

INDIANA'S LIFE SCIENCES INNOVATION ENGINE:
Full Steam Ahead?
Tuesday, February 8, 2011

Innovation in the life sciences continues at a breath-taking pace but the track is often a long and winding one. For patients needing the potentially life-saving discoveries and the researchers developing them, the often winding route to commercialization may seem endless.

Framework is an educational series focused on relevant Indiana Life Sciences topics and issues. The first event brought together some of Indiana's thought leaders to share perspectives on how to increase connectivity and collaboration in the life sciences industry within the state's borders and around the globe.

BioCrossroads was launched in 2002 to purposefully build much-needed connections among Indiana's life sciences research institutions, corporations, philanthropies and state government to create new opportunities and prepare for a future that will increasingly be global, networked and entrepreneurial. The industry is a vital part of Indiana's current and future economy and critical for improving quality while lowering healthcare costs for a rapidly aging society with often complex diseases. In order to provide better differentiated treatments needed by patients and demanded by regulators and payers, innovation involves solving difficult scientific, technical and medical problems with different approaches and entirely new ways of stoking the innovation engine.

Innovation and Collaboration

In his keynote address, **Jan M. Lundberg, Ph.D., executive vice president, Science and Technology, and president, Lilly Research Laboratories** explained how Eli Lilly and Company is part of a growing web of collaboration in the life sciences, expanding our network of drug discovery, development and manufacturing. Lilly's move from a fully integrated pharmaceutical company to a network or "FIPNet" model is designed to bring expertise from partners; enabling Lilly to share investment, risk, and reward rather than always through outright Lilly ownership. This wider network, both locally and globally, encompasses work in China and India as well as Indiana.

One example of FIPNet is the sale of Lilly's research site in Greenfield, Indiana to Covance. The contract research organization continues to provide long-term support for Lilly, but is also expanding the campus and hiring additional employees for high-paying jobs to serve other customers. Lilly followed a similar strategy by selling its Tippecanoe Laboratories manufacturing site in Lafayette, Indiana, to Evonik Industries.

Dr. Lundberg also highlighted Lilly's virtual early-phase drug development network called Chorus. The small, cross-disciplinary group of Lilly scientists designs, interprets and oversees early-stage development work through a network of organizations. Using this approach, Chorus currently manages 15 molecule programs with a dedicated staff of around 30 scientists, each with a very specific area of expertise. Applying a lean development model, Chorus has been able to reach clinical proof-of-concept about 12 months earlier and at half the cost compared to



BioCrossroads

the current industry model; saving Lilly more than \$100 million in the process and the ability to reach the endpoint faster. The frontrunner, an anti-BAFF antibody, is now in Phase III trials for rheumatoid arthritis and lupus.

Another example of Lilly's collaborative efforts is its phenotypic drug discovery initiative (PD2), which uses the company's biological screening technology to evaluate the therapeutic potential of compounds synthesized in university and biotechnology laboratories around the world including those in Indiana. The first signed agreement was with the University of Notre Dame. Affiliated institutions, universities, biotech labs and other institutions, submit compounds in key disease areas for evaluation. Intellectual property rights remain with the submitting researcher or institution. After testing is complete, Lilly has exclusive first rights to negotiate a collaboration or licensing agreement. PD2 has also partnered with Indiana University's Kelley School of Business to explore alternate business models for interesting compounds Lilly doesn't have the capacity to handle.

PANEL DISCUSSION:

Nate Feltman, J.D., President, Home Health Depot Inc.

Marie Kerbeshian, Ph.D., Vice President, Office of Technology Commercialization, Indiana University Research and Technology Corporation

Jan M. Lundberg, Ph.D., Executive Vice President, Science and Technology, and President, Lilly Research Laboratories

Joe Trebley, Ph. D., Senior Project Manager, Office of Technology Commercialization, Purdue Research Foundation

Pete Yonkman, J.D., Executive Vice President, Strategic Business Units, Cook Group, Inc.

One area where connectivity and collaboration are most productive is in partnerships between industry and academia. The panelists shared their perspectives on several questions.

What is needed to help innovation continue to thrive and survive in Indiana?

PETE YONKMAN: Lilly is facing some of the same challenges we are. Where we need help is in earlier collaboration with academia. Right now there's a reluctance to involve industry and we are late in joining the discussions; often when there's no mechanism for input. Companies like Cook and Lilly can provide deep expertise on what may be commercially and viable early on in the process.

JOE TREBLEY: One of the things we're learning from Endocyte is trying to instill a sense of urgency into the development so the patents don't run out. The Purdue Research Foundation has found success in deploying the Trask Innovation Funds (TIF) to help with this. If there is funding early on, we are 50 percent more likely to get a commercial partner; combined with government funds, the number is more like 80 percent. We're also involving industry people on the TIF Advisory Council to help determine where to best deploy funds; providing funding in weeks rather than months with some federal grant programs.

How are you leveraging resources differently in order to speed innovation?

MARIE KERBESHIAN: A little bit of information can be powerful. Hiroki Yokota, a professor of biomedical engineering at IUPUI developed a drug that stimulates bone growth. Normally a technology transfer might have occurred, but we were able to leverage a lot of resources through Indiana University (IU). Indiana Clinical and



BioCrossroads

Translational Sciences Institute (CTSI) resources allowed us to hire a private contractor to create a new formulation that was better. Lilly scientists were invited to provide input on what they would do next. Kelley School of Business life sciences students helped develop a marketing plan that identified a potential market for broken bones in addition to osteoporosis. As a result, we hope to use this model to speed the process from the research bench to the bedside.

How do you help speed innovation and collaboration?

NATE FELTMAN: Success has a way of focusing people at universities and entrepreneurs to come together and look for other successes. Endocyte and Marcadia are recent examples. Indiana got it right when the 21st Century Research and Technology Fund was created. We realized success takes so much longer than many may think. Indiana had it right early on by putting capital at risk; now we need to maintain this opportunity especially in light of the shrinking venture capital available. Where we need improvement is removing barriers for vendors and small businesses trying to partner with larger companies. Lilly's Chorus is an example of each partner doing what each does best. In our business, we've been lucky to partner with IU Health Ball Memorial to leverage our expertise in home health and respiratory so that nurses can focus on treatment, not home medical equipment.

JOE TREBLEY: More conversations between academic institutions. Once example is how a Purdue engineer with an existing relationship with an IU doctor is now collaborating on a project. It increases innovation and we need more.

How are you overcoming some of the regulatory hurdles?

JOE TREBLEY: The regulatory hurdles can be life or death for a start-up -- uncertainty and time are really detrimental. Collaboration with experts can help remove some of those challenges.

MARIE KERBESHIAN: One of the things we do look at is regulatory pathway. How are we going to be able to make this work given the investment and the ultimate revenue? This can be frustrating for IURTC and researchers. We have to look at atypical ways of commercialization when patents are close to expiring. Perhaps it involves donating the patent to a foundation which raises money for research, resulting in a journal publication that is distributed to doctors so they may adopt the treatment protocol.

JAN LUNDBERG: Regulatory paths mean more patients and trials and results. With cancer drugs, it's not just about shrinking the tumor – it's about meaningful survival rates. We should be change agents in helping regulators understand unmet needs.

How do you establish trust for innovation - internally and externally?

NATE FELTMAN: Rising costs are forcing people to talk to each other. There is now more of a natural desire to have conversations that wouldn't have happened five or ten years ago.

PETE YONKMAN: Collaboration and trust have to be there. It's about exposure and face time, getting the groups together to understand each other as well as their own agendas and fears. It's why we try to foster interaction between agencies and institutions and need to continue to do so.