FEATURE
Fast Track
by Amy Erickson

Very quietly, almost under the biotech radar, a new institute has emerged in Tucson, with a mission to reduce medication costs and accelerate the time it takes to bring new drugs to market. This small institute has received millions of dollars in local funding and is the result of a nonprofit partnership with some very big names—the University of Arizona, the Federal Drug Administration and SRI International, a nonprofit tech-development company from California. With a business plan in place and a new $1 million grant, the Critical Path to Accelerate Therapies Institute, or C-Path, stands ready to make an impact in Arizona and across the nation.

Tucked in among bright flowers, tiled courtyards, splashing fountains and the mission-style architecture of St. Philip's Plaza in northern Tucson, C-Path's modest 2,500-square-foot offices house just six full-time employees—quite typical for a spanking new biotech startup. Led by Dr. Ray Woosley, M.D., Ph.D., a noted clinical pharmacologist and former head of UA's Arizona Health Sciences Center in Tucson, C-Path was created to help solve one of the biggest obstacles facing modern medicine: outdated methods for developing new drugs. The solution starts with bringing together entities that are known more for their competition than cooperation.

Developed as an essential component of Arizona's broadening biotechnology strategy and beyond, C-Path's primary goal is to act as a forum for the FDA, industry and academia to work together to create new ways to develop drugs, which will ultimately lead to safer and cheaper medications. "We are developing drugs the same way today as we were 40 years ago," explains Woosley, 62, president and CEO of C-Path. "The reason we're not using cutting-edge technologies to develop drugs is because they are not methods that have been approved by the FDA because they are so new."

For manufacturers, this translates into a very real possibility that the FDA might not approve a particular drug, and until recently, pharmaceutical companies have not been willing to take that chance. "Now, the FDA is interested in attempting to develop new protocols for drug development that use these sophisticated technologies, and to do this, the FDA needs partnerships. C-Path

answered that call," says Woosley, who has a long-standing relationship with the FDA in the arena of drug discovery. "C-Path is a completely novel concept. There is nothing like it in Arizona, and the potential for synergy with local organizations such as the Translational Genomics Consortium [TGen] is huge. Together we can really improve medical-product development."

Currently, it takes an average of 12 to 15 years and more than $1 billion to take a potential drug from discovery to market. For most people, even one year is simply too long to wait for a cure. Woosley and his C-Path team aim to revolutionize the drug-development process by accelerating the time it takes to bring drugs to market, while at the same time ensuring their safety. The decreased timeline results in lowered R&D costs, which will eventually lead to cheaper medications for patients.

"Our focus is to find new technology and new protocols to evaluate safety," says Bruce Wright, associate vice president for Economic Development at UA. "Current techniques and procedures don't guarantee a drug is as safe as it should be. We believe with the application of new technology, we can do it faster and safer, leading to better drugs."

The idea for C-Path was hatched in early 2004, and was further solidified and validated by a report from the FDA that assessed the agency's recent slowdown in the number of innovative medical therapies reaching patients. According to the report, although today's revolution in biomedical science has raised new hope for the prevention, treatment and cure of serious illnesses, there is a growing concern that discoveries in recent years might not quickly yield the effective, affordable and safe medical products patients need. The report notes that not enough scientific work has been done to create new tools to get better answers about how the safety of new drugs can be demonstrated in faster time frames at a lower cost. Acknowledging the need for a critical path to new medical products, the FDA began to look for ways to update the process of drug development.

Concurrent with the FDA's release of the report, Woosley was in talks to bring SRI International to Tucson from Menlo Park, Calif., and together with UA and the FDA, the idea came about to develop an institute that would champion the FDA's critical path initiative. "The FDA was ready to be part of the solution to the problem. The question was, 'Could Arizona be responsive to the document?' " says Woosley. The answer to that question was a resounding yes, and under the leadership of Woosley, C-Path was born.

Funding a project of this magnitude is a serious commitment, and the city of Tucson and the county stepped forward. A year and a half ago, UA, FDA and SRI International each committed $750,000 per year for five years. The city of Tucson and the county both pledged $375,000 a year for the next five years, totaling $7.5 million. In August, C-Path received a $1.25 million grant from the Phoenix-based Flinn Foundation to fund operational functions such as scientific and education programs. Ultimately, the institute will be sustained through federal funding sources and unrestricted endowment from pharmaceutical foundations, grants and donors.

Even though by today's standards it takes more than a decade for

a drug candidate to be tested and brought to market, there is no guarantee a drug is safe. “As physicians, we are sworn to do no harm, yet it’s difficult to ensure drug safety,” says Dr. David Thorpe, a medical doctor and drug-discovery scientist at Sanofi-Aventis in Tucson. “How do you study enough to prove a drug is safe? It’s easy to say it won’t cause a side effect, but harder to prove it will do no harm.”

C-Path’s operations focus on three programs—Fast Path, Safe Path and Ed Path—to address scientific, safety and educational aspects of drug development meant to support the FDA's Critical Path Initiative. Models, including the use of industry/FDA consortia, interactive seminars with FDA personnel, biomarker validation consortia and a unique public database development, will be applied to specific medical problems like cancer or cardiovascular disease. The institute also will look at medicines for rare and orphan diseases. Although the FDA already has a voluntary system called MedWatch to report adverse effects, C-Path is working on a pilot program that will be housed in community pharmacies that will serve as an early warning system, which will record how many problems occur in what number of people. The information will be then forwarded to the FDA.

