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**FOR IMMEDIATE RELEASE**  
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**C-PATH LEADS NOVEL TRANSATLANTIC DRUG SAFETY EFFORT;  
YIELDS FDA/EMEA QUALIFICATION OF NEW DRUG TESTS FOR KIDNEY SAFETY**

**Companies receive go ahead from FDA and EMEA to use new improved tests  
when assessing safety of new drugs**

TUCSON -- [The Critical Path Institute](#) (C-Path) is pleased to announce the first results emanating from a collaboration that was created by C-Path to identify improved methods to test the safety of new drugs in development. This collaboration, the [Predictive Safety Testing Consortium](#) (PSTC), is composed of over 200 scientists from the sixteen largest pharmaceutical companies, non-profit research organizations, and advisors from the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

The first-of-its-kind scientific proposal submitted by the consortium has now been evaluated by the FDA and EMA and seven new tests have been deemed by the agencies as "qualified" markers of drug-induced kidney injury in animal studies. The tests measure the levels of seven key proteins or "biomarkers" found in urine that can provide additional information about drug-induced damage to kidney cells, also known as renal toxicity.

Dr. Raymond L. Woosley, President and CEO, Critical Path Institute stated that "the PSTC is proving that government and industry scientists can – and should - work together to improve the methods for testing the safety of new drugs. The qualification of these seven new tests is the critical first step towards their use in clinical drug development."

According to Dr. Wm. Mattes, C-Path's director of the PSTC, "Using current kidney tests that were developed over 100 years ago, 70 percent of kidney function must be lost before damage can be detected. The newly approved biomarkers are far more sensitive and specific for drug-induced kidney damage." The PSTC has begun work to further qualify the biomarkers for use in human studies.

Please see EMA announcement at:  
<http://www.emea.europa.eu/htms/human/mes/biomarkers.htm>

Please see FDA announcement at:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01850.html>

More information about C-Path and the PSTC is available at: [www.c-path.org](http://www.c-path.org)

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