on capital, in-licensing opportunities, rationalization of redundant individual labs or facilities postmerger, and use of excess manufacturing capacity to manufacture third-party therapies.
- THE PHARMACEUTICAL SECTOR**
- Large increases are evident in the level and type of outsourcing. A proprietary survey shows that the pharmaceutical sector is focusing on outsourcing more than ever before.
  - 57% of surveyed companies will outsource 20% or more of R&D operations by 2006; this is nearly twice as many as in 2003 (33%).
  - 50% have a centralized procurement/outsourcing department for clinical-development operations.
  - More than half (54%) outsourced at least 20% of ADMET in 2003. This is expected to reach 94% in 2008, with about half of companies expected to outsource more than 80% of ADMET operations by 2008.
  - Outsourcing of clinical development will continue, driven by a doubling of the number of companies from 2003 to 2008 that outsource more than 80% of operations.
  - The level of outsourced manufacturing is expected to increase moderately from 2003 to 2008.
  - The key drivers of outsourcing for big pharma are a focus on core competency and utilization of external expertise and, secondarily, improved speed to market and improved cost productivity.
- THE BIOTECHNOLOGY SECTOR**
- Most biotech companies have no choice but to outsource given financial and human resource constraints as well as high capital expenditures for equipment and facilities. Small biotechnology companies require established, experienced partners and the improved credibility and capability they deliver.

Source: Cambridge HealthTech Advisors, Waltham, Mass., Pharmaceutical R&D Outsourcing Survey, July 2004. For more information, visit [chadvisors.com](http://chadvisors.com).

challenges up front, mitigates risk, and manages through the challenges. A successful partnership requires a clear decision-making process, up-front expectations, and ongoing communications.

### MEETING SPONSOR NEEDS

*Sponsors are looking for experienced, clinical-trial outsourcing partners that are flexible and responsive and can anticipate their study requirements.*

**CHARLES.** Within our global development organization, we generally outsource to enable optimal capacity flexibility. Having alliance partners fully enabled to use our data systems, standards, and business processes, with comparable SOPs, provides a capacity solution that feels like a virtual company within a company.

**AHN.** We look for vendors that have a relevant track record of success, great references, and are candid about capabilities and limitations. I appreciate enthusiasm, but overpromising and underdelivering are my biggest worries because investors rightly expect us to meet our timelines.

**LIPSET.** I want to know that the people I'm working with have done a project before, not just that the company has done it before. I want to know that the people I'm working with can leverage expertise to make a project work better. A supplier has to be able to bring more than just bodies to the table; it has to have the brains and experience.

**MILLER.** If we're looking at a particular thera-

- Biotechnology firms also are experiencing a significant increase in outsourcing, as evidenced by the following survey results:
  - 50% of surveyed companies have a centralized procurement/outsourcing department for discovery research operations.
  - 44% of companies outsourced 20% or more of ADMET operations in 2003; this percentage is expected to grow to 67% by 2008.
  - More companies will outsource a small portion of research and discovery operations.
  - A significant increase of outsourced clinical development will occur by 2008, with 85% of companies outsourcing at least 20% of operations, an increase from 43% in 2003.
  - The portion of companies outsourcing at least 80% of manufacturing will almost double by 2008, from 16% to 29%.
  - The key drivers of outsourcing for biotech companies are primarily use of external expertise and focus on core competency and, secondarily, improved cost productivity, improved quality, and improved speed to market.

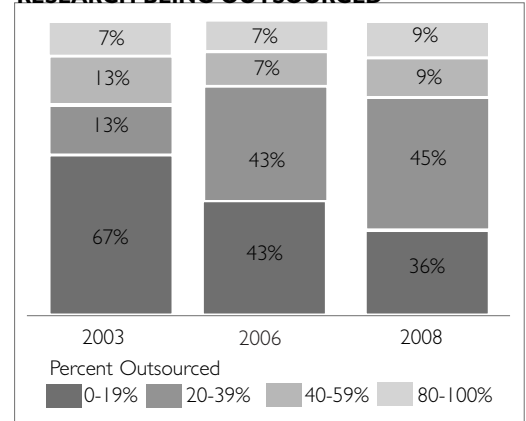
### OUTSOURCING TRENDS

- Measuring the operational performance of outsourcing partners is occurring at a greater pace.
- Measurement of the total cost of ownership allows the creation of up-front performance criteria and parameters for partners that can in turn be integrated into a contract.
- Managing and reducing outsourcing risk has taken on elevated importance in line with the increase in outsourcing. As such,

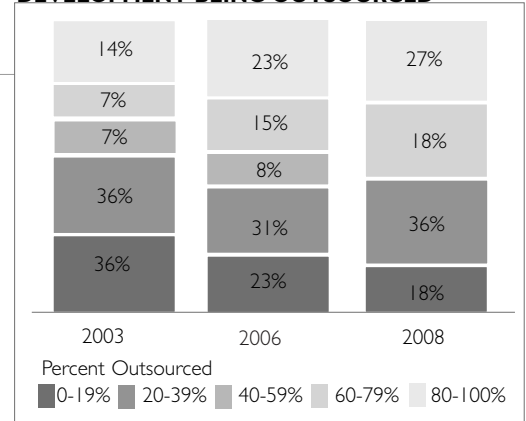
companies are coordinating risk-management policies across the organization.

- Increasingly, outsourced players are being asked for assurance of informed consent for clinical trials, effective IRB review, and proof of supporting documentation.
- Specific and definitive contract clauses align a company's risk and benefit for activities, including clinical development and manufacturing.
- Significant increases in cost savings from outsourcing are anticipated by 2008. For the areas of discovery and research, clinical development, and drug manufacturing, a three-fold increase is expected in the percentage of companies that will reduce costs through outsourcing by 25% or more.
- In 2004, about 6% of companies expected to save 50% or more through outsourcing discovery and research areas; this is anticipated to grow to 16% of companies by 2008.
- In 2004, about 7% of companies expected to save 50% or more through outsourcing clinical development; this is anticipated to grow to 25% of companies by 2008.
- In 2004, virtually no companies expected to save 50% or more through outsourcing drug manufacturing; this is anticipated to grow to 16% of companies by 2008.

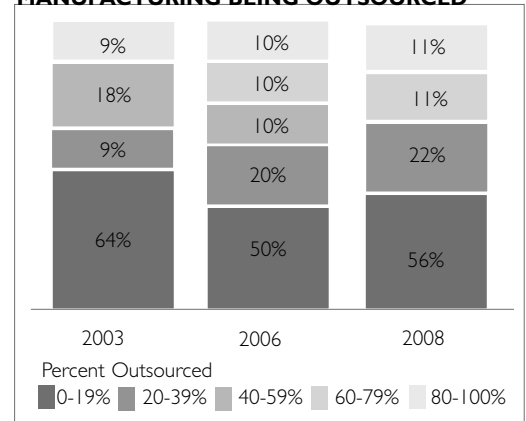
### PERCENTAGE OF DISCOVERY RESEARCH BEING OUTSOURCED



### PERCENTAGE OF CLINICAL DEVELOPMENT BEING OUTSOURCED



### PERCENTAGE OF FULL-SCALE MANUFACTURING BEING OUTSOURCED



peutic area or class of drugs, then we want a CRO that is very proficient, has experience running studies in that area, and is familiar with physicians who work in that area.

