BY ROBIN ROBINSON

VIRTUAL PHARMA

CHEAPER AND FASTER, BUT DOABLE?

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CollabRx's Team:
Back row, left to right: Kai Mildenberger, Sean Gaherty, Tony Ley, Smruti Vidwans, Stephanie Nevins, Randy Gobbel, Mike Travers, Wendy Liu, and Jeff Shrager (behind partion). Front row, left to right: Sandra Noack, Aytek Çelik, Martha Dehnow, Jay "Marty" Tenenbaum, Keren Wasserman, and Catherine Ley, and Jonathan Jacoby.

DR. JEFF SHRAGER, CollabRx

COMMERCE HAS GONE TO AN INTERNET-BASED, SUPPLY-CHAIN WORKFLOW MANAGEMENT MODEL, and it's just a small step to make the equivalent move in a science-based industry.

Taking Stock

Our experts, all proponents of a virtual pharma concept, discuss the value, funding possibilities, and uptake of a new type of business model.

BERNARD. BERNARD ASSOCIATES. The uptake of the virtual pharma concept varies based on three key factors: corporate size, age, and strategy. Many of the larger, established pharma companies have been transitioning to a virtual model for years, particularly since the late 1990s. Almost every core and supporting pharmaceutical function can be and has been outsourced, including distribution, manufacturing, clinical development, and significant parts of sales and marketing. The last bastion of in-house functionality, product discovery, has been increasingly outsourced to biotechnology companies and other research entities. With increasing competitive and cost pressures, progressive large and small pharmaceutical companies are strategically transforming to more virtual, networked models.

GARCIA. ENOVIA. Each phase of the business model — drug discovery, development, marketing, distribution, production, etc. — has different characteristics that need to be considered when it comes to virtual. The first area to go virtual has been manufacturing. One could say manufactur-

More and more science-based projects are being shared across silos, networks, and organizations. At the same time, biomedical knowledge is expanding rapidly, but the existing drug-discovery process is unable to keep pace. THE INDUSTRY NEEDS TO FIX WHAT IS BROKEN, and the solution, our experts say, is in the evolution of a virtual business model.

ing was one of the early steps in moving to a virtual company. Outsourcing parts of the business that aren't high on the list of core competencies and keeping key areas in-house will help differentiate a pharmaceutical company. One of the factors that enabled manufacturing to be the first area to go virtual was a communications channel. Years ago, communications consisted of faxes and phone calls, but now, more and more electronic systems integrate the business processes of the supplier with the business processes of the pharma company. Underlying all virtual organizations in general — not just pharma — are better communications and efficiencies, which allow different organizations in different geographies to communicate. With these factors in mind, drug development is probably the next most likely process to go virtual. And the early-stage science portion of drug development is already starting to move that way. First-stage science has become more of a network collaboration, including academia, contract research organizations, pharma, etc. An important requirement for getting a drug to market more quickly is having wider networks of brainpower to tap into.

MUNOS. LILLY. Much of the interest in virtual pharma originally came from the neglected diseases communities and, to a lesser extent, the biodefense arena. The first steps were facilitated by WHO, which around 2000 encouraged the creation of public-private partnerships (PPPs) as a means to perform drug R&D for neglected diseases. Since they had to operate on shoestring budgets, these organizations came up with innovative processes to conduct and fund R&D across a range of diseases, such as malaria, tuberculosis, leishmaniasis, Chagas, and so on. At the same time, the cloning of major pathogens, the Internet and widening of broadband access, the creation of vast online databases, and the launch of the Entrez platform by NIH put enormous resources within reach of almost anyone wishing to freelance as a drug hunter. Suddenly, retired scientists, college professors, Ph.D. students, mathematicians, physicists, and moonlighters of all stripes everywhere in the world had free access to nearly the same resources that were once the province of large pharmaceutical firms. The creation of The Global Fund and the rise of the Gates and other foundations added billions of dollars to the effort. All of this has happened during the last seven or eight years, so the model is still being sorted out, but the interest is strong and growing. For instance, a few months ago, the government of India launched a $38 million open-source drug-discovery initiative focused on tuberculosis. Leading universities, such as Johns Hopkins, are contemplating getting involved. Harvard and MIT have already joined efforts aimed at malaria and Lou Gehrig's disease. DARPA is pursuing a well-funded effort of its own, books

