

John Hubbard, Ph.D.,  
senior VP and worldwide head  
of development operations,  
Pfizer

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# A New Paradigm For Strategic Partnerships

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By Rob Wright

**T**he year was 1849. Two cousins, Charles Pfizer and Charles Erhart, borrowed \$2,500 to found Charles Pfizer & Company as a fine-chemicals business in Brooklyn, NY. Pfizer experienced expansion, propelled by the demand for painkillers, preservatives, and disinfectants utilized during the U.S. Civil War. One hundred and sixty-two years later, Pfizer (NYSE: PFE) ranks as the largest pharmaceutical company in the world, with 2010 sales revenue eclipsing \$58 billion. Having survived one civil war and two world wars, the question remains, can Pfizer survive the 2011 patent cliff?

In November, the maker of the world's top-selling drug, Lipitor, will lose patent exclusivity for manufacturing the cholesterol pill. It is estimated that Pfizer stands to lose between \$10 and \$13 billion dollars a year through generic incursion. This type of loss requires a willingness to make the bold strategic business decisions necessary to not only survive the fall, but climb to new heights.

So far, Pfizer has demonstrated it has the gumption to proactively address the situation. This year alone, the company cut its R&D budget by \$1.5 billion and announced the closing of its 86-hectare R&D center in Sandwich, United Kingdom. It has also been acquiring companies and strategic partners (e.g. Synbiotics Corp.,



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King Pharmaceuticals, Ferrosan's consumer healthcare business, and recently Icagen, to expand its position in the pain relief disease area). In an unprecedented move, John Hubbard, Ph.D., senior VP and worldwide head of development operations for Pfizer, announced the strategic partnering with two CROs, ICON and PAREXEL, as preferred clinical trial outsourcing providers.

Hubbard sat down with me to discuss how the two-partner model evolved and how it is going to help spur innovation at the pharma giant.

## PARTNERING FOR PRODUCTIVITY: THE TWO-PARTNER MODEL

In May, Pfizer announced the culmination of seven months' worth of work in the form of a strategic partnership with two CROs, ICON and PAREXEL. The goal of this collaboration is to increase R&D productivity. I asked Hubbard what prompted Pfizer to move toward increased outsourcing of its clinical research. His response, "When we did our analysis, looking at R&D productivity, we felt we could do better by looking at this in a more holistic way."

WHAT ADVICE WOULD YOU GIVE TO OTHER EXECUTIVES WHO MAY BE IN THE PROCESS OF IMPLEMENTING A STRATEGIC PARTNERSHIP SIMILAR TO THE ONE YOUR COMPANY COMPLETED WITH PFIZER?

**Josef von Rickenbach, chairman and CEO, PAREXEL:** Generally, critical elements of these relationships include the ability to create value for the sponsor and deliver benefits, such as faster cycle times. Strategic relationships allow sponsors to focus on their priorities such as innovative research, while relying on partners to improve development effectiveness and operating efficiency.

Partnerships must be characterized by best-practice processes and high levels of quality, as well as the ability for the service provider to take ownership and infuse innovation into program design and execution. To be successful, partnerships must have well-developed governance constructs, open collaboration, a deep level of information exchange, and an outcomes-based approach focused on sharing the risks and rewards.

**Alan Morgan, group president, Clinical Research Services, ICON:** I think communication is key. There must be full transparency and an open flow of communication between both companies. With our existing strategic partnerships, we have a comprehensive set of shared metrics that help drive transparency and lead to more successful outcomes.

### What specific benefits do you perceive Pfizer gaining from this strategic partnership?

**Morgan:** Moving from their prior model, which included more than 17 separate vendors, to the new two-partner model will enable Pfizer to work more strategically to reduce complexity, duplication, and the number of handoffs. It also will increase clarity of accountability in the management of both risk and quality and increase line of sight and transparency in decision making.

**von Rickenbach:** Through the partnership with PAREXEL, Pfizer will gain innovative solutions and expertise to complete clinical trials, accomplish development goals, and reduce the time and cost of development. Another factor that contributes to success is assigning a dedicated relationship management team that adheres to a strict governance structure and is supported at a senior level by both companies. Finally, the use of strong collaborative tools, processes, and systems is also a critical component of a successful strategic relationship.