**BLANKSTEIN.** In terms of what we look for in a vendor,

we want a company that is financially secure. We want a company that has demonstrated that it can deliver what was promised. We want a company to have the expertise in house to effectively implement and complete the project. And we want a fair price.

## Opportunities for European Pharmaceutical and Biotechnology Companies in Indian and Chinese Markets



*“Patent reform will encourage investments while increasing funding opportunities,” says Himanshu Parmar, Industry Analyst at Frost & Sullivan. “It is likely to encourage MNC entries via joint venture, collaborations, and partnerships through technology transfer and licensing agreements.”*

**D**ESPITE having more than one-third of the world’s population, Asia accounts for only one-fifth of global pharmaceutical drug consumption. As income levels rise, demand from this large population base is set to burgeon, opening up new growth opportunities for pharmaceutical and biotechnology companies. Even as emerging markets such as Brazil, Mexico, Poland, and Russia exhibit strong development potential, the most exciting growth prospects are forecast for two Asian powerhouses: India and China.

As Europe grapples with rising R&D costs and declining drug outputs and as governments attempt to contain spiraling healthcare outlays, European pharmaceutical and biotechnology companies are beginning to explore other emerging markets, which offer a low-cost structure along with other potential benefits, such as a sizeable domestic market and opportunities for clinical-trial licensing and outsourcing.

High domestic pharmaceutical consumption levels coupled with their importance internationally as a supplier base for active pharmaceutical ingredients (APIs) and intermediates have made India and China a magnet for pharmaceutical and biotechnology companies. At the same time, these countries also hold the promise of being able to conduct low-cost, large-scale clinical trials.

Both countries, however, offer distinct challenges, such as invariable bureaucratic delays, corruption, and red tape along with the prospect of less transparency in China. Such hurdles are being offset by several encouraging trends. The market for over-the-counter (OTC) drugs is expanding. Industry participants and governments are increasingly displaying a global vision, demonstrated by the enhancement of patent-protection legislation.

An improved patent-protection situation is expected to favor foreign entry even as government initiatives to attract foreign direct investment (FDI) gain momentum. Licensing opportunities for large biotech/pharmaceutical companies offer another incentive to enter these regional markets. Overall, the large and rapidly expanding economies of India and China are set to have a positive ripple effect on both pharmaceutical and biotechnology sectors.

“As a destination for FDI, both the Tiger and the Dragon have proved themselves most popular among the emerging markets in the world,” says Himanshu Parmar, industry analyst at Frost & Sullivan. “The problem remains that the Dragon is more hidden whereas India is a crouching tiger; a slow taker, waiting to capitalize on the opportunities it presents to the West.”

Both India and China offer the benefits of low-cost R&D, a strong scientific base, as well as a large and skilled (and in India’s case English-speaking) labor pool. While significant government involvement and well-developed research infrastructure offer added advantages in the Chinese context, India offers further inducements in the form of a strong IT industry, good natural resources, and an expanding infrastructure.

In China, opportunities in drug development for indigenous diseases — an area that has strong governmental support — and stem-cell R&D also offer growth potential. In India, European Union companies are poised to capitalize on low-cost R&D and cost-effective clinical trials.

Partnerships and mergers and acquisitions, and joint ventures with Chinese/Indian biotechnology, pharmaceutical, or other technology companies, such as IT, offer opportunities for European companies to make their mark in China and India. There is also the prospect of technology transfer or strategic partnerships with institutes.

In India, such strategies are expected to minimize the investment risk on contract research even as patent reform is expected to clarify IP protection and bring it in line with globally accepted mandates.

“Patent reform will encourage investments while increasing funding opportunities,” Mr. Parmar says. “It is likely to encourage MNC entries via joint venture, collaborations, and partnerships through technology transfer and licensing agreements. Innovation is likely to be promoted among Indian firms thus giving another incentive to European firms for entering into partnerships with Indian firms.”

Underlining the growing appeal of these two regions, several European pharmaceutical/biotechnology companies are looking to expand their presence. Roche intends to make India one of its larger sourcing hubs for active ingredients and bulk intermediates. Novartis is investigating clinical-trial opportunities in both countries. And Lilly, Pfizer, and Roche have established clinical-trial programs in India.

Source: Frost & Sullivan, San Antonio, Texas. For more information, visit [healthcare.frost.com](http://healthcare.frost.com).

**Roughly 20% of our organization's total R&D dollars are outsourced.** We would outsource all services depending on the size and scope of the project, except for clinical project/trial management and safety reporting.



**Ed Campanaro**

Cubist Pharmaceuticals

**CAMPANARO.** We look for depth of experience in the organization and proposed vendor team, quality systems, responsiveness, flexibility, and the proven ability to deliver on time and on budget. Competitive bidding is also a standard practice and part of the consideration.

**CHARLES.** Beside all the usual considerations, there is an increasing emphasis on having global capabilities; and we value providers that can expand to nontraditional regions to capitalize on recruitment possibilities in developing markets, where there is a relative lack of saturation of competing studies. Customer service with a focus on problem solving and institutionalizing lessons learned are other desired qualities of our preferred providers.

**REUTER.** The key is to select a vendor with whom the

relationship can proceed as smoothly as possible during the course of the project. The corporate culture of the vendor company must be compatible with that of the sponsor; as must the communication styles of the individuals who will interface with the sponsor's team. Selecting a vendor that communicates in a way that will mesh with the team at the sponsor is essential.

**BLANKSTEIN.** We look for suppliers to provide us with feedback on our protocol and design. We consider whether they can add efficiencies or have a unique solution to deal with the challenges we face with our clinical development. There are so many vendors out there that one way they can distinguish themselves is to provide meaningful comments on a protocol or synopsis that I send them. If I send a protocol or a synopsis to a supplier and they get

## Outsourcing Can Lead to Process Excellence

**P**HARMACEUTICAL manufacturers, biotech companies, and makers of medical devices are using outsourcing to make significant and rapid gains in process or functional expertise. Far from sacrificing expertise through outsourcing, these companies are using outsourcing as a strategy to achieve process excellence. Business executives at pharmaceutical and medical products companies have discovered that outsourcing delivers demonstrable benefits, including significant cost savings. Yet any consideration of outsourcing must also address certain concerns. One is the belief that outsourcing entails a loss of in-house expertise.

In a new global survey of outsourcing practices, *Driving High Performance through Outsourcing: Achieving Process Excellence*, Accenture found that 92% of companies reported improvements in process expertise and capabilities as a result of outsourcing. The improvements reported include: processes that operate more efficiently, more effectively, at a lower cost, with a greater degree of accuracy, and with a higher level of quality. Almost all respondents (96%) cited one or more of these improvements; one in four (25%) cited all of these beneficial gains.

Reports of declines in capabilities were few and far between. In certain areas, the gains were significant. For example, 60% of respondents reported gains in innovation, market intelligence, and information, and 77% cited improvements in functional expertise as a result of having the latest technology in the function. More than half (53%) reported gains in access to the market intelligence needed to spot trends.