Thought Leaders

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MICKEY GARCIA. Director, Life Sciences Industry Strategy, Dassault Systèmes Enovia, Woodland Hills, Calif.; Dassault Systèmes develops and markets PLM application software and services that support industrial processes and provide a 3D vision of the entire life cycle of products from conception to maintenance; Enovia, which supports global collaborative life-cycle management, is part of its portfolio. For more information, visit 3ds.com.

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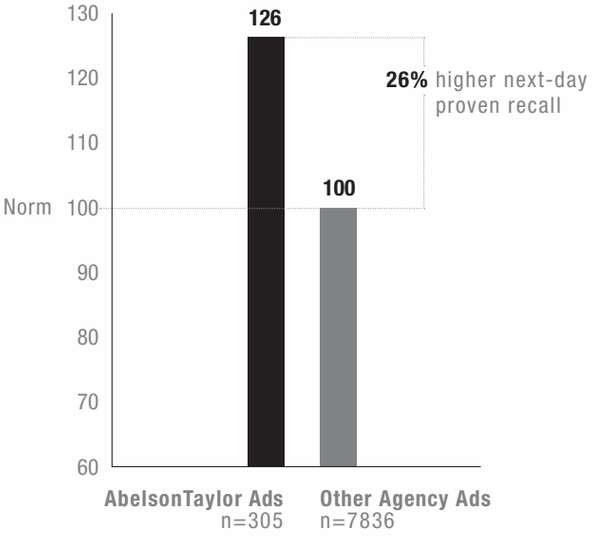

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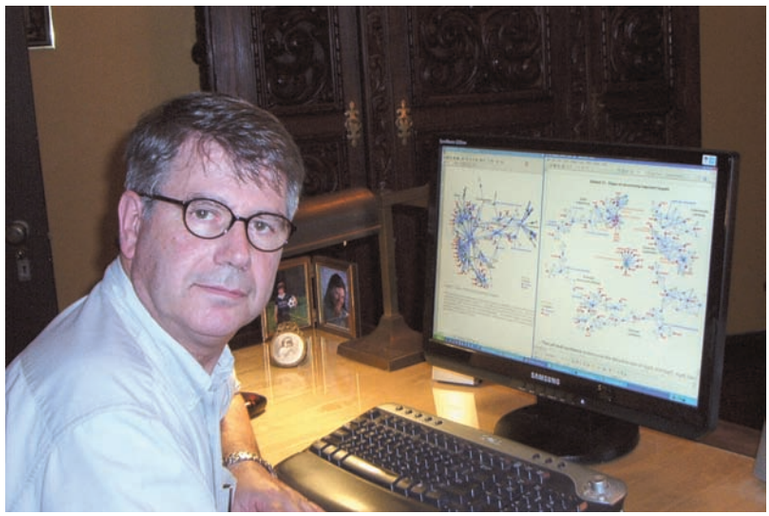


BERNARD MUNOS, Eli Lilly

As pharma joins the virtual trend, **IT RESPONDS TO THE NEED TO BE INNOVATIVE, NIMBLE, FASTER, AND CHEAPER**, despite science that has reached mind-numbing levels of complexity.

are coming out, and collaborative Websites are spreading. Some pharmaceutical companies are also embracing the movement. Lilly has been a pioneer in this regard. In 2000, at the same time that WHO was spawning PPPs, Lilly launched its own division, eLilly, tasked with the goal of harnessing the power of the Internet to speed drug R&D. Out of this initiative came a series of innovative experiments that have been widely written about, such as InnoCentive, Chorus, Collaborative Drug Discovery, as well as its own public-private partnership, the Lilly MDR-TB, focused on the treatment of drug-resistant tuberculosis. Smaller firms also are getting into the act, such as CollabRx, which was recently featured in The Wall Street Journal.

