

The Business End of Translational Research

University science and business faculties work together to advance science and medicine. **BY DANA TREVAS**

Translational research — taking scientific advances from the bench to the bedside — often involves transforming great ideas into concrete products — devices, drugs, tools or processes. It must, of course, be financially feasible both to develop and to disseminate these products. Thus, there is a clear role for a business-minded approach that helps propel translational research forward. With its focus on multidisciplinary collaboration, the Clinical and Translational Science Award (CTSA) program creates an environment in which business principles can inform scientific development, speeding up the translational process. A number of CTSA grantees have forged relationships with business schools that take advantage of a natural synergy of resources. One example is the Institute of Translational Health Sciences (ITHS) at the University of Washington in Seattle.

At the ITHS, individual health scientists have been collaborating with business school faculty and students on isolated projects for some time. In crafting its CTSA proposal, faculty members learned that “the business school already had structures set up that were being used by some investigators, but nothing was institutionalized,” said Nora Disis, who heads the ITHS. “People in both the business school and the law school had already been thinking about working with health scientists, so that began an easy synergy.”

“The West Coast is a collaborative environment in general,” Disis continued. “At the University of Washington, we have an

entrepreneurial academic environment. Because we don’t get very much money from the state legislature, we depend on each other for grants and infrastructure.”



■ Nora Disis capitalizes on the collaborative environment and entrepreneurial spirit at the University of Washington. As head of the Institute of Translational Health Sciences, she paved the way for a group effort that brought together faculty and students in genetics research, bioengineering, business and law and resulted in a startup company that is pioneering a novel drug delivery device as well as other innovative approaches.

GOING LEAN

The ITHS has instituted a number of programs that draw on the expertise of its business and law schools. Among the most significant steps taken may be the move toward implementing the principles of “Lean” production, the basis of the Toyota Production System. This method defines value from the perspective of the customer and seeks to eliminate waste — that is, anything that does not provide value to the customer.

Lean involves the distillation of a process down to its basic level to identify any redundant, counter-productive or otherwise wasteful steps within that process. Although the method may appear intuitive and simple to implement, it involves a tremendous commitment throughout every level of an organization to analyze complex systems, such as those found in health care and research facilities. Lean also involves dedication to continuous performance improvement (CPI) to ensure constant vigilance in waste reduction. The method is time-intensive and arduous, but when it works, it works well — as evidenced principally by cost reductions.

“Seattle is a hotbed for the Lean system,” said James Hendricks, head of the Research Institute at ITHS partner Seattle Children’s Hospital, which utilizes Lean. In the early 1990s, aircraft manufacturer Boeing, then Seattle-based,



■ James Hendricks heads the Research Institute at Seattle Children’s Hospital, an Institute of Translational Health Sciences partner and among the first medical centers in the country to apply the Toyota Motor Company’s successful Lean management improvement methods to health care. Hendricks spearheaded a continuous performance improvement process that dramatically reduced the time it takes for research proposals to be reviewed and approved by cutting out unnecessary paperwork and redundant steps.

dramatically reduced its production costs when it implemented the system. Health care systems in the area picked up on the idea, and their success generated even more enthusiasm. The University of Washington’s Clinical Research Center (CRC) and Seattle Children’s Hospital are two cases in point, and Hendricks has spearheaded implementation of the concept at both institutions.

The hospital’s Research Institute targeted the length of time it takes for research proposals to complete the institutional review board (IRB) process. IRBs consider the ethical, policy and regulatory issues surrounding patient research, but investigators often find that providing all the materials required for review and responding to IRB requests for information is complex and time-consuming. Rapid performance improvement workshops were aimed at streamlining the administrative tasks around IRB review without sacrificing patient safety. As a result, the Research Institute reduced the time from initial submission to final IRB approval from 86 to 46.5 days. The number of steps in the process decreased from 57 to 35. That’s just one example. Hendricks said that despite the difficult economic climate, the Research Institute has guaranteed its staff that there will be no layoffs. “We can do that because we’ve pulled out the waste, and we are so much more productive now.”