Equally impressive was the rapidity of the gains reported. Some 90% of pharmaceutical and medical products companies reported achieving gains within one year of beginning an outsourcing arrangement.

More than half of the respondents (56%) cited general gains in the process as a main benefit for outsourcing, reporting that outsourcing improved the speed, accuracy, or quality of the process outsourced and that outsourcing actually raised their company's access to expertise in the function.

Contrary to concerns about a loss of expertise, outsourcing raises the typical company's access to expertise and knowledge, resulting in higher overall capability in the business process or function.

Source: Accenture, Philadelphia. For more information, visit [accenture.com](http://accenture.com).

back to me with a great price, but without feedback or questions about what I sent them, they may not get the project. It is demonstrating this interest in our work, in terms of supplying comments or suggestions, that

sets a company apart. Even if the company charges more money, I may give it the project because of the feedback.

**CAMPANARO.** For us, it's important that a service part-

## Lilly, Wyeth, and Genentech Ranked as Top Sponsors by U.S. Researchers



*We're seeing improvements in the area of project management, specifically the organization and preparation of the companies. Sponsors also are putting more effort into their payment processes, which means they are paying their investigators on time, says Mary Jo Lamberti, Ph.D., Senior Manager of Market Intelligence, CenterWatch.*

**R**ESULTS of a Thomson CenterWatch survey identified the top three pharmaceutical and biotechnology companies, according to clinical research centers (sites). Of the 15 companies evaluated, the survey results rank Eli Lilly and Co., Wyeth, and Genentech Inc. as the top three sponsors in 2005. Lilly has the top overall score for the third time in eight years, but the numbers are extremely close: 79% of sites rate the quality of their relationship with Lilly as "good" or "excellent;" Wyeth and Genentech are only 1% behind with 78%.

Wyeth is the most improved overall, up 15% from the 2003 survey. The Genentech top-three ranking illustrates the growing influence of biotech firms as they continue to increase their clinical-development efforts.

These survey results exemplify that to simultaneously cut costs and replenish drug pipelines, drug sponsors need to continually improve their ability to effectively collaborate with investigative sites.

By conducting this research every two years, CenterWatch not only provides

sponsor companies a benchmark for their performance, it ultimately improves the level of service received by sites throughout the United States.

When compared with the 2003 findings, the 2005 survey suggests an overall progression in industry relationships with 75% of investigational sites rating relationships with drug sponsors as "good" or "excellent," up from 70%.

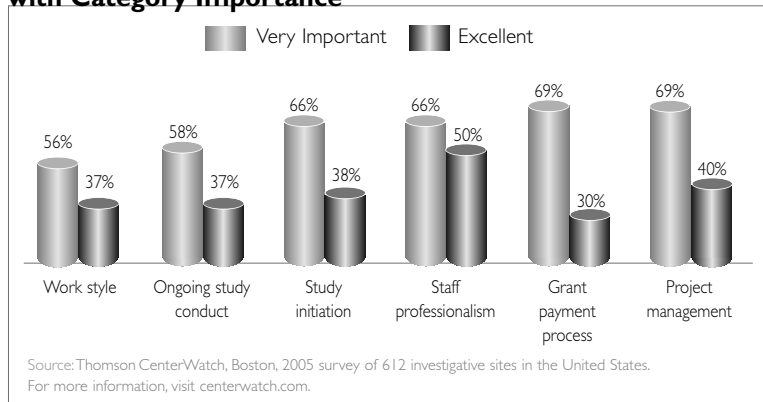
"We're seeing improvements in the area of project management, specifically the organization and preparation of the companies," says Mary Jo Lamberti, Ph.D., senior manager of market intelligence at CenterWatch. "Sponsors also are putting more effort into their payment processes, which means they are paying their investigators on time."

According to Dr. Lamberti, the reason for the increase is fairly clear; pharmaceutical companies are recognizing strong sponsor-site relationships are key to speeding up the drug-development process and therefore cutting their time to market.

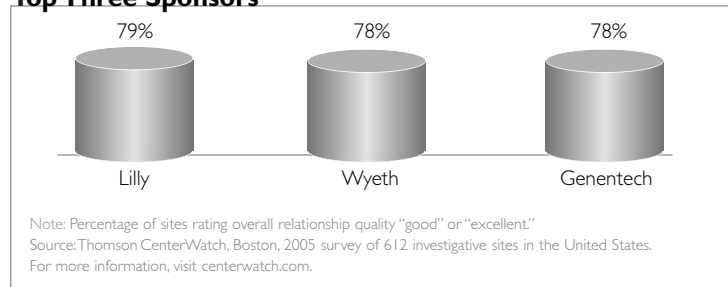
These new results conclude "organization and preparation" to be the single-most important attribute to sites. This area also realized the greatest improvement over the 2003 findings, with 82% of respondents rating sponsors "good" or "excellent" at preparing their trials.

In the 2005 survey, 612 investigative sites were asked to rate the sponsors they dealt with in the past two years on 27 separate attributes and responsibilities. In addition to ranking sponsors, investigators were asked to rate the importance of all the attributes in terms of the success of their clinical studies.

### Comparing Performance Quality with Category Importance

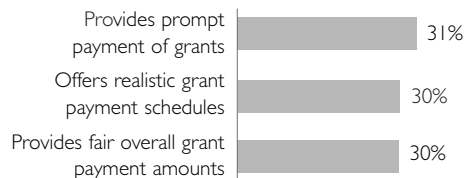


### Top Three Sponsors

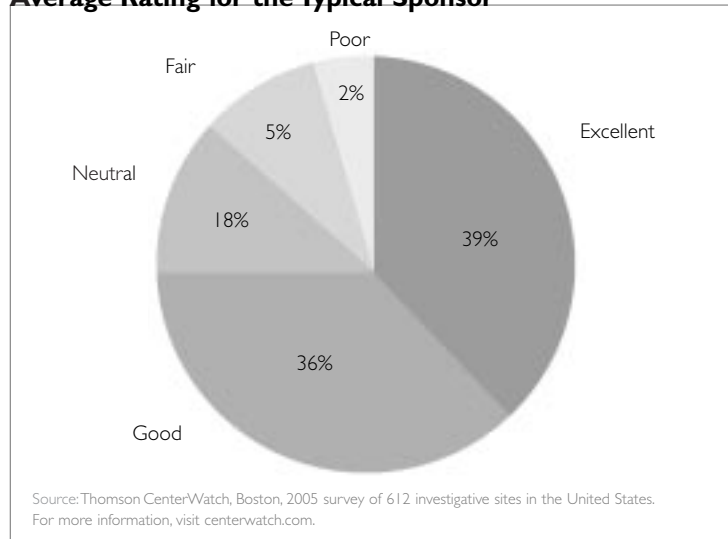


### Quality of the Grant Payment Process

#### Average percentage of sites rating sponsor "Excellent"



### Average Rating for the Typical Sponsor



ner has the right mix of staff responsible for executing and managing clinical trials on our behalf, and the ability to forge a strong partnership with us, so that study challenges are faced head on and together as a team.