SHRAGER. COLLABRX. Funding opportunities are often focused on rare and neglected diseases by patients groups and patient advocacy groups. Usually, these groups are represented by foundations, but CollabRx also has had significant interest from individuals and/or their families. Moreover, the scientists working on neglected diseases have expressed great interest. Collaborations that are widely distributed make it possible to get more done by bringing the best minds and processes to bear on the problem. Compared with the number of scientists who are working on a major disease, such as Alzheimer's, in a single large institution, there might be 10 researchers in the world who are focused on a rare disease, such as Niemann-Pick Type C. Aside from funding, these researchers need to form collaborations that enable them to work efficiently across barriers of time and distance. We've also had strong interest from service providers, for example, companies that are involved with molecular analytics and even biotech companies that have developed a particular platform and that view the virtual model as an efficient channel. Finally, we've had lots of interest from various organizations that have government mandates, for example from NIH, to collaborate on translational research.

Driving the Virtual Need

The Internet, more competition, greater communications capabilities, generic pressures, and the increase in the number of outside contractors for all disciplines of drug discovery are fueling the move to a more efficient virtual model.

BERNARD. BERNARD ASSOCIATES. The primary driver of virtual pharma is the maturation of the pharmaceutical industry. Like many other industries, such as airlines, telecommunications, and automobiles, the U.S. pharmaceutical industry has evolved into the competitive stage of its life cycle, resulting in increased competition, slowing sales growth, and declining profits and productivity. During this stage, there is far greater emphasis on reduced costs and customer service. For many companies, transition to the competitive stage requires fundamentally new approaches to almost every major pharmaceutical function. The virtual approach is an appealing solution, offering cost efficiencies, productivity enhancements, capacity flexibility, and increased customer responsiveness. This trend has been accelerated by the availability of skilled labor as a result of industry contraction and vendor maturation; novel external R&D technologies and products requiring companies to pursue licensing deals and partnerships; and new information technologies that facilitate communication and partner management.

GARCIA. ENOVIA. There has been a huge increase in contract research organizations and that is precipitated by an increase of members within the network for developed drugs. Twenty years ago, drug development was very centralized within big pharma, and companies had big R&D organizations that generated the bulk of innovation and discovery. Over time, drug discovery and development functions have shifted and are now shared with partners that have specialties in different areas of the process.

MOSKOWITZ. GENOMED. Back in the 1990s, most of the drug market was dominated by branded products and there were many more companies that invested in basic science. But in the past 15 years, generics have become more prominent as managed care switched to

MICKEY GARCIA, Enovia

An important requirement for getting a drug to market more quickly **IS HAVING WIDER NETWORKS OF BRAINPOWER TO TAP INTO WITH A VIRTUAL MODEL**.

off-patent products whenever possible. Up to 70% of the actual prescription market is generic now and the percentage goes up a few points every year. As more blockbusters lose patent protection, more pharmaceutical companies are consolidating, and whenever industry consolidates, it's because there's not enough market share for all of the players. Just as preventive molecular medicine finally becomes available for the baby boomers, there isn't any money to pay for the new drugs. That's why there has to be a new financial model, and that model has to be virtual.

MUNOS. LILLY. The overwhelming driver is the need to speed up innovation and to reduce costs. Another driver is the need to extend drug R&D to diseases and areas that have not been able to support the high cost of modern research. For the last 12 years, the number of novel drugs approved by the FDA has been on a downward trend despite a large increase in R&D spending. There are concerns that this is not sustainable, hence the flurry of initiatives to improve or redesign the drug R&D model, many of which would fall under the umbrella of virtual pharma.

