BY DENISE MYSHKO

» R&D OUTSOURCING

CONTINUED

OUTSOURCING EXPECTED

Sponsors are expected to develop better resource planning and forecasting methodologies that rely on more integrated relationship structures with contract research organizations.

While global spending on new drug development has been growing at an annual rate of 9.1% during this past decade, spending on contract clinical services has been growing almost 50% faster, at an annual rate of 13.4%, according to the Tufts Center for the Study of Drug Development.

Even as the number of companies with active clinical projects worldwide increased by 80% between 2000 and 2008, sponsors have kept their R&D headcount level by working with CROs. The trend to work even closer — to improve R&D efficiency — will continue as both parties develop alliances in place of traditional transactional relationships.

Companies are moving toward the outsourcing of the entire development phase rather than components through new strategic partnering arrangements.

"This provides companies with the ability to drive more effective risk sharing arrangements that help to minimize the loss of ROI through late stage failures," says Terri Cooper, principal and national leader, life-sciences R&D practice, Deloitte Consulting. "In development, the objective should be to mitigate execution, financial, and regulatory risk."

Beth Price, executive VP at The Medical Affairs Company, says pharma has clearly accepted and embraced the value of outsourcing spanning a variety of services respective to the early phases of preclinical development to the more advanced commercialization phases.

"It is without question that our industry continues to receive enormous pressure to reduce costs, get drugs to market as quickly as possible, and use internal resources as efficiently as possible," she says. "With respect to the area of medical affairs commercialization strategies, pharmaceutical, biopharmaceutical, and medical device companies have significantly expanded their use of outsourced, field-based medical personnel, including medical science liaisons, drug information, and pharmacovigilance services during the peri-launch and launch phases of drug development through partnerships with contract medical organizations (CMOs)."

She says the smaller, emerging and mid-size companies comprise the lion's share of companies outsourcing these pre- and early-market medical affairs services because of a host of factors, including: limited internal resources, lack of infrastructure, expertise surrounding these competency areas, and, oftentimes, the risks associated with not having a formal FDA-approved drug.

"The flexibility and convenience afforded to companies from partnering with CMOs during this provisional growth period enables them to thoughtfully and strategically launch their medical affairs commercialization structure while simultaneously developing an internal medical affairs department," Ms. Price says.

Dr. Amar Sethi
Pacific Biomarkers
"Early collaboration with CROs establishes a greater amount of confidence on the part of the drug developer, which in turn leads to comfort in working collaboratively or as partners in creating potential companion diagnostics."

FACTORS THAT CONTRIBUTE TO A SUCCESSFUL R&D TRANSFORMATION

- Assemble the correct team: Involve members from all levels of the organization. Provide teams with necessary resources and mix of skills.
- Communicate effectively internally: Explain changes and rationale to employees at all levels.
- Maintain leadership engagement: Serve as an example and prevent reversion to legacy processes.

Source: Deloitte. For more information, visit deloitte.com.

Susan Bornstein
eClinical Solutions
"Since EDC and clinical data management are not core competencies for sponsors, they outsource them, leaving time for them to focus on their area of expertise: the science."

Dr. Jason Hwang
Innosight Institute
"For many traditional pharmaceutical companies, outsourcing discovery has become necessary simply because the timeline and end-products of discovery are highly unpredictable, while the commercial operations of the firm demand predictability."

The majority of outsourcing is in the later phases of drug development, but this is changing, says Amar Sethi, M.D., Ph.D., VP, science and technology at Pacific Biomarkers.

"Late-phase work is outsourced because later phases require more regulation and standardization, and this can be readily monitored," he says.

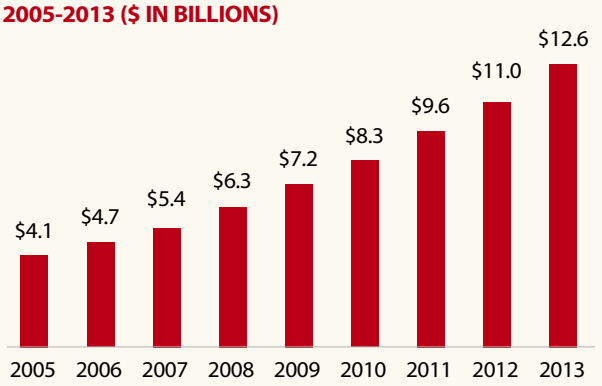
OUTSOURCING DISCOVERY

Experts are beginning to see more companies outsource sooner in the development process. In fact, many smaller biotech companies are outsourcing early-phase development, says Graham Reynolds, VP of marketing and innovation pharmaceutical delivery systems at West Pharmaceutical Services.

"Manufacturers are outsourcing noncore competencies and increasingly relying on CMOs to provide solutions and expertise," he says. "Early partnerships with device and technology providers help reduce time to market while helping to ensure that the final product meets all requirements, and is delivered in a safe, effective, and identifiable package."