**BLANKSTEIN.** I want to work with service suppliers that can provide me with solutions for dealing with issues. If patient recruitment is an issue for a particular study, I would like to hear vendors talk about their capabilities for identify-

Twelve of the 15 companies rated improved their scores relative to the last survey conducted of investigative sites in the United States, which was in 2003.

In fact, the lowest score from 2005 is 10% higher than the lowest in 2003, up from 61%. This would seem to indicate that sponsors and sites are communicating better, which is good news in unsettled times for the industry.

**AREAS THAT STAND OUT MOST FOR IMPROVEMENT INCLUDE:**

- **Flexibility.** Willingness to modify protocol or budgets was the area that received the lowest scores in the survey. On average, only 62% of sites found sponsors "good" or "excellent" in this area. Sites find this attribute crucial; it was rated "very important" by almost two-thirds of respondents.
- **Grant payment process.** While improving overall, the grant payment process continues to be a broad category that leaves sites less than satisfied. Just two-thirds of sites find grant payments prompt.
- **Contract and budget negotiations.** More than 50% of sites listed contract and budget negotiations as most likely to cause delays in conducting a trial.
- **Query handling process.** The query handling process was considered efficient by 64% of sites.

**OTHER FINDINGS OF NOTE INCLUDE:**

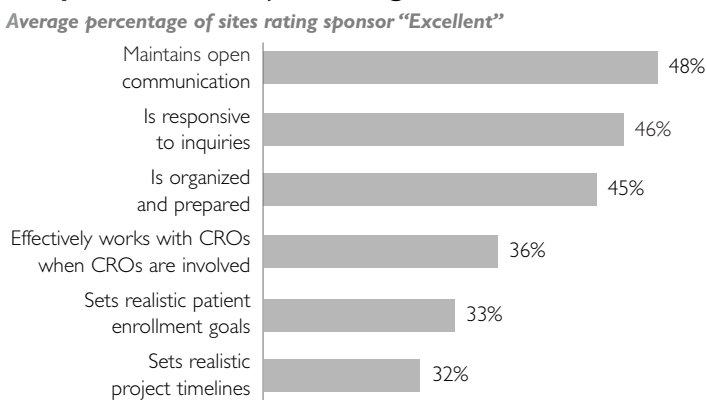
- **EDC.** Asked what could best help prevent future delays, 45% of sites listed electronic data capture (EDC) technologies as the most important of any factor.
- **Organization and preparation.** The single most important attribute to sites was organization and preparation, which was the single greatest improvement compared with 2003, with 82% of respondents finding sponsors "good" or "excellent" at preparing their trials.
- **Patient recruitment.** While 62% found patient-recruitment funding important, only 48% sought recruitment planning help from sponsors.

An aspect of the survey that was approached differently in 2005 involved rating the importance to clinical success of all of the attributes that contribute to a company's rating. These attributes, which all were listed as "very important" by more than 80% of respondents, also were rated "good" or "excellent" by more than 80%.

**SITES RATED THE FOLLOWING ATTRIBUTES AS THE MOST IMPORTANT TO STUDY SUCCESS IN 2005:**

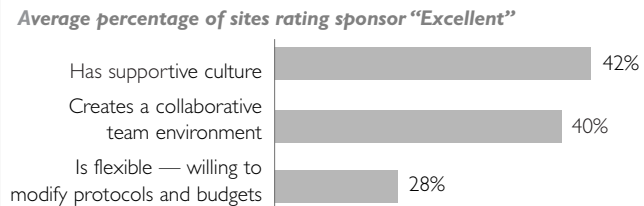
- Organization and preparation (86% listed as "very important," 82% found sponsors "good to excellent").
- Professional, well-trained monitors/CRAs (82%, 82%).
- Open communication (81%, 82%).
- Good overall protocol design (81%, 84%).
- Responsiveness to inquiries (80%, 81%).

**Quality of General Project Management**



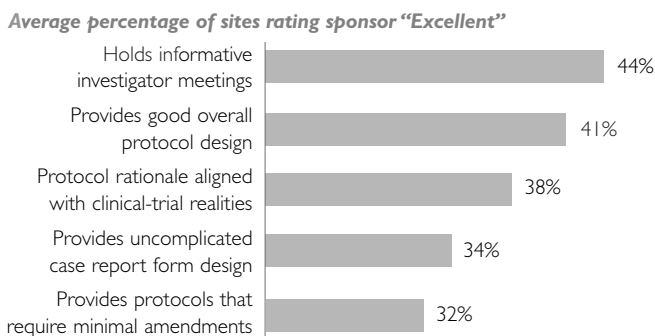
Source: Thomson CenterWatch, Boston, 2005 survey of 612 investigative sites in the United States. For more information, visit centerwatch.com.

**Quality of Work Style**



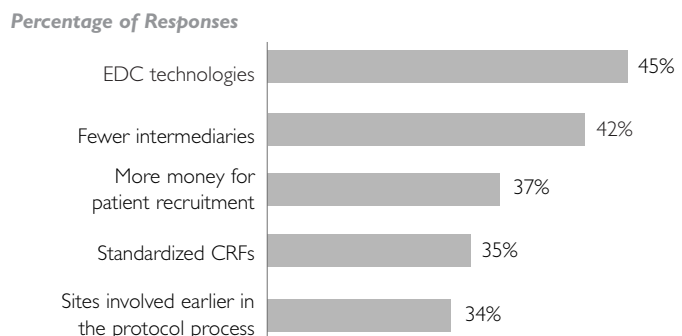
Source: Thomson CenterWatch, Boston, 2005 survey of 612 investigative sites in the United States. For more information, visit centerwatch.com.

**Quality of Study Initiation Process**



Source: Thomson CenterWatch, Boston, 2005 survey of 612 investigative sites in the United States. For more information, visit centerwatch.com.

**Factors That Could Best Prevent Future Delays**



Source: Thomson CenterWatch, Boston, 2005 survey of 612 investigative sites in the United States. For more information, visit centerwatch.com.



**Owen Charles**

Bristol-Myers Squibb

**Our target is to outsource 30% or more of our clinical activities across our global development organization.** We outsource to CROs, central laboratories, central ECG companies, IVRS companies, independent radiology review organizations, rater training firms, and other clinical R&D services companies.

ing demographics for certain patients. I want to know that the service provider has different ways or different technologies to meet our clinical-trial needs, which then differentiates them from other providers. I want the service supplier's senior people to come to the table with an understanding of what they believe the challenges are in our

protocol and what their solutions are for dealing with those challenges.

**AHN.** You get what you put into relationships. The best-laid plans go through ups and downs, particularly in drug development. Success with suppliers comes from creating mean-

## FDA Issues Final Risk Minimization Guidances

**I**n March 2005, the Food and Drug Administration (FDA) issued three final guidance documents to help develop new ways and improve methods to assess and monitor the risks associated with drugs and biological products in clinical development and general use. The documents are part of FDA's ongoing and comprehensive efforts to minimize risks while preserving the benefits of medical products.