SHRAGER. COLLABRX. Early on, lone-wolf scientists made major discoveries, but most of the low-hanging fruit, at least in terms of drug development, has been picked. Now it has become critical to form collaborations to put the best minds together with the best service providers to get large complex projects done. This has happened in every scientific field, and it is now happening in biomedicine. Unfortunately, until recently collaboration wasn't easy; interactions were via phone, physical mail, or airplane. In the 1980s fax and Excel facilitated the communications and data-sharing parts, but biological knowledge has grown much faster than anyone can absorb, and the "art" of bioscience became heavily instrument-oriented. Scientists had to be where the biggest and latest machines were, or they weren't able to get anything done. In the 1990s, the Web partly ameliorated the knowledge-sharing problem through universal databases and formatting standards such as XML, which replaced Excel as the standard, but the problem of getting complex work done remained. Meanwhile, commerce has gone completely to an Internet-based, supply-chain workflow management model. It's a small step from there to the equivalent in science. There are some different hurdles to jump, but conceptually it's the same thing that scientists have always done, and have wanted to do, only now they can run at Internet-speed, made possible by Web-based, computational, supply-chain workflow management. The missing pieces aren't futuristic science fiction; all that's needed is an adjustment to think about science as a complex, supply-chain workflow management problem.

The Reality of Virtualization

While some skeptics may think the type of collaboration needed to successfully bring a drug to market using a virtual model is impossible, our experts report they are confident that virtual drug development is a matter of when, not if.

BERNARD. BERNARD ASSOCIATES. Virtual pharma is not a religion; it's increasingly a way of doing business. It is important to understand that the adoption of virtual pharma runs along a continuum from very limited to extensive outsourcing of operations. For example, I worked recently with a small pharma company that had licensed a product that was being developed and manufactured outside of the company. The product marketing team consisted of an in-house marketing VP and product manager, as well as 14 different marketing vendors. Many large companies are continuing their transition to what I call a hybrid virtual model, where they completely virtualize some functions, such as distribution, and then virtualize parts of other functions. For example, Eli Lilly recently announced several large deals to have Covance, Quintiles, and i3 manage a Lilly R&D facility, monitor clinical trials, and manage clinical data, respectively.

GARCIA. ENOVIA. Pharma companies will continue to specialize in their core competencies, particularly drug development, and outsource the rest to specialists. This will result increasingly in a virtual company. Because the core competency of pharma companies is their IP, pharma is one of the industries most amenable to virtualization.

MUNOS. LILLY. My opinion is that the virtual model is realistic, and the achievements so far are encouraging. At the same time, I do not want to portray virtual pharma as the answer to all problems. It is true that the better PPPs, such as MMV, have built up credible pipelines for 10% to 20% of the cost that would have been incurred by a traditional, fully integrated pharma company. Yet, because of the long R&D timelines, they have not registered any products, and, until they do, skepticism is understandable. I think it is wrong to position virtual pharma opposite traditional pharma. They are synergetic and can benefit from working side by side. Virtual pharma can help a great deal with energizing drug discovery because it taps into the global brain. This type of model can bring together as much intellectual diversity as one is ever going to get, which is the most important ingredient in innovation. Traditional pharma, however, has the edge when it comes to shepherding a compound through clinical development. Study after study has shown that the probability that a drug will successfully complete development is greater if a big pharma company is in charge. There are so many things that can go wrong, so experience is definitely a plus.

SHRAGER. COLLABRX. Well, of course we think a virtual pharma model is realistic, but

there are skeptics. Mostly, they are worried whether scientists can be cajoled into sharing data. But this is a red herring; scientists have collaborated forever, and they desperately want to collaborate to get complex projects done efficiently. We're not forcing them do anything they don't want to do; we're just facilitating the collaborations that the scientists already want to see happen. They don't have the technology or time to attend to both the content of science and its management. Another area of concern is whether there's enough money available to do drug development for rare diseases. Certainly there isn't enough return to get a big pharma company interested, but if we can move the early phases of research forward, most foundations can take a specific plan to their constituents and get funding.