"We had to ensure good quality, and it's a lot easier to do with two partners than it is to do with 17 functional providers."

"The industry as a whole has been very capital-intensive in terms of the amount of money spent versus each dollar received. We thought we should be able to get a higher efficiency against the amount of capital we spent, and that's what drove the decision to move from around 17 functional service providers to 2 strategic partners." In addition to the benefit of greater capital efficiency, the two-partner model also provides other benefits.

## BENEFITS OF THE TWO-PARTNER MODEL

Given Pfizer's size, one might think reducing collaborations from 17 to 2 as being overly aggressive. Why not three or four? "At one point, there was consideration for just one," Hubbard replies. But, Pfizer wanted to build in some redundancies, which is one of the reasons it decided to implement the two-partner model. "When you have two, they really feel accountable," explains Hubbard. "When you start getting to four, there's a diffusion that occurs." Hubbard believes volume is one of the keys to the two-partner model being successful. He wanted to be able to provide partner CROs with a volume of work significant enough to keep everyone's

attention. To achieve this, Hubbard felt it necessary to pick CROs of adequate scale where the percentage of work would represent a significant part of their business, but not to the point at which they couldn't support it.

In addition to the benefit of volume and accountability for CROs, Hubbard thinks the two-partner model provides for tighter control over development activities. "I don't have to chase down multiple providers to find out if there's a problem," he affirms. "It gives me a clear picture by function and by therapeutic area into two providers." Hubbard explains, "We just held our first executive steering committee meeting, and the governance of the new relationships is already easier to manage by meeting with the senior executives from both organizations together and having very candid and open discussions regarding our progress and potential challenges. Given the size of our organization and the number of projects we run, simplicity, focus, and accountability are really critical." Other benefits Hubbard sees of the two-partner model are increased meeting frequency and better alignment of objectives.

One way to achieve better alignment is to incentivize strategic partners in the same areas critical to your organization's success. A tool that can prove useful to achieving this is a balanced score card (BSC) — a strategic performance management tool used to keep track of the execution of activities. According to Hubbard, Pfizer built a BSC into its agreements with ICON and PAREXEL. "We wanted to make sure we were very clear and put clear penalties and incentives in place to ensure, first and foremost, quality metrics are achieved," Hubbard says. Performance and cost metrics were, of course, also included, but Hubbard sees quality as the most important measurement. "We had to ensure good quality, and it's a lot easier to do with 2 partners than it is to do with 17 functional providers," he concludes.

Pfizer recently developed an integrated quality management

plan (IQMP), which clearly defines the critical-quality indicators, individualized to each study. "This approach creates clarity around the definition of quality for each study and decreases the potential for problems downstream using a quality-by-design approach," Hubbard explains. "Further, having clearly established critical-to-quality indicators enhances alignment of all parties, including regulatory agencies." Hubbard concludes, "Individual diagnosis by study, thoughtfully applied, will create greater value and reduce risk."

## THE CRO SELECTION PROCESS

Hubbard described the selection process as similar to stepping onto a moving train. "When I came on board, there had been some initial work done on the selection process, but what was missing was a deep dive into the details of what makes a good CRO partner for Pfizer and how the model would operate." The initial selection team consisted of 10 members and included representation from clinical, medical, development operations, R&D business units, procurement, finance, R&D, legal, quality, and external consulting support. As the process moved forward, additional members were added to the team, such as those with quality auditing and corporate compliance expertise. The expanded team eventually totaled 18 members and had the clearly established goals of simplifying the R&D model, achieving more consistent quality, and providing for clarity on accountability, governance, and value.

Because of Pfizer's size and the desire to outsource to just two strategic partners at significant volumes, the field of truly global CROs with fully integrated services was fairly narrow. According to Hubbard, only about six CROs had the capability of handling the volume of work in the two-partner model. Other considerations in the selection process included the CROs' geographic footprint, track record, financial stability, quality, ability to partner, ability to have a robust infrastructure, and procedures that would stand up

## Q&A: JOHN HUBBARD OF PFIZER

***How do you successfully manage more than 700 clinical projects throughout the world in various phases of development?***

"You need to review project metrics, speak with clinical project managers, and recognize when things are starting to get a little wobbly. When you've been in the industry a long time, you can sort of see where there might be potential things percolating. Then, I'll call the project manager to see if I can be of assistance. By asking questions, I can usually tell pretty quickly whether things are under control or whether I need to get more involved."

