



NEWS

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Pharmaceutical Companies and FDA Making Strides Toward Safely Speeding Medical Discoveries to Americans *C-Path Predictive Safety Testing Consortium Reaches One-Year Mark*

PHOENIX (April 3, 2007) – Developing a new drug is a costly and time-intensive venture. It often takes years to safely develop, test, and ultimately gain Food and Drug Administration approval to bring the drugs to market. In 2004, the FDA issued a white paper analyzing the hurdles involved in medical product advancement and calling for collaboration between government, research institutions and manufacturers to promote the public health by getting effective, innovative products into the hands of the public. The report described the urgent need to modernize the medical product development process – the Critical Path – to make product development more predictable and less costly.

The following year, the FDA announced a first-of-its kind partnership with the Tucson, Arizona-based Critical Path Institute (C-Path), an independent, non-profit institute comprised of scientists from FDA, academia and industry. The group was established to accomplish goals outlined in the Critical Path Initiative (CPI), FDA’s premier program to improve the efficiency and safety of medical product development. C-Path is the only institution created solely to fulfill the mission of the Critical Path Initiative.

“The Critical Path Institute was founded to provide ‘neutral ground’ for the collaboration of scientists from the FDA, academia and industry. This provides C-Path and the FDA with access to the expertise that will be essential to the testing and evaluation of innovative methods for developing new medical products” said Raymond Woosley, MD, PhD, President and CEO of C Path. “C-Path is neutral because it is not vested in the development of any medical products, so we act as catalyst for bringing resources together to break new ground in science and then share it broadly to be used by different entities in product development.”

C-Path Predictive Safety Testing Consortium Celebrates One-Year Anniversary

In March 2006, The FDA and C-Path announced the formation of the Predictive Safety Testing Consortium between C-Path and five of America’s largest pharmaceutical companies to share internally developed laboratory methods to predict the safety of new treatments before they are tested in humans.

One year later, the consortium has grown to include 16 pharmaceutical companies that together have made great strides toward modernizing the drug development process and helping to speed new medical discoveries to Americans faster and at lower cost.

The goal of the Predictive Safety Testing Consortium is to enable pharmaceutical companies to share knowledge and resources. Consortium members share the details of the methods that have been developed for specific kinds of lab tests and then collectively determine which of the tests should be recommended by the FDA to screen drugs and better understand the potential side effects before the drugs enter clinical testing in humans.



William Mattes, the Director of the Consortium reports that “in the short time this Consortium has been operating companies have already shared the results of their internally developed assays, and in the process given them confidence that these assays should be advanced to the level of qualification and regulatory consideration.”

Members of the Consortium include: Abbott, Amgen Inc., AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, GlaxoSmithKline, Iconix Biosciences, Inc., Johnson & Johnson Pharmaceutical Research & Development, LLC, Merck and Co., Inc., Novartis Pharmaceutical Corporation, Pfizer, Inc., Roche Palo Alto, LLC, sanofi-aventis U.S. Inc, Schering Plough Research Institute, a division of Schering Corporation, Wyeth Pharmaceuticals, Inc. and SRI International, who participates in the Consortium as a founding partner of C-Path.

BIO 2007

The Arizona Department of Commerce will lead a delegation of Arizona companies and organizations at BIO 2007, the world’s largest annual conference and exposition devoted to the biotechnology industry. BIO 2007 will take place in Boston, May 6-9, and is expected to draw more than 18,000 participants.

The Arizona Pavilion “Biozona: Advancing Science, Enhancing Life,” will be anchored by the science and research conducted at the state’s three universities and will focus on Arizona’s core competencies of cancer therapeutics, neurological sciences, bioengineering, optical sciences and bioinformatics.

William Mattes, Ph.D, Director of Toxicology of the Tucson-based Critical Path Institute (C-Path), will be one of the featured speakers the Arizona Pavilion at BIO 2007. Mattes will speak at the Arizona Pavilion on May 8 at 10 a.m. and 2 p.m.

William Mattes coordinates the Predictive Safety Testing Consortium, a collaboration of 16 of the world’s largest pharmaceutical companies, the FDA and Europe’s regulatory agency, EMEA. Before joining C-Path, Mattes was senior scientific director of toxicogenomics at Gene Logic, where he directed the genomics-based mechanism of toxicity program. He has more than 20 years of industry experience in the fields of genetic, molecular, and investigative toxicology and chaired a subcommittee within the International Life Sciences Institutes that established a public toxicogenomics database at the European Bioinformatics Institute. His academic accomplishments include a BA from the University of Pennsylvania and a Ph.D. in biological chemistry from the University of Michigan.

Media Note: If you are interested in scheduling an interview with Dr. William Mattes of the Critical Path Institute, please contact Megan Rose at mrose@gcjpr.com or 602-274-1988.

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About The Critical Path Institute

Headquartered in Tucson, Arizona with an office Rockville, MD, C-Path was established in 2005 as a publicly funded, nonprofit research and education institute to serve as a trusted third party for collaborations between scientists and others from government, industry and academia. C-Path’s mission is to help implement the FDA’s Critical Path Initiative by developing faster, safer and smarter pathways to new medical products. Visit www.C-Path.org for more information.