"As one of the five initiatives announced in November 2004 to further strengthen our drug-safety program, these guidances are further evidence of the FDA's commitment to transparency in risk management decision-making," says Dr. Steven Galson, acting director, Center for Drug Evaluation and Research. "Continuing to improve the way safety is assessed and monitored will lead to the earlier identification of safety problems and enable a more proactive approach to minimizing these risks."

The final guidances, "Premarketing Risk Assessment," "Development and Use of Risk Minimization Action Plans," and "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment," describe additional safety testing, monitoring, and interventions that may be helpful in selected circumstances and address premarket risk assessment; the development, implementation, and evaluation of risk-minimization action plans (called RiskMAPs); and good pharmacovigilance practices and assessment of reported adverse events.

The final guidance on premarket risk assessment focuses on measures companies might consider throughout all stages of clinical development of products. For example, a section on special safety considerations describes ways that risk assessment can be tailored for those products intended to be used chronically or in children. General recommended risk-assessment strategies include the use of long-term controlled safety studies, enrollment of diversified patient populations, and Phase III trials with multiple dose levels. Some key components of the guidance include:

- Providing specific recommendations to industry for improving the assessment and reporting of safety during drug development trials.
- Improving the assessment of important safety issues during registration trials and to provide best practices for analyzing and reporting data that are developed as a result of a careful preapproval safety evaluation.

- Building on (but not superceding) a number of existing FDA and ICH guidances related to preapproval safety assessments.

The final guidance on development and use of RiskMAPs describes how industry can address specific risk-related goals and objectives. This guidance also suggests various tools to minimize the risks of drug and biological products. Some key components of the guidance include:

- Establishing consistent use and definition of terms, and a conceptual framework for setting up specialized systems and processes to assure product benefits exceed risks.
- Broader input from patients, healthcare professionals, and the public when making recommendations about whether to initiate, revise, or end risk minimization interventions.
- Evaluating RiskMAPs to assure that risk minimization efforts are successful.

The final guidance on heightened postmarketing vigilance identifies recommended reporting and analytical practices to monitor the safety concerns and risk of medical products in general use. Some key components of this guidance include:

- Describing the role of pharmacovigilance in risk management. Pharmacovigilance refers to all observational post-approval scientific and data gathering activities relating to the detection, assessment and understanding of adverse events with the goals of identifying and preventing these events to the extent possible.
- Describing elements of good pharmacovigilance practice from identifying and describing safety signals, through investigation of signals beyond case review, and interpreting signals in terms of risk.
- Describing development of pharmacovigilance plans to expedite the acquisition of new safety information for products with unusual safety signals.

The final guidances fulfill the FDA's commitment to risk-management performance goals as part of the reauthorization of the Prescription Drug User Fee Act in June 2002. They are based on three concept papers released on March 7, 2003, and on comments the agency received following a subsequent public workshop and publication of the draft guidances in May 2004.

Source: The Food and Drug Administration, Rockville, Md. For more information, visit [fda.gov](http://fda.gov).

If we're looking at a particular therapeutic area or class of drugs, then we want a CRO that **is very proficient, has experience running studies in that area, and is familiar with physicians who work in that area.**



**Rick Miller**

Solvay Pharmaceuticals

ingful partnerships and aligning interests. Having winning partnerships with vendors, as well as all partners, is a function of clear goal setting, candid communications, mutual accountability, and long-term commitment.

### LESSONS LEARNED

*To fully realize the advantages of an outsourcing relationship, sponsors stress the need for communications, oversight, and clear expectations.*

## Study Finds Most Companies Fail to Think Strategically About Outsourcing

**C**OMPANIES continue to make outsourcing decisions that are driven by cost reduction and the desire to focus on their core operations, rather than pursue outsourcing in an effort to drive more revenue and seize competitive advantage. That is the conclusion of a new research study conducted jointly by CAPS: Center for Strategic Supply Research and A.T. Kearney. The study, *Outsourcing Strategically for Sustainable Competitive Advantage*, surveyed 165 companies representing 24 industries.

More than 80% of companies in the study said reduced operating costs, reduced capital investment, and the need to focus on their core business were the primary reasons for their outsourcing activities. Fewer than half of the companies cited reasons related to revenue growth, such as increased speed to market (46%), improved quality (42%), and faster customer response time (40%).

The majority of companies with cost-related goals for outsourcing said they met or exceeded those goals. The average cost savings for these companies was 13%, but more than one-third reported savings greater than 15%. In contrast, the majority of companies with revenue-related goals for outsourcing reported falling short of those goals.

"It's clear there are two different approaches to outsourcing at work," says Bill Markham, a principal with A.T. Kearney and coleader of the study. "Companies seeking quick savings focus their efforts on finding less expensive alternatives to operating their business today. Companies focused on tomorrow's business needs are seeking more significant long-term benefits and looking to leverage marketplace skills, technologies, and scale to cut costs and increase revenue."

The study examined the breadth and depth of outsourcing across 14 different activities in research and development, marketing and sales, supply, manufacturing and distribution, and corporate support. Every company studied reported outsourcing at least one of the activities, with 50% saying they outsourced parts of more than eight activities.

The most common activities being outsourced were information technology (reported as outsourced by 36% of companies), distribution/fulfillment (32%), legal/regulatory affairs (30%) and manufacturing/operations (24%).

But companies are not outsourcing at a very deep level according to the study; 86% percent of study participants said they outsource less than 25% of activities overall. The average level of outsourcing penetration across the 14 activities was 15.8%. Even in information technology, the area with the deepest penetration by outsourcing, only 14% of respondents said they outsource more than 25% of their IT activity.

"Tactical outsourcing is a follow-the-leader approach, not a road to competitive advantage," says Robert M. Monczka, Ph.D., C.P.M., study coleader and director of strategic sourcing and supply chain strategy research at CAPS and research professor of supply chain management in the W. P. Carey School of Business at Arizona State University. "Strategic outsourcing can create new ways to compete and possibly rewrite the rules for whole industries."

The report suggests companies define from the outset whether the strategic intent of their outsourcing efforts is cost reduction or revenue generation. It also recommends the following steps to give companies an edge in achieving their outsourcing goals:

- Anticipate shifts in the future business environment such as political and social backlash, changing demographics in emerging economies and dwindling natural resource supplies, and consider the effect these shifts would have on future outsourcing activities.
- Build tomorrow's corporation by seeking skills, technologies, and scale from the marketplace rather than assuming that these capabilities must be developed internally.
- Address the execution issues inherent in any outsourcing activity by clearly defining roles and responsibilities across the corporate functions involved.

Sources: A.T. Kearney Inc., Chicago. For more information, visit [atkearney.com](http://atkearney.com). CAPS: Center for Strategic Supply Research, Tempe, Ariz. For more information, visit [capsresearch.org](http://capsresearch.org).