***Why did you pursue a second-degree black belt in martial arts, and how has it helped you in your working career?***

"I started my first training when I was about 15 and pursued it off and on over the years. When I turned 46, my wife said, 'You know, you're really boring because all you do is go to work and talk about work, and you're not doing anything else. Why don't you start martial arts again?' So, I did, and now I am working on my third degree. A lot of people ask, 'How can you be so calm with all of this going

on?' In large part it is due to the training. You just learn to center."

***Did you ever have someone you would consider a mentor?***

"I've had a lot of good mentors over the years. I think the first one in the industry who really had a profound impact on me was Dr. Vic Bauer, former president of Hoechst-Roussel Pharmaceuticals. He advised me and provided me with opportunities to learn and experience new things from research through commercialization. It's given me a broad view. From him I learned the importance of stepping outside of my comfort zone and trying something new."

***What book have you read that made the greatest impact on your life?***

"I'm sort of a believer that life is the biggest impact in your life. How you live your life and the things you do and the people you interact with really shape your life more than books. With that said, the ones I really like are *The Fifth Discipline* by Peter Senge, *Good to Great* by Jim Collins, and *The Innovator's Dilemma* by Clay Christenson."

to Pfizer interrogation and review. The selection process included an internal accreditation component, where the team had to sign off on all the processes and procedures used to select these providers. It was endorsed at three different levels all the way up to the executive leadership team. Hubbard had previously worked on the CRO side of the business. In his opinion, "To my awareness, this was the most robust analysis that has been done."

The key for Hubbard was to have transparency with CROs in the selection process. He described it as getting naked. "Tell me what you're not good at," Hubbard explains, "because I need to build contingencies around those areas." He wanted companies to expose the areas where they weren't strong or building capacity. This was not to exclude them from the selection process but to provide Pfizer with the insight on where it might need to backfill or retain the additional capacity and experience necessary to be successful. Hubbard believes this level of transparency helped create a real partnership feeling right away. "We were truly building this together as opposed to a typical transactional model," he says. "Any of these companies can do the job; we have to pick the best combination of companies that will not only work best with us, but work best with each other."

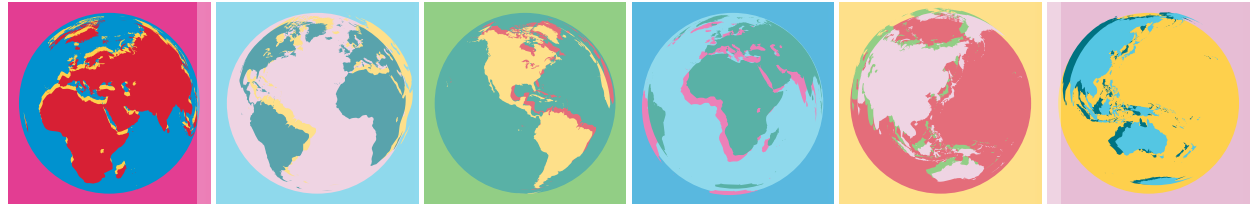
Hubbard's advice to other executives selecting a CRO: "Understand how your organization works, and map it against the

CROs in terms of how they are structured and how they operate." The decision to outsource clinical research or reduce the number of outsourcing partners necessitates companies not only doing thorough research on their potential partners, but also taking a hard look at realigning their internal structure to best capitalize on the collaboration. Hubbard surmises, "This wasn't simply about whom we picked; it was about how we structured ourselves as well."

## BENCHMARK FOR SUCCESS

Hubbard believes Pfizer has created a model with enough incentives to spur innovation, though he is not sure if it will be disruptive innovation. Nonetheless, he expects to see better protocol delivery, better quality, fewer errors, less rework, and more on-time or ahead-of-time deliveries. "We've benchmarked historical performance so we have a baseline to work from," he states. Some of the benchmarks include cost per study, cost per patient, number of trials that end on schedule, number of audit findings, and number of regulatory findings. Hubbard asserts that the best way to know if something is beneficial is to establish a baseline so you know where you are starting. He concludes, "We have to demonstrate improved value, which means less overall cost per study with better information. You can do this more efficiently and effectively in a two-partner model compared with working with 17 providers."

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