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**CLINXUS PARTNERSHIP DEVISES IMPROVED TESTS TO DETECT KIDNEY  
DAMAGE FOR NEW DRUGS IN DEVELOPMENT**

*Biomarkers can indicate negative drug effects on kidneys earlier than current methods*

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**Grand Rapids, MI (August 5, 2008)** – The Critical Path Institute (C-Path) Predictive Safety Testing Consortium (PSTC), which includes Grand Rapids-based ClinXus, has identified seven new tests to assess the safety of new drugs in development, specifically to monitor the drugs’ effects on the kidneys. The U.S. Food and Drug Administration (FDA) and its equivalent in Europe, the European Medicines Agency (EMA), recently approved the use of these tests in the pre-clinical phase of drug development, as well as the use of five of the tests in some cases bridging pre-clinical and Phase I clinical 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. Currently, researchers and clinicians typically look for changes in serum creatinine and blood urea nitrogen (BUN), but these may only show up after the onset of kidney injury, which can be permanent.

According to William Mattes, Ph.D., 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.” -more-

Many of the newly approved biomarkers are not new to the research and clinical community. But the lack of specific scientific “rules” or standards about their utility has prevented companies from using them for fear that data from the studies could further delay the FDA and EMEA approval process. By quantifying biomarker information and getting approval to use the tests from these regulatory bodies, the PSTC has eliminated a significant barrier to the drug development process.

The next steps are to gather more data to support using these tests more broadly in clinical studies, and eventually to get approval to use some or all of the biomarkers to help guide medical decision-making.

“ClinXus has always been dedicated to introducing molecular biomarkers into the clinical trial process,” said ClinXus Board President Craig P. Webb, Ph.D., Van Andel Institute scientific investigator and director of translational medicine. “Our role in the next phase of the Critical Path’s PSTC effort will be to facilitate the clinical evaluation of these new biomarkers and diagnostic tests.”

This is the most significant accomplishment to-date of the PSTC, which was created in 2006 to identify improved methods to test the safety of new drugs in development and bring life-saving drugs to the FDA more quickly and safely. The collaboration involves over 200 scientists from the sixteen largest pharmaceutical companies, non-profit research organizations, and advisors from the FDA and the EMEA. ClinXus, a community-based clinical research alliance focused on innovative devices/medicines, became the first nonprofit to join the PSTC earlier this year.

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*ClinXus was formed in July, 2006 to establish innovative clinical trial designs that are primarily biomarker driven and to increase access to clinical research and emerging technologies provided by member organizations, enhancing patient care and establishing West Michigan as a national destination for innovative clinical research. The alliance’s six founding members include Grand Valley Medical Specialists, Grand Valley State University, Jasper Clinical Research & Development, Saint Mary’s Health Care, Spectrum Health and Van Andel Institute.*