In addition, C-Path is planning to launch several educational programs designed to provide the most advanced experiences for researchers in the pharmaceutical industry, including global drug-development issues, FDA regulatory education, training and policy study.

With an estimated total of 11 employees by the end of the year and a projected 40 employees by year five, C-Path’s plan for growth is to keep full-time staff to a minimum. Most researchers will be affiliated with C-Path on a temporary basis in order to solve specific problems, and then eventually return to their organizations. As part of a UA land swap with KB Home, initial plans are under way for C-Path to relocate its headquarters to a proposed biosciences park. Although nothing is yet set in stone and the potential move is several years down the road, C-Path’s space could eventually grow to 30,000 to 40,000 square feet, housing conference rooms, training rooms and office space.

At present time, personalized medicine is at the forefront of medical technology. Cancer treatments are becoming more specific, and eventually a specific drug will be given to an individual patient based on his or her genetic makeup. It follows that the drug-discovery process also will become more individualized. According to Susan Rosenfield, a patent attorney with Fennemore Craig P.C. in Phoenix who has been working in the pharmaceutical field for nearly 15 years: “What we need now is more emphasis on the individual patient and targeting drugs to make them safer, rather than using something that is not effective or can harm them. If a drug is helping a group of people, then we want the ability to say ‘Okay—the drug is working’ and because of the group’s genetic makeup, the drug works better. This is what C-Path is working toward.”

With seed funding in place for the next five years, C-Path is currently looking for collaborative opportunities to research biomarkers. Industry and pharmaceuticals are interested in finding early markers that can determine if a drug candidate is

toxic. The field of toxicogenomics began as a cottage industry and is now at the forefront of drug development. “If researchers can get a better sense of what sort of biomarkers are out there, then we can standardize what a good marker is at a genetic level,” explains Thorpe. “At this point in time, it is not well known what the standards are.”

C-Path is in talks with the state’s three universities and is investigating early projects organizations such as TGen. “Agents developed at TGen and around the world will call upon C-Path’s brain power,” says Dr. Daniel Von Hoff, director of the Translational Research Division at TGen and a noted pancreatic cancer researcher.

When TGen was launched in Phoenix more than two years ago, it created a great deal of awareness about Arizona’s commitment to biotech, and many feel C-Path is in the same category. “C-Path has the potential to be analogous to TGen,” says Larry Aldrich, a general partner in the Tucson- and Tempe-based venture-capital fund Valley Ventures III, which focuses on early stage investing in high-tech businesses in the southwestern United States. Aldrich is C-Path’s interim COO and will permanently take over the position in January 2006.“TGen is more hands-on work, clinical research and discovery, while C-Path is more white paper research and on the process side of drug development.”

According to Wright, C-Path is a perfect complement to the Arizona biomedical strategic plan and new medical campus in Phoenix. “If TGen identifies new drugs, then C-Path can review efficacy and help get it to market. This strengthens Arizona’s position as a major player in drug discovery, spawning a significant biotech industry focused on getting drugs approved,” he says.

TGen’s Von Hoff and C-Path recently began discussing the potential for testing new pancreatic cancer therapeutics. “We are looking for a new endpoint that will help us find out rapidly whether a new drug will work for an individual patient rather than looking at hundreds of patients before we know,” says Von Hoff. For example, if a drug for pancreatic cancer is discovered, C-Path’s new protocols could one day help test the safety and efficacy of the drug as quickly as possible.

“C-Path is really important in terms of getting new therapeutics to patients as rapidly and safely as possible,” explains Von Hoff. “Dr. Woosley has a very distinguished track record in working with the FDA and discovering drug interactions. He is building on that knowledge by a having a think tank that plans for very innovative ways to determine—with very minimal patients exposed—whether or not a new drug would work for patients with cancer or other diseases.”

C-Path’s potential global impact is very real. With the FDA serving as the governing body for all drug approvals in the United States, C-Path’s mission, centered on changing the process of drug development in a fundamental way, is significant. If C-Path can serve as the basis for developing new approval methods, then it is advantageous for every U.S. drug company to come to Tucson to learn new protocols and to better understand drug development.

Many in the community see the launch of C-Path as an essential cornerstone to Tucson's budding biotech industry and realize that, if it's successful, it could attract national attention. "I expect this will attract contract research organizations, drug companies and research scientists who are interested in learning about a new drug-approval process," says Wright. "We hope that C-Path can be a spark in Tucson like TGen was with downtown development in Phoenix."

"C-Path is a very important thing not just for our community and nation, but for setting the standards of drug development on a global scale," explains Thorpe.

With cancer, cardiovascular disease and other illnesses on the rise, drug development requires safe but faster processes. "C-Path can impact all of our lives by being successful in our mission to speed up the drug-development process and create safer drugs," says Aldrich. "In this way, C-Path has the potential to become a central piece in Arizona's and the nation's biotech and drug-development strategy."

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