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FDA News

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FDA and the Critical Path Institute Announce Predictive Safety Testing Consortium Consortium Will Share Tests to Understand Safety of Potential New Drugs Earlier

The Food and Drug Administration (FDA) and The Critical Path Institute (C-Path) today 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. The FDA, while not a member of the Partnership, will assist it in an advisory capacity. This unprecedented sharing of potential early indicators of clinical safety may streamline the cost and time of preclinical drug safety evaluation and better inform the use of "personalized medicine". The Consortium was announced today at a press conference detailing the release of the Critical Path Opportunities List -- 76 initial research priorities that, if accomplished, will modernize the drug development process by 2010 and help get new medical discoveries to Americans faster and at a lower cost.

"The power of public-private partnerships is vital to accomplish the tasks set forth in the Critical Path Opportunities List," said Health and Human Services Secretary Mike Leavitt... "The Predictive Safety Testing Consortium is a prime example of a collaborative culture that must exist to modernize the development process. The collective sharing of scientific information and research across the entire healthcare community is crucial to igniting the medical innovation required to keep pace with biomedical research."

The goal of the Predictive Safety Testing Consortium is to enable pharmaceutical companies to share knowledge and resources. This will allow the pharmaceutical companies to determine which of the lab tests that they have developed individually should be recommended by the FDA to screen drugs and better understand the potential side effects before the drugs enter clinical testing in humans. Companies will share the details of the methods that each has developed for specific kinds of tests and then agree to test another's method to determine if it is reproducible. The results of the comparison will be collected and summarized by C-Path for submission to the FDA. Those methods that the FDA finds to be reliable and reproducible will form the basis for agency-issued guidelines about which safety tests should be used in the drug development process. The information provided by the eight Members of the Consortium -- Bristol-Myers Squibb Company, GlaxoSmithKline, Johnson & Johnson Pharmaceutical Research & Development, LLC, Merck and Co., Inc., Novartis Pharmaceutical Corporation, Pfizer, Inc., Roche Palo Alto, LLC, Schering Plough Research Institute, a division of Schering Corporation and SRI International (participating in Consortium as a founding partner of C-Path) -- is expected to help energize drug development by making it more predictable and efficient, and less prone to failure.

"This is a concrete example of the power of the collaborative nature of the Critical Path Initiative, our road map for modernizing the development of medical products," said Dr. Janet Woodcock, the FDA's Deputy Commissioner for Operations. "The use of predictive

safety biomarkers in early animal and laboratory studies will strengthen the product's safety screening before it's introduced into humans. It will also enable researchers to better select initial human doses, and monitoring for side effects in early trials. As a result, pharmaceutical companies will be able to learn more from smaller clinical trials, and get new, safer therapies to patients faster and at a lower cost."

Currently, predictive safety tests internally developed and used by each individual company are of limited value to the FDA because the methods used have not been validated by an independent party. Under this Consortium, member companies will share the information that will enable them to have their tests validated by C-Path's outside experts and other members of the Consortium. FDA will assist this process in an advisory capacity.

"C-Path's mission is to accelerate the development of safe medical products, and to foster education and training in applied research and regulatory sciences," said Dr. Raymond L. Woosley, President and CEO of C-Path. "The Predictive Safety Testing Consortium is an excellent example of the value of the 'neutral ground' that C-Path creates for the industry and FDA to focus on the science that is important for drug development. This is just the first of many projects that C-Path plans to support."

C-Path is uniquely positioned to serve as neutral ground so that scientists from the FDA, academia and industry can more readily collaborate to enable the safe acceleration of the medical product development process. C-Path, in conjunction with its partners, is working to provide faster, safer and smarter solutions for drug and devices on the path from the laboratory to the patients. The collaborative agreement between FDA and C-Path is one of many strategic partnerships formed in anticipation of the release of the Critical Path National Opportunities List, so advancing some of the projects in development by C-Path will help to accomplish objectives outlined in the Opportunities List.

About the Critical Path Initiative

The Critical Path Initiative is the FDA's premier initiative to identify and prioritize the most pressing medical product development problems and the greatest opportunities for rapid improvement in public health benefits. Its primary purpose is to ensure that basic scientific discoveries translate more rapidly into new and better medical treatments by creating new tools to find answers about how the safety and effectiveness of new medical products can be demonstrated in faster timeframes with more certainty and at lower costs. For more information about the Critical Path Initiative and for status of projects on the Opportunities List go to <http://www.fda.gov/oc/initiatives/criticalpath/>

About The Critical Path Institute

Based in Tucson, Arizona, The Critical Path Institute (C-Path) was established in 2005 as an independent nonprofit research and education institute to facilitate collaboration among its founding partners: the Food and Drug Administration, The University of Arizona, and SRI International. The Institute has received more than \$11 million in contributions from the State of Arizona, the City of Tucson, Pima County, regional municipalities, foundations, organizations and private individuals. For more information about The Critical Path Institute, go to <http://www.c-path.org>.

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