By bringing together everyone involved in the process for a multiday workshop, breaking the process down into steps, then analyzing the purpose of each step, the hospital was able to get rid of excessive hand-offs and backlogs. Furthermore, “involving the customer as well as the worker keeps people honest and helps them make hard determinations about what really is waste,” Hendricks said. When you look closely at these processes, you find that “waste is cleverly disguised as work.”

Hendricks worked with Havivah Schwartz of the ITHS to use the Lean system to improve the process of scheduling visits for CRC research subjects. Researchers had long expressed dissatisfaction related to scheduling, including the excessive lead time to schedule appointments and a high rate of no-shows. “We had been trying to address the issue for about two years with little success,” Schwartz said. She stresses the importance of identifying areas for improvement that resonate with customers. Looking into the problem, she said, “We were under the mistaken impression that we needed to improve scheduling primarily for the benefit of the researchers. We came to discover very quickly that it was also of paramount interest to the staff” and will likely benefit patients, as well.

Success with CPI requires a tremendous commitment of time and resources. “We spent three months preparing for the

workshop,” Schwartz said. “Collecting information about what to address, for example, via survey, is just the tip of the iceberg.” Preparation includes interviews and evaluation to map out the targeted process at its most granular level. Staff and researchers contribute to the preparation process and take time out of their schedules for the workshop itself, which can last as long as a week. “There’s no way we could get that commitment unless it was something that makes a difference to their work and life,” Schwartz said.

By standardizing methods and implementing software and other tools to simplify and streamline processes, the CRC stabilized staffing assignments, making the workload more predictable and reducing overtime costs. It decreased the number of no-shows from 21 to 14 percent. The result is a more transparent system that allows unit managers to make more informed decisions. The increased efficiency among staff allows them to better meet the needs of researchers.

One key component of the Lean process is the “continuous” part of CPI. There is always more waste to cut. Hendricks noted, “My investigators are happy that we cut the IRB time in half, but it’s been about a year and a half. And now, they want to know what we’re going to do to pull out more waste.”

Lean is a philosophy, not just a set of tools, and it requires buy-in from the entire organization, Hendricks stressed. But once you see the results, you see how valuable the philosophy can be. Hendricks said the goal of working with Schwartz and others at the ITHS to implement CPI processes is “to reduce the cost of doing clinical research so there’s more money for informatics and other areas that are dollar-intensive and can contribute to better clinical research.”

“When I first saw the results of the IRB process improvement at Children’s, it was jaw-dropping,” Schwartz said. “But at the time — even though we were told differently — we understood Lean as a set of tools to increase efficiency. Now, I see it as a philosophy, a broader approach that we can apply outside of workshops to our overall strategic development” at the ITHS.

Hendricks underscored the similarities between the principles of CPI and those of the scientific method: “The scientific method, like CPI, is based on gathering empirical and measurable evidence to formulate and test a hypothesis,” he said. “In CPI, the hypothesis takes the form of opportunities for eliminating waste and adding value for the customer.”

Disis noted that when the ITHS announced its intention to apply Lean principles to its infrastructure, “people came out of the woodwork” to get involved. “Two faculty members in the undergraduate engineering program who do research on industrial efficiency came to us to research our experience with Lean.”

R&D MEETS MBA

Facilitating research is just one side of the equation. Investigators whose work leads to promising techniques or devices face the daunting task of production and marketing. At the University of Washington, the Department of Bioengineering

had funding from the Wallace H. Coulter Foundation to promote translational research and was seeking individuals with MBAs to

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assist with product commercialization. The ITHS created the needed link with the university’s School of Business. Piggybacking onto the existing fellowship program of the School of Business’ Center for Innovation and Entrepreneurship, the ITHS-Coulter Fellowship supports summer internships for second-year MBA students to work with scientists in moving their discoveries toward the marketplace.

