Notice of launch of multi-stakeholder pilot to address quality assurance of molecular diagnostics

In 2013, a premier group of healthcare leaders from across the United States convened the Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) Working Group. SPOT/Dx was a multiyear effort focused on improving patient outcomes by equipping healthcare leaders with tools to advance clinical decision making, the diagnosis and treatment of cancer, and the regulatory and reimbursement infrastructure that underlies the field of precision medicine. In service to the SPOT/Dx mission, participants proposed a "Quality Assurance Pilot" rewarding molecular diagnostic quality.

The pilot focuses on the creation and adoption of platform-agnostic (commutable) consensus performance standards set by the specifications of a CDx and targeted drug in phase 3 of development (pre-market process). The goal is to equip labs with traceable quality control (QC) materials (including preanalytic and analytic components) in the pre-market phase that will subsequently enable them to demonstrate appropriate and equivalent levels of molecular diagnostic performance. Labs will be able to demonstrate their ability to accurately discriminate at the clinical decision point for a given product regardless of whether they are using an FDA-approved in vitro companion diagnostic (IVD) or a laboratory-developed test (LDT). The pilot will involve key stakeholders impacted by molecular diagnostics including: patient advocates, clinicians (pathologists and oncologists), payers, regulators, drug and diagnostic developers, labs, and an array of subject matter experts. The proof of concept pilot is initially oncology-focused with a potential candidate CDx that will be a two gene (multiple variant) NGS panel proposed by a pharmaceutical participant. The intention is to start deliberately with a small scale in this pilot. The pilot will involve 15 or so labs on a voluntary basis to test and evaluate this approach.

For further background information please refer to http://www.tapestrynetworks.com/initiatives/healthcare/oncology-therapeutics-and-diagnostics-working-group.cfm and contact: Cathy Lofton Day, Amgen