Risks and Benefits

The benefits of the virtual model include accelerated therapy development and increased competitiveness, which most experts believe counterbalance the risks: funding challenges, virtual network management, and the general failure rate of innovative science.

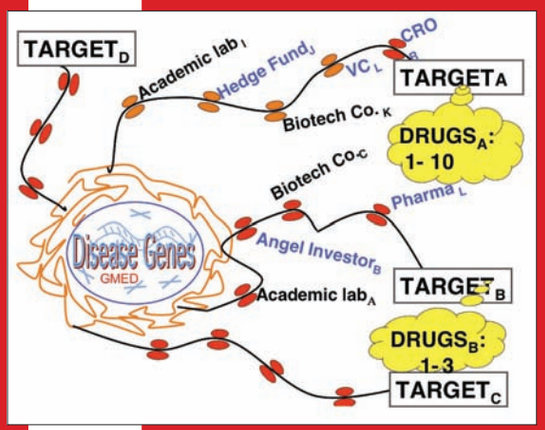
BERNARD. BERNARD ASSOCIATES. The greatest challenge pharmaceutical companies face is effective management of their virtual network. The most significant potential benefit is greater competitiveness resulting from better, higher-value products; improved cost and operating efficiencies; and enhanced customer service. The risks and benefits of virtual models have been displayed in companies in many other industries. For example, Boeing used a virtual model to build its new Dreamliner 787 commercial jet. Instead of designing and building the airplane itself, as Boeing traditionally has done, the company farmed out 70% of the 787 work to almost 50 partners and top-tier suppliers at 135 sites spanning four continents. Unfortunately, a few of Boeing's virtual partners have failed to deliver parts of the airplane on time, resulting in a 20-month delay. On the other hand, experts have hailed the jet as a "game-changer" and an evolutionary step in commercial aviation, helping sales of the jet to skyrocket. Dell, Nike, and many other companies have demonstrated how companies can become industry leaders by adopting virtual models.

GARCIA. ENOVIA. Anytime a business focus or business model changes, there is a certain amount of risk, specifically when it comes to making specific areas of the value chain virtual. Was the right area of the value chain selected, and can enough differentiation in the area be built to show a return?

MOSKOWITZ. GENOMED. Big pharma companies are buying good technology but that is still the wrong approach. The main problem with American science is that it is more addicted to technology than to thinking. Companies don't want to buy a conceptual approach that promises to solve diseases. The problem with many big companies is that their pipelines are dry. At biotech companies, there is an opposite approach. Scientists are actively pursuing leads and hunches. Biotechs are risk-seeking not just risk-tolerant. Science fails 99.9% of the time. But the risk is mitigated because of genomics. Genomics offers thousands of disease targets, enough to guarantee that more than one will succeed. Success is a highly improbable event and the only way to win is to do things thousands of times, and that's what genomics allows. But the crux of virtual pharma is getting the funding; big pharma wants to buy Phase III drugs, but biotech companies can't get the $500 million to get through a Phase III trial.

MUNOS. LILLY. The greatest risk for the virtual pharma model is that it will fail to live up to its billing. Even if this happens, however, some good may still come out of it. For instance, it might help the broad scientific community develop an appreciation for the enormous complexity of drug R&D. Beyond that, virtual pharma is so diverse that many of its approaches will survive, even if the model does not. InnoCentive, for example, is unlikely to go away. The vast databases that archive our expanding knowledge will keep growing, and, as they do, they will continue to transform the way R&D is being conducted. The greatest benefit that could accrue from a successful virtual pharma model would be a dramatic lowering of R&D costs and a shortening of timelines. Today, if one includes the costs of failed projects, it takes far more than $1 billion to bring a new molecular entity to the market. For virtual pharma, the rule of thumb is that every time someone figures a way to move a task from the lab to computers, costs and timelines are slashed by 80% to 90%. It is not possible to do everything using computers, and the FDA will not allow it. At some point, new drugs must be tested on patients. Yet, virtual pharma can offer substantial benefits during the drug-discovery process and