Ms. Cooper says companies are outsourcing discovery for the same reasons as in development: life-sciences companies are looking for strategic partnerships that will leverage an increase in the risk sharing and thereby provide them with increased funding to drive more products through the discovery pipeline, and to mitigate scientific risk.

GLOBAL DRUG DISCOVERY OUTSOURCING MARKET 2005-2013 ($ IN BILLIONS)



Source: Kalorama Information. For more information, visit kalorama.com.

Experts from Kalorama Information say several trends have led to an increase in demand for contract services in drug discovery:

- Development of new technologies that continued to increase the number of targets and accelerate the identification of active compounds;
- Pressure to develop new lead compounds because of the near-term loss of patent protection for many drug products;
- Increased pressure to reduce the time spent in drug discovery and to bring drugs to market sooner;
- Increased focus on converting fixed costs to variable costs and streamlining operations by contracting for research and development services;
- Heightened regulatory environment and increased complexity that made the internal management of complicated discovery projects more difficult and costly; and
- Biotechnology and emerging pharmaceutical companies, in many cases, lacking the required in-house drug discovery and development expertise.

The time-consuming and labor-intensive nature of discovery programs makes it a target of outsourcing to gain cost-efficiency, says Paul Chung, chief operation officer of ISI.

"There are several reasons for this, the top three include the usual suspects: cost, speed, and yields," he says "But intellectual property-related concerns remain and careful administration of the programs and governance measures will need to be applied."

Jason Hwang, M.D., executive director of healthcare at Innosight Institute, says for many traditional pharmaceutical companies, outsourcing discovery has become necessary simply because the timeline and end-products of discovery are highly unpredictable, while the commercial operations of the firm demand predictability.

"To compensate for this incongruence and feed the beast, firms have had to look outside for help," Dr. Hwang says.

Another major trend that continues to gain momentum is choosing outsourcing partners in Asia and Eastern Europe.

Pharmaceutical and biotech companies are increasingly outsourcing discovery programs and collaborating with CROs more and more," says Glenn Gormley, M.D., Ph.D., chief science officer, co-head, research & development, Daiichi Sankyo, and global head of development, president, at Daiichi Sankyo Pharma Development (DSPD).

"In fact, CROs provide the flexibility in the workforce necessary to manage through difficult very turbulent times," he says. "Additionally, CROs allow companies to react to contracting portfolios when projects fail, which is the model that provides the most flexibility today."

Another trend, Mr. Reynolds says, is outsourcing specialized testing, such as extractables and leachables testing and functional testing related to the delivery system.

Dr. Sethi says early collaboration with CROs establishes a greater amount of confidence on the part of the drug developer, which in turn leads to comfort in working collaboratively or as partners in creating potential companion diagnostics.

"These can be used in later phases of development and postmarketing," he says. "Also, if the discovery program is heavy on technology requirement outsourcing could be less costly and faster. Regulatory requirements at GLP level could also drive early collaboration or partnership."

Dr. Gormley says one of the main drivers for outsourcing discovery programs is cultivating long-term relationships that allow all parties to benefit from the shared knowledge, technology, and key learnings.

"This approach will ultimately simplify and streamline the planning and implementation of clinical studies, reduce study conduct delays, and improve investigative site adherence and overall performance," Dr. Gormley says. "Partnership models with real risk-sharing relationships are becoming more common, replacing the traditional contractor-based relationships."

OUTSOURCING DEVELOPMENT

Susan Bornstein, executive VP at eClinical Solutions, says clinical operations are most frequently outsourced because sponsor companies require the ability to scale resources based on the phase of the clinical trial, the volume of the data, the pace of patient enrollment, and the ability to find patients.

"Since EDC and clinical data management are not core competencies for sponsors, they outsource them, leaving time for them to focus on their area of expertise: the science," she says.

Todd Reul, director of clinical services at ClearTrial, says Phase I and early Phase II are crucial to the success probability of a program.

"In the early phases of clinical research, sponsor companies are motivated to be as close to the drug candidate as possible to ensure they have a good understanding of the safety, pharmacokinetic, and pharmacodynamics of the drug," he says. "This knowledge is then used by the sponsor to determine the next research steps to take to increase the success probability of the drug candidate. Secondly, they want to minimize a perceived risk in outsourcing activities. The view is that outsourcing is best suited for operational efficiency, not scientific exploration."

After this stage, he says, outsourcing is more palatable because clinical trials are less about scientific discovery and more about building a clinical database to ensure the drug is both safe and effective.

"In addition, the size and scope — number of sites, subjects, location of sites, etc. — of late Phase II, Phase III, and Phase IV clinical trials typically demand more resources than are available at most sponsor companies," Mr. Reul says.

