

Critical Path Institute Receives Regulatory Support for Liver Injury Biomarker



Tucson, AZ — January 22, 2018 — [Critical Path Institute](#) (C-Path) announced today that the [European Medicines Agency \(EMA\)](#) has issued a Letter of Support for measurement of glutamate dehydrogenase (GLDH) as a biomarker of hepatocellular liver injury. The letter was awarded to C-Path's Predictive Safety Testing Consortium (PSTC) and Duchenne Regulatory Science Consortium (D-RSC) to encourage the further study of serum GLDH for monitoring hepatocellular liver injury.

The letter—in response to data submitted by the PSTC Hepatotoxicity Working Group (HWG) and D-RSC—describes EMA's thoughts on the value of GLDH and supports further evaluation. In it, EMA encourages PSTC and D-RSC to investigate “the voluntary and complementary use of serum GLDH, in conjunction with currently used biomarkers of liver injury, as a clinical biomarker of liver injury.” EMA also supports PSTC's generation of additional clinical safety data, and plans for further clinical studies to potentially enable formal qualification of GLDH in the future.

“Many of the proteins currently monitored to evaluate liver safety are also found in muscle tissue,” says Jane Larkindale, D.Phil., Executive Director of D-RSC. “In situations where a patient has underlying muscle injury, such as muscular dystrophies, levels of these enzymes may be high in the absence of liver injury. Monitoring of GLDH levels may allow liver injury caused by novel drugs to be detected in this population of patients.”

D-RSC is dedicated to developing tools to accelerate development of safe drugs for Duchenne, and monitoring safety of such drugs is important. PSTC is dedicated to the development of safety biomarkers, so collaboration between the two C-Path consortia accelerated development of this biomarker.

“At C-Path, we are constantly looking to work in partnership across our many consortia, and the GLDH biomarker qualification presented the perfect opportunity for such a collaboration between PSTC and D-RSC,” says John-Michael Sauer, PhD, Biomarker Program Officer and Executive Director of PSTC.

EMA support encourages the biomarker's use in both nonclinical and exploratory clinical studies as a marker of hepatocellular liver injury, and indicates that this biomarker has strong potential for use in humans and warrants additional exploration and gathering of data.

Says C-Path President and CEO Martha A. Brumfield, PhD, “The data package submitted to EMA supporting use of this liver-injury biomarker, developed by PSTC and D-RSC in partnership, exemplifies successful cross-consortium collaboration at C-Path, and EMA's support of this biomarker is a harbinger of future success for both consortia. Developing reliable biomarkers remains one of the most productive methods of aligning and streamlining research and regulatory processes.”

The Letter of Support for this biomarker is posted on the [EMA website](#), and can also be accessed via the C-Path [PSTC website](#).



Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established 12 global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

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