**Craig Lipset**

Compound Therapeutics

**We outsource manufacturing, lab/analytics, toxicology, and pharmacology. In some cases we outsource based purely on capacity — not from a human resource standpoint, but from a technology and physical space perspective.**

**REUTER.** During the selection process, two methods have greatly assisted in identifying which vendor would be the best partner over the long-haul. The first is to meet the team. It is essential to meet the team members who will be doing the actual work and with whom the sponsor's team will interface. This should be done early in the selection process, and definitely before a vendor is selected. The second is to have a working meeting rather than "dog and pony show." Instead of spending time hearing the corporate information and marketing pitch — the grants and contracting department can obtain this information — it is helpful for the first meeting between the vendor and the sponsor to focus specifically on how the vendor would address the project at hand. The sponsor can determine what aspect of the project is the most key in selecting vendors, and ask all vendors to present the approach they would take. Making this an interactive session, with the team responsible for the project at the sponsor asking questions, as well as the exchange of ideas makes the time spent productive. This approach also provides an opportunity for both parties to experience how the other communicates. Spending time actually brainstorming together about the specific project, rather than using time on hypo-

thetical issues, is much more useful in obtaining the type of information that will be helpful in choosing the best outsourced partner.

**MILLER.** I really think outsourcing is about developing a close relationship with suppliers and communicating on a regular basis, letting them know exactly what the expectations are, and then following up with them as the studies progress.

**BLANKSTEIN.** The worst thing a pharmaceutical sponsor can do is turn all the work and responsibility to the service provider. Companies need to provide constant oversight and management of vendors, and that can take anywhere from one to three people depending on the size and complexity of the trial. There should be someone from data management, biostatistics, and the clinical group at least, as part of the team that is responsible for overseeing the suppliers.

**CAMPANARO.** A best practice that we learned is to establish clear and concise expectations early in the process, which both sponsor and supplier agree to. And both sides

## Pharmaceutical R&D Outsourcing Strategies: An Analysis of Market Drivers and Resistors

**S**HAREHOLDER appetite for growth has not diminished, in stark contrast to the pharmaceutical industry's ability to generate return on capital employed. While R&D and sales and marketing have traditionally been held sacred as core competencies, the time has to come to reassess this assumption and the alternative — outsourcing. Based on an extensive program of research, including interviews with senior pharmaceutical industry executives, conducted by Business Insights, key findings include:

- Of the 44 products generating blockbuster sales in 2000, 33 will lose patent protection in the United States before 2007, exposing about \$45.5 billion of U.S. ethical revenues to generic competition.
- Estimates of the proportion of clinical development (Phases I-IV) outsourced vary between 20% to 40%, while many analysts estimate that less than 15% of preclinical evaluations are outsourced.
- An effective outsourcing strategy will determine the optimal level of in-house versus outsourced R&D activity and maintain this, allowing for fluctuations in resource demands.
- While the larger CROs have been adding additional services to their portfolios in an attempt to act as one-stop-shops, it is clear that many pharmaceutical sponsors are not yet comfortable with outsourcing entire portions of their R&D activities to single providers.

Source: Business Insights Ltd., London. For more information, visit [globalbusinessinsights.com](http://globalbusinessinsights.com).

The key is to select a vendor with whom the relationship can proceed as smoothly as possible during the course of the project. **The corporate culture of the vendor company must be compatible with that of the sponsor, as must the communication styles of the individuals who will interface with the sponsor's team.**

monitor the expectations at set time points throughout the relationship.

**BLANKSTEIN.** Because there are so many suppliers out there — and many of them are very good — I look for the small things that set one vendor apart from another. The differentiation might be responsiveness to phone calls, whether they come back to me with questions, the experience of their staff, or whether they have a particular technology that others do not.

**MILLER.** I had a global group with people from Europe, Japan, and the United States. In hindsight, it would have been nice if we all could have gathered at one location for an extended period of time to go through the project. Sometimes, processes became drawn out because people were not available. I would recommend more face-to-face meetings with suppliers and maybe even pulling people together for a few weeks during the high-pressure points for a particular project.

## WHAT IS AND ISN'T BEING OUTSOURCED

*Pharmaceutical and biotechnology companies are finding value in outsourcing many of their clinical-trial operations to meet their study requirements.*

**AHN.** Like most biopharmaceutical companies, Hana collaborates with contract research organizations to accelerate the pace and geographical scope of our clinical trials. We try to keep core activities, such as protocol writing, in the company. Currently, the minority of Hana's R&D budget is outsourced.

**BLANKSTEIN.** We outsource clinical services, data management, clinical monitoring, statistics, medical writing, preclinical GLP studies, analytical development, and so on. We don't outsource safety monitoring. We want to have a much better understanding and dialogue with individuals who

report safety issues about our drug rather than going through a third party. This is one of the areas that we are diligent about maintaining control over.

**CHARLES.** Our target is to outsource 30% or more of our clinical activities across our global development organization. We outsource all services associated with conducting a project, including prestudy clinical services, project management, safety reporting, study start up and recruitment, medical monitoring, and data services. Other services we outsource, though less frequently, are biostatistics and programming services, clinical study reporting, and protocol preparation. We outsource to CROs, central laboratories, central ECG companies, IVRS companies, independent radiology review organizations, rater training firms, and other clinical R&D services companies. We generally do not outsource activities involving contact with regulatory authorities, critical safety activities, and even less frequently, drug supply management, biostatistics and programming, and medical writing services. We generally do not outsource Phase IIa and proof-of-concept trials. Very small studies or ones that may share sites with in-house studies would also be less likely to be outsourced.

**LIPSET.** We outsource manufacturing, lab/analytics, toxicology, and pharmacology. In some cases we outsource based purely on capacity — not from a human resource standpoint, but from a technology and physical space perspective. That might be for certain preclinical work where we simply don't have the space for another study or it might be for manufacturing and GMP work, where certain technology is needed that we are not interested in purchasing. There aren't any services that we wouldn't consider outsourcing.

**CAMPANARO.** Roughly 20% of our organization's total R&D dollars are outsourced. We would outsource all services depending on size/scope of project, except for clinical project/trial management and safety reporting. As we continue to build capacity and capabilities, we expect to carry-out more clinical operations and biometrics/data management work internally.



**Sherry Reuter**

Alexion Pharmaceuticals

**BLANKSTEIN.** We outsource based on our internal resources. If we don't have the available resources and want to move forward with a project, then we'll outsource a part of the work or all of the work. We prefer to do the work internally if we can, but if we can't then we'll outsource. We believe we have much more ownership of our projects than any supplier. We would also outsource work when we do not have the expertise. For example, we may need a core

laboratory to do ECG reads for us or we may need a company to create patient-recruitment advertising campaigns.

**CHARLES.** As scientific and market environments change and technology advances, we plan to prepare accordingly. The need to increase productivity in R&D is being widely discussed in the industry. At BMS, the way we manage outsourcing has undergone a transformation over the past two

## R&D Outsourcing in Big Pharma



*By 2010, we predict that 50% of big pharma R&D will be outsourced to more capable firms to maintain a strong and vital pipeline of new blockbuster drugs, says Neil J. Nelson, President, Cofounder, and Chief Services Officer of Clarkston Consulting.*

**T**RADITIONALLY, pharmaceutical company successes have been dependent on innovation and research and development (R&D) efforts, which are responsible for bringing new blockbuster drugs to market. Today, pharmaceutical companies are met with many challenges as they attempt to continue their success and appease strong masses of shareholders.