John Blakeley
ERT
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THE CONVERSION OF DATA INTO INSIGHTS

R&D organizations will be empowered for high performance only if they develop a fundamental, underlying new capability. This critical new capability is D2i: the ability to convert data into product-shaping, market/customer-influencing insights. In the future, these capabilities will be game changing. For example:

- The global attributes of the future model are already evident today in many organizations' multinational regulatory intelligence capabilities. In five years, areas of global capability will have expanded to include sentiment monitoring across patient support and advocacy groups, regulatory advisory panels, and physicians.
- The transparency attributes of the future model are likely to take fuller shape in such capabilities as pharmacovigilance and predictive toxicology.
- The networked aspect of the future model is already evident in genomic target qualification and validation, which connects the dots across research sources.
- The outcomes focus that lends itself to the bundling of healthcare services is evident today in tools such as patient characterization and segmentation, cohort analysis, predictive modeling, simulation/modeling for protocol design and adaptive clinical trials, and patient recruitment.
- In five years, this focus will have emerged more fully in such applications as evidence-based medicine that leverages health outcome data; trial design based on information contained in electronic health records; and the conversion of genomic data into insights for truly personalized medicine.

Source: Accenture.
For more information, visit accenture.com.

Dr. Gormley says with development portfolios changing with greater variances than they used to, it's important to react to sudden bursts of need for a large development expertise.

"That is why pharmaceutical and biotech companies are increasingly outsourcing critical functions, such as site selection, clinical site management, safety surveillance, IT support, compliance training, and even the implementation of electronic clinical trial technology," he says.

Some organizations are far more comfortable with outsourcing than others.

"Companies that are strategically outsourcing are able to speed the development of drug candidates much more than those that are tactically outsourcing," says John Blakeley, executive VP at ERT. "Those that are tactically outsourcing tend to do so on a functional basis and are cautious when they believe outsourcing encroaches into the intellectual property. Larger companies tend to be more tactical while smaller companies often allow vendors closer to the intellectual property as they need a broader base of expertise from which to work."

Mr. Reul says one significant outsourcing trend — increasing levels of sponsor/CRO

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The Medical Affairs Company
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collaboration — has emerged in efforts to make the sponsor/CRO relationship more efficient, and this is a natural extension of the shift toward preferred provider relationships.

"A growing number of biopharmaceutical and medical device companies are entering into more extensive relationships with CROs in order to integrate systems and processes and achieve higher levels of efficiency," Mr. Reul says. "As such, pharmaceutical companies are transferring more operating risk to contract service providers. They also are taking steps to achieve greater transparency and deeper sharing of development cost and time data in order to exploit the efficiencies offered by more integrated relationships. New organizational approaches as well as new technology are making this possible."

James DeSanti, CEO of PharmaVigilant, says sponsors need transparency into data and projects so that they can comfortably outsource.

"Sponsors can no longer ask vendors to self-police; they must have checks and balances in place," he says. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

EXPERTS

JOHN BLAKELEY. Executive VP, ERT is a global provider of technology and services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit ert.com.

SUSAN BORNSTEIN. Executive VP, eClinical Solutions, a division of Eliassen Group, which takes a strategic approach to managing clinical trial data by combining data management with statistical programming, reporting, and customized training solutions integrated with a clinical data repository to deliver a complete end-to-end data management solution. For more information, visit eclinicalsol.com.

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JAMES J. DESANTI. CEO, PharmaVigilant, a SaaS company, provides broad technologies to streamline the clinical trial process for biopharmaceutical companies. For more information, visit pharmavigilant.com.

GLENN GORMLEY, M.D., PH.D. Chief Science Officer, Co-head, Research & Development, Daiichi Sankyo, and Global Head of Development, President, Daiichi Sankyo Pharma Development (DSPD), is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. For more information, visit dsi.com.

JASON HWANG, M.D. Executive Director of Health Care, Innosight Institute, a nonprofit, nonpartisan think tank whose mission is to apply Harvard Business School Professor Clayton M. Christensen's theories of disruptive innovation to develop and promote solutions to the most vexing problems in the social sector. For more information, visit innosightinstitute.org.

BETH PRICE. Executive VP, The Medical Affairs Company (TMAC), a provider of strategically aligned and customized MSL programs. For more information, visit themedicalaffairscompany.com.

TODD REUL. Director, Clinical Services, ClearTrial, which provides clinical trial operations (CTO) software that makes the planning, forecasting, and tracking of clinical project and financial performance faster and more accurate. For more information, visit cleartrial.com.

GRAHAM REYNOLDS. VP, Marketing and Innovation Pharmaceutical Delivery Systems, West Pharmaceutical Services Inc., a global manufacturer of components and systems for injectable drug delivery, including stoppers and seals for vials, and closures and disposable components used in syringe, IV, and blood collection systems. For more information, visit westpharma.com.

AMAR SETHI, M.D., PH.D. VP, Science and Technology, Pacific Biomarkers (PBI) provides biomarker laboratory services and contract research services to support pharmaceutical and diagnostic manufacturers conducting human clinical trial research. For more information, visit pacbio.com.

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