

25th World Congress on**CANCER SCIENCE AND THERAPY &**10th World Congress on**BIOMARKERS & CLINICAL RESEARCH**

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***John Michael Sauer****Critical Path Institute, USA***The predictive safety testing consortium: Qualification of translational safety biomarkers for use in drug development**

The use of novel safety biomarkers in clinical trials has the potential to profoundly impact the ability of drug development innovators and health authorities to evaluate and improve patient safety. Many of the biomarkers currently being used to evaluate clinical safety suffer from a lack of sensitivity or specificity for detecting drug induced organ injury. Therefore, several groups including the Critical Path Institute's Predictive Safety Testing Consortium (PSTC) have been working towards the regulatory qualification of novel safety biomarkers with the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to gain scientific and regulatory endorsement of these biomarkers. However, these efforts have been hampered by the lack of well-defined scientific and regulatory expectations or evidentiary criteria. Therefore, the objective of this presentation is to discuss and align the expectations for qualification of novel safety biomarkers to be applied during drug development. Furthermore, the general approach to the regulatory qualification of translational safety biomarker will be discussed using several case studies focusing on safety biomarkers.

Biography

John Michael Sauer is a Toxicologist by training with over 20 years of experience in drug discovery and development. He has been responsible for leading multiple functional areas across several pharmaceutical companies. He received his Doctorate degree in Pharmacology and Toxicology from The University of Arizona. Currently, he is working as the Program Officer of Biomarker Programs and the Executive Director of the Predictive Safety Testing Consortium at the Critical Path Institute, as well as an Adjunct Research Professor in the Department of Pharmacology at the University of Arizona, College of Medicine.

jsauer@c-path.org

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