*Some of the most daunting challenges currently facing the pharmaceutical R&D executive include:*

- Shorter product life cycles;
- Slow FDA approval times for new drugs and changing requirements;
- Increased competition; and
- Lack of ingenious and innovative R&D.

Expediently capitalizing on R&D expertise or intellectual property is an important success factor in today's competitive business climate. Some pharmaceutical companies have taken the course of mergers and acquisitions to address filling their pipelines, while others have started outsourcing R&D to ensure an attractive and robust pipeline for the future. Over the past decade, outsourcing solutions have commonly been applied to the pharmaceutical industry in the clinical development

and testing phases. that are generally the nonstrategic support functions in an organization, such as IT infrastructure support or telephone maintenance. More recently, outsourcing core business processes has become increasingly popular, and outsourcing solutions have become geared toward stripping the cost of large-scale, manually intensive business processes through BPO (business process outsourcing). Some of these core functions include managing back-office operations, such as accounts receivable, payroll, and MRO purchasing.

Partnering with outsourcing service providers facilitates the organization's processes to improve organizational efficiency and lower operating costs. More recently, in consideration today, is value-added partnering, which benefits companies in areas that are more connected to the company's ability to grow and increase shareholder value. Value-added outsourcing partnerships are often referred to as strategic alliances or joint-venture relationships. Examples of value-added outsourcing include activities involving manufacturing, marketing, and R&D.

A strategic alliance, the fastest growing type of service partnership, aims to deliver client value with creative solutions and project management skills and to structure meaningful contracts that accommodate change. These alliances also allow the outsourcing agents to pursue full-service and/or global outsourcing deals.

On the other hand, joint venture is a type of relationship that offers a new business model for outsourcers to work more strategically and creatively with their clients and potentially develops revenue-producing business opportunities.

### FOCUS ON R&D

Pharmaceutical companies have their greatest assets in R&D, the "crown jewels" for any growing pharmaceutical company. Double-digit growth and escalating market caps are not possible without the consistent advent of new blockbuster drugs. Many executives are sure to balk at the notion of letting the livelihood of their firms be the responsibility of another; but over time, this will change.

Pharmaceutical companies can extrapolate from the lessons learned from the biotech market and from experiences in partnering with academic institutions to research new drugs. According to the Centre for Research in Innovation and Competition, University of Manchester, firms — even large multinational corporations — can no longer expect to be totally dependent on their in-house research and technology resources to maintain innovative performance.

Another driver for cooperation and outsourcing in R&D is expected from the FDA and other regulatory authorities. The FDA is determined to improve the review and approval processes to help highly effective drugs and new therapeutic principles become available faster. But safety concerns require more, and often additional, tests and cause delays for the time to market of all pharmaceuticals. Using a development partner for a specific patient population will definitely shorten development time and cost and it may also help improve the safety of a novel drug. Mandatory are selective diagnostic tests that provide enough information about a target patient group to provide effective drugs with a tolerable side-effect profile. Big pharma is well advised to

and testing phases.

In 1998, U.S. pharmaceutical companies outsourced 15% of their manufacturing projects, 21.5% of their clinical evaluations, and 14% of their R&D endeavors. In 2003, CROs accounted for about 20% of the pharmaceutical and biotechnology R&D budget.

Outsourcing relationships between companies are often complex and not easily defined. These relationships differ based on the services outsourced as well as management's approach to outsourcing activities and how much control they exert. In some outsourcing relationships, the buyer may not instruct the supplier on how to deliver results by performing a set of tasks, but may only be interested in achieving the desired results. But in other cases, the buyer may seek more involvement and control in defining how the results should be delivered.

According to Clarkston's Advantage Advocate, an organization of influential, senior-level executives from the life-sciences industry who convene and discuss current issues, the evolution of outsourcing has moved through three phases: outsourcing of support functions; process outsourcing of core functions; and value-added partnering.

To most people, outsourcing is associated with noncore, mundane activities

years, substantially improving our business processes and enabling us to work much more efficiently — and closely — with our alliance partners and preferred partners. We have established successful alliance partnerships that leverage implementation of shared IT and data systems, shared business and clinical processes, and a supplier relationship management (SRM) initiative. With an emphasis on up-front planning, standardization of processes globally, and an

armamentarium of outsourcing tools that include an outsourcing handbook and a project-management charter designed for each project, I believe we have advanced Bristol-Myers Squibb to the forefront in the way we manage outsourcing. Currently, we are considering making greater use of program-level awards, EDC implementation with partner CROs, and increasing outsourcing in India, China, and other developing markets.

include in its R&D program cooperative steps with diagnostic research facilities to incorporate the relevant assay development for using selective tests in their development process.

### THE GROWING TREND OF OUTSOURCING R&D

Before the 1990s, the preclinical stages of R&D, particularly drug discovery, were not outsourced, often because of the proprietary and secrecy issues surrounding patented information. Now, even big pharmaceutical companies recognize the need to outsource drug discovery. This shift in attitude is attributed to the fact that most drugs marketed today were not discovered in-house. There is more intellectual property outside the organization, especially with the impact of genomics and proteomics in therapeutics. In most cases, outside discovery work proves to be cheaper and faster.

Pharma companies have traditionally been willing to forge alliances with outside organizations to generate new ideas and be on the brink of new breakthrough technologies, which historically have had roots in academia or biotech firms. This form of outsourcing — pseudostrategic alliances — includes pharmaceutical companies partnering with biotech firms, university research centers, contract research organizations, and other third parties.

These alliances have allowed pharma companies to use other organizations' research expertise, bring products to market faster, and mass produce drugs after FDA approval. But a more pressing need is to move toward the formal outsourcing of R&D activities to established firms that specialize in the business of R&D outsourcing, particularly in the area of drug discovery.

Thus, R&D outsourcing is becoming not just a trend, but a way of life — and survival — for even the largest pharmaceutical companies.

"The pharmaceutical industry is currently in a very challenging period," says Neil J. Nelson, president, cofounder, and chief services officer of Clarkston Consulting. "The days of blockbuster drugs filling product portfolios and year over year double-digit top-line growth are becoming much harder to realize. Firms that are able to adapt to this new paradigm will emerge as the new leaders in this industry. Some of the household names from the past may find themselves scrambling to secure their future and maintain their level of confidence with investors and shareholders.

"It will be those companies that are able to step outside of their own sand box and reach out to small and more focused, research-oriented specialty firms that complement their traditional processes," he continues. "One challenge those large houses will face is harnessing the intellectual capital and sheer energy into a disciplined approach that can lead to success. Companies that can infuse an excellent and balanced project management capability with an emphasis on control of schedule slippage and cost overruns, without compromising outcome deliverables, will rise to the top of the industry."

Additionally, maintaining a consistent methodology related to GxP compliance around deliverables that will be the subject of regulatory inspections before prod-

uct distribution will help fend off any unwarranted delays in product development cycles.

"In short, it will be firms that have invested in the development of their internal and external business practices that can then successfully port that discipline to their development partners that will lead the new pharmaceutical model for the 21st century," Mr. Nelson says.

