



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology
9650 Rockville Pike, Bethesda, Maryland 20814
Tel: 301-634-7939 • Fax: 301-634-7990 • Email: amp@asip.org • www.amp.org

AMP Comments at FDA Meeting on Next Generation Sequencing

The Association for Molecular Pathology (AMP) gave public comments at the US Food and Drug Administration's (FDA) meeting on next generation sequencing and called on officials to partner with professional associations as they develop a program to evaluate sequencing based diagnostics.

June 23, 2011 (Bethesda, MD): Today, on behalf of the Association for Molecular Pathology (AMP), Dr. Elaine Lyon gave public comments at the US Food and Drug Administration's (FDA) meeting on "Ultra High Throughput Sequencing for Clinical Diagnostic Applications – Approaches to Assess Analytical Validity." As they begin developing their program to evaluate sequencing based diagnostics, AMP advised FDA officials on many important considerations for evaluating analytical validity.

The analytical validation requirements for NGS will vary based on the clinical application at issue, such as a mutation panel for a Mendelian disease versus transcriptome analysis. Also, performance of, and coverage needs for, a given platform are likely to differ depending on the nucleic acid analyzed, the characteristics of the DNA regions and the type of variations interrogated, the relative allele proportions of particular variants, and whether quantitative or qualitative results are desired. For these reasons, Dr. Lyon noted "this necessitates flexibility and individualization in the development of validation protocols, guidelines, and controls on an application-by-application basis."

While the analytical validity of a NGS instrument may be intrinsically very high, its data conversion and analysis software may have design flaws or performance limitations. As such, AMP told the FDA that for optimal FDA review of the test system, the analytical validity of the instrument and the performance of the bioinformatics software should be evaluated both independently and as a complete system.

AMP also pointed out the role of molecular pathology professionals in determining the most appropriate platform and technologies for answering the clinical question at issue and advised the FDA to be careful not to limit the practice of medicine. "Optimal patient care requires the ability of molecular pathology professionals to use their professional opinion of the most suitable technological approach," added Dr. Lyon, "and any FDA policy to review analytical validity should include a role for the molecular pathology professionals performing the test."

AMP calls on the FDA to partner with professional associations to benefit from their wealth of experience and expertise on next generation sequencing (NGS) and its clinical applications. "We have an important reservoir of experience and expertise within our organization," explained Dr. Lyon, "and we encourage the FDA to allow us to collaborate to ensure that this technology is safely, effectively, and appropriately used for the benefit of our patients." AMP is also currently working on professional practice guidelines to address the many ethical, social and legal implications for the clinical use of NGS, which will be beneficial for the entire medical community including the FDA.

About AMP:

The Association for Molecular Pathology (AMP) is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics, and genomics. For more information, please visit, www.amp.org.

CONTACTS:

Mary Steele Williams
mwilliams@amp.org
(301) 634-7921