

Barbara Zehnbauer, PhD, for the Diagnostic Quality Assurance Pilot

Update for April 13, 2016 CLIAC Meeting RE: Quality Pilot

On March 30, 2016, the Steering Committee of the multi-stakeholder Diagnostic Quality Assurance Pilot (Quality Pilot) held its first meeting bringing together representatives from industry, payers, clinical oncology and the patient advocacy community, as well as regulators from FDA and CMS participating as observers. The pilot's Technical Working Group, managed by the College of American Pathologist (CAP), will launch on April 14, 2016.

The Quality Pilot emerged from the Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) working group. SPOT/Dx was launched in 2013 by Tapestry Networks as a multi-year 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 to recognize molecular diagnostic quality."

The objective of the Quality Pilot is to create platform-agnostic (commutable) performance standards and a transparent pre-market approach linked to a targeted Phase III drug. The pilot aims to ensure that labs can demonstrate their ability to accurately discriminate the clinical decision point for a given molecular companion diagnostic assay (CDx) regardless of whether they are using an FDA-approved in vitro companion diagnostic (IVD) or a laboratory-developed test (LDT).

The initial proof of concept pilot is oncology-focused with a candidate CDx comprised of a two gene (multiple variant) NGS panel voluntarily proposed and underwritten by Amgen. CAP is overseeing all technical aspects of the project, including providing the technical working group expertise, and support and engagement with laboratories to implement the pilot.

An independent Steering Committee chaired by former CDC laboratory research and evaluation branch Chief Barbara Zehnbauer will advise CAP and other organizations involved in executing the pilot and provide relevant inputs to the pilot process from their institutions' points of view. The Steering Committee will share learnings from the process and outcomes during the pilot with the public to foster collaborative learning and ensure an unbiased approach.