### R&D OUTSOURCING: PROS AND CONS

#### THE ADVANTAGES:

- **Reorganization Benefits.** In the pharmaceutical industry, some proponents of outsourcing R&D activities cite the need to have a tighter focus on core competencies. With outsourcing, organizational benefits exist whereby pharmaceutical companies are able to redistribute internal resources to best support core business functions after an R&D outsourcing arrangement.
- **Greater R&D Business Benefits.** According to the Advantage Advocate forum, outsourcing will bring many R&D benefits by reducing development time, decreasing the cost of development, and generating greater revenue.

***Outsourcing requires a long-term commitment, but will generate tremendous benefits if done correctly. In addition, multiple products can be sought with the help of outsourcing, thus yielding a larger pipeline and an expanded product portfolio.***

- **Reduced R&D Complexity.** Outsourcing also helps reduce R&D complexity, which is sometimes faced by large pharmaceutical companies. To develop competent intellectual property, outsourcing provides: access to technological innovations, rapid access to additional R&D capacity, access to therapeutic expertise, and alignment with diagnostic tests for safer and more effective therapies.
- **Financial Benefits.** According to the Advantage Advocate Forum, outsourcing enables the supplier and buyer to: share costs, share benefits, decrease development risks, improve profitability, and overcome liquidity bottlenecks.

The buyers' up-front capital requirements are reduced and operating costs are controlled. With these financial benefits, outsourcing works best in increasing profitability.

#### THE CONSIDERATIONS:

- **Proprietary Concerns.** When outsourcing any key business activity, it is important to ensure that core intellectual property is not at risk of being given away. A trust/partner relationship must be fostered with the outsourcing supplier.

***The pharmaceutical company should decide what key strategies and confidential information should be shared with the supplier, and have that captured in a carefully structured legal agreement.***

- **Management Concerns.** Outsourcing activities require efficient management skills to facilitate the progress of bringing the drug into the pharmaceutical

**CAMPANARO.** Factors we consider when outsourcing include whether upcoming trials will compete for internal resources already deployed — and to what percent; timelines; project objectives; and unique expertise that may reside with certain contract vendors.

**AHN.** As Hana grows from early-stage clinical trials

to registration trials, our needs for conducting trials in multiple sites and geographies will drive greater levels of collaboration with corporate partners and CROs.

**PHARMALINX LLC**, publisher of the VIEW, welcomes comments about this article. E-mail us at [feedback@pharmalinx.com](mailto:feedback@pharmalinx.com).

## R&D Outsourcing in Big Pharma (continued)

company's downstream pipeline processes. The management process has to be agreed upon by both supplier and buyer. There may be a concern on the buyers' part of ultimate loss of project control if the outsourcing relationship is not managed correctly. Additionally, management needs to assess the temperament and impact on internal employees of the outsourcing activities and ensure that low morale does not result. Managers with clear responsibility and knowledgeable and empowered staff are needed to oversee management of outsourcing activities.

**In addition, management must be flexible so that the supplier can deliver creative solutions.**

- Establishing Good Standards. According to the Advantage Advocate Forum, a well-defined process needs to be in place as technology and design requirements are transferred and communicated; each activity needs to be carefully assessed and recorded. To evaluate delivery of products and services, quality standards and associated performance metrics need to be determined early on in the outsourcing agreement.

### BEST PRACTICES FOR OUTSOURCING R&D

- Contract. The key issue in a successful outsourcing relationship is for the supplier to understand the buyer's goals and objectives. In the outsourcing agreement, a strategic vision and a plan that define a common set of objectives must be scoped out. A properly structured contract, containing expectations of both the buyer and supplier and incentives to make the relationship work, needs to be tailored.
- Trust. There needs to be open communication during the life of the outsourcing agreement. Outsourcing suppliers require open and honest communication, and trust is naturally established on shared information. Quality time needs to be spent between the supplier and buyer; and integrity and clear expectations should be developed.
- Professionalism. Both the supplier and buyer need to enter into the relationship with openness, and they need to be willing to accept that cultures of both supplier and buyer could be different. A paramount relationship requires: team-building endeavors and new work processes as needed, documentation of all agreements so that neither party is misled; senior executive support, outside advice to foster a successful relationship, development of people's collaboration skills, and establishment of clear governance and measurement processes to assess progress. In addition, do not ignore personnel issues, and make sure to address them with good management skills.
- Management. In the outsourcing relationship, a great management process can either make or break the deal. Effective results of cutting operating costs in the pharmaceutical company could fail if a good management system is not in place to provide guidance and accountability. Key predictors for great management are finding a great leader; who need not be from either the supplier or buyer companies. Also, seek an executive sponsor who will have ownership of the project and will provide clear direction for projects, remove any obstacles, resolve problems quickly, give advice and guidance in vendor selection for outsourcing efforts, and provide reinforcement and encouragement.

The program management office (PMO) is an effective management solution that has been shown to deliver projects on time and budget, cut costs, and improve efficiency. The PMO's main responsibility is to instill a level of structured leadership and methodology across all projects and make the best use of resources. The objective of a PMO is to promote consistent, repeatable practices that result in successful projects and use business resources efficiently. A successful PMO can provide guidance in assessing outsourcing options resulting in plans to understand and leverage alternatives for achieving greater results and improved services. In addition, the PMO solution offers a risk-mitigating, ongoing governance structure for a R&D outsourcing relationship. It has an effective management structure with the right controls in place.

### KEY CONSIDERATIONS

**Is it more effective to outsource certain R&D activities to an innovative organization than to acquire that organization?**

**Yes.** If the innovative organization is acquired, then its inventiveness will over time become stifled by the controls that are inherent to larger organizations.

The regulatory controls are the same for all firms involved in the manufacture of pharmaceutical products. Smaller, innovative organizations save a great deal of time in areas such as purchasing, HR, and communications because decisions are usually made quickly, and action is taken that results in shortened cycle times.

**Are larger pharmaceutical companies more capable of cGMP compliance than smaller, innovative organizations?**

**No.** Compliance with cGMP is actually easier to achieve in smaller, innovative organizations. Once alignment has been achieved regarding compliance deliverables, the innovative organization will quickly organize to achieve these deliverables.

**Is it true that smaller, innovative firms can do things faster because they are willing to take risks that large, established pharmaceutical firms will not take?**

**Yes.** But these should not be regulatory exposure risks. There are risks that can be taken that do not compromise cGMP compliance. Employees at smaller, innovative firms are often encouraged and empowered to both propose and take risks that close the gap between scientific soundness and compliance with cGMP.

The culture and modus operandi are effective in decreasing the time required to move a compound through the R&D process.

**Does acquisition (compared with outsourcing) provide more control of proprietary information?**

**No.** Firms that provide outsourcing services are highly motivated to protect their customers' information. It is in their interest to do so to protect their reputation and secure future business.

**Is in-sourcing a team of innovative people as effective as outsourcing to a similarly innovative organization?**

**No.** Although in-sourcing can work in a highly disciplined and well championed environment, in reality the in-sourced group will tend to lose its innovative edge as influenced by even limited sponsor management and QA oversight.

Source: "R&D Outsourcing in Big Pharma. The latest trend: Is it for you?" October 2004, Clarkston Consulting, Durham, N.C. For more information visit, [clarkstonconsulting.com](http://clarkstonconsulting.com).