This collaboration of people and funding across disciplines has already produced tangible results. At the University of Washington’s DNA Sequencing and Gene Analysis Center, Center Director and Associate Dean Rodney Ho worked with John Hoekman, a doctoral student in pharmaceuticals, to develop a novel pressurized olfactory drug delivery device that enables drug administration via the nose directly to the brain. The approach speeds up the drug delivery process while at the same time bypassing the potential for toxic systemic reactions that can be caused when high concentrations of drugs are delivered orally or intravenously.

With an ITHS-Coulter Fellowship, the scientists teamed up with MBA students Michael Hite and Peter Olagunju to conduct market analysis and develop a business plan. The effort earned the team \$50,000 from the University of Washington TechTransfer’s Technology Gap Innovation Fund and won the \$25,000 grand prize in the university’s annual business plan competition. The team licensed the technology from the university and spun off a company, Impel NeuroPharma, to further develop the product.

On the basis of the early success of the fellowship program, Kim Folger Bruce, director of research partnerships at the ITHS,



■ Seattle Children's Hospital, an Institute of Translational Health Sciences partner, is leading the way in applying continuous performance improvement methods long used by successful manufacturers to improve the basic building blocks of health care: quality, safety, cost, delivery and engagement. Continuous performance improvement brings together everyone involved in the system at every level. Here, staff at Seattle Children's Hospital are learning about day-to-day operations from a clinician's perspective so they can work together to find better ways to deliver the highest quality service and value to patients while removing wasteful practices.

anticipated increased investment and participation. "It seems like a natural fit, but someone has to establish the relationships," Bruce said. "The need is there, and there are many MBA students interested in medical applications. So, once you have those relationships, then it's just matchmaking."

During the past four years, ITHS Director Disis has put in place changes intended to make the CRC function in similar fashion to a commercial clinical trial research unit. She sought business expertise to determine appropriate fees for the center to charge researchers and turned to the School of Business. The school identified an MBA student to take on the task as an intern. The intern is conducting interviews and gathering information from investigators, commercial research units and other sources to create a business plan to ensure the financial success of the center.

AN ENTRY POINT FOR ENTREPRENEURS

The Entrepreneurial Law Clinic (ELC) at the University of Washington offers faculty members legal consultations in such areas as commercial potential of a new technology, business planning, regulatory issues and intellectual property concerns. The ELC combines a traditional law clinic with an externship. Investigators are matched with a team of law and business students, attorneys, and successful entrepreneurs who provide confidential findings and recommendations at no cost.

"I do translational research, develop products and take them into clinical trials — but I had never heard of the ELC!" Disis said. With additional funding from the CTSA program, the

ITHS established a direct link that helps health scientists take advantage of the ELC's services. Impel NeuroPharma did so before submitting its entry to the business plan competition. Sean O'Connor, who directs the ELC, said, "The primary initial service my ELC provides for start-ups is a due-diligence exercise similar to what real-life investors will do" when they consider a business plan. After the competition, the ELC assisted Impel with the regulatory support services provided by the ITHS. The company continues to work with the ELC on patent issues.

Investigators at the University of Washington can also take advantage of "From Invention to Start-Up," a free eight-week lecture series on entrepreneurial issues unique to high-tech start-up companies. Each session is videotaped and posted online at www.inventiontostartup.washington.edu, along with each speaker's slide presentation.

IN GOOD COMPANY

A number of other CTSA grantees have expanded their relationships with academic business schools. For example, Harvard University's Linkages program integrates the skills and resources available within Harvard's Law School, Business School, School of Engineering and Applied Sciences, Kennedy School of Government, and Graduate Schools of Education and Design to support clinical and translational research innovation. Duke University has an active collaboration with the Health Sector Management program at the Fuqua School of Business, which addresses both health care and entrepreneurship. The University of California, Davis, has developed several programs to educate faculty regarding entrepreneurship, intellectual property and business development with an emphasis on biotechnology. As institutions break down the walls between their research and business communities, they pave the way for more and better collaboration and translational science. (For a detailed list, see the CTSA Web site at CTSAweb.org, under "Building Connections.") ■