GenoMed's Virtual Pharma Business Model



GenoMed has already discovered several thousand cancer-associated genes, which allow for the construction of the systems biology of cancer, i.e., to order cancer-causing genes in pathways. The number of targets already found greatly exceeds the capacity of the global research pharmaceutical industry to absorb them. To commercialize these valuable drug targets ahead of the competition, the company must process them in a massively parallel fashion. Novel science requires a novel business model. GenoMed is therefore constructing a "peer-reviewed virtual pharmaceutical company." Partners capable of each step in the drug- development process will be chosen. Many academic investigators and biotech companies will ultimately be employed in this fashion.

Initial financing will be obtained from risk-welcoming investors, such as hedge funds (Hedge Fund j) or angel investors, (Angel Investor B) as represented in the figure above. Late financing will be obtained from risk-averse venture capitalists (VC L) and large research pharmaceutical companies (Pharma L). Intellectual property will be pooled, and revenue from eventual drug sales shared equitably.

Source: GenoMed, St. Louis. For more information, visit genomed.com.

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Large and small pharmaceutical companies **ARE STRATEGICALLY TRANSFORMING TO MORE VIRTUAL, NETWORKED MODELS**.

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SHRAGER. COLLABRX. The greatest benefit is obviously vastly accelerated therapy development and being able to facilitate and accelerate both R&D in drugs and other therapies to the point that some diseases that were a death sentence become, at worst, a chronic condition. This has happened in many diseases, such as TB, diabetes, and HIV. There are certainly limitations in our knowledge and limited resources for exploration of possible treatments, but these aren't the fundamental bottlenecks in most cases; these are not so much the unknown as the untried. We bring together what is known and efficiently feed and run a pipeline to chase down leads. The important step, then, is to efficiently bring the learnings back from the lab or field to close the loop and guide what goes into that pipeline based on what's learned. Our bet is that this will lead to more knowledge used faster, leading to better therapies.

The Future of Virtual Pharma

According to our experts, the potential of the virtual pharma business model is certain, and the industry will begin to move toward more virtual collaborations within the next five to 10 years.

BERNARD. BERNARD ASSOCIATES. As competitive and cost pressures increase in the pharmaceutical industry, we will see an acceleration of the virtual pharma trend. More start-up companies will adopt this model from the outset, while larger pharmaceutical companies will increasingly outsource core and non-core functions to partners. Just as we have seen in other maturing industries, industry leaders emerge from companies that are best able to leverage and manage virtual partners, processes, and products.

GARCIA. ENOVIA. Virtual pharma is more a matter of when, not if, it's going to happen. It might take 20 years before this model is anywhere near final, but parts of the process have started already. As tools for collaboration improve, including online meetings, teleconferencing, unified communications, document/data sharing, and document/data collaborative authoring, the need for co-location will diminish. In 20 years, the main reason for co-located work will be social and for team building. We are in the first stages of virtual pharma already, and I don't think the pharma industry in general is going to make this transition entirely on its own. Bigger companies will be driven by market forces and smaller and emerging companies will adopt the virtual model from the outset.

MUNOS. LILLY. In the next five to 10 years, there will be a major increase in virtual pharma initiatives by small companies, large companies, universities, and public research institutes. It is already happening because it is a smarter way to do drug R&D. I think there is no turning back.

SHRAGER. COLLABRX. In general, the virtual pharma model is obviously the next wave in all science. There are already dozens of virtual biotech companies that are running via e-mail and Excel. Soon there will be hundreds of companies that will use their cross-learnings to efficiently discover effective therapies for hundreds of neglected diseases, and maybe even a few big ones. ✦

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