# CollegeNews

## ACMG Makes Public Comments at Recent FDA Meeting: Next Generation Sequencing

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ACMG's Executive Director, Dr. Michael S. Watson represented the College at the recent US Food and Drug Administration meeting on Next Generation Sequencing. Dr. Watson acknowledged how hard it has been for regulatory agencies to keep up with the rapid pace of development of technology and genetic testing and offered input, recommendations and an overview of actions that ACMG is taking.

ACMG is taking several important steps in the area of Whole Genome Analysis and Next Generation Sequencing including:

1. ACMG is appointing an official Task Force on Whole Genome Analysis (WGA) and Next Generation Sequencing (NGS) which will be tasked with looking broadly at the types of actions that will be needed as these technologies move forward and what ACMG and its committees should be addressing;
2. ACMG is offering a short course on Next Generation Sequencing at next year's annual meeting;
3. Development of recommendations of how families and patients could be informed and consented for testing in ways that were understandable to them;
4. ACMG has developed two practice guidelines out in *Genetics in Medicine* in July; one focuseD on technical standards and guidelines for interpreting and reporting whole genome copy number studies and the other on recommendations for the design and performance of these whole genome copy number analyses;
5. ACMG's Lab QA Committee is developing a technical standard and guideline on Next Generation Sequencing;
6. The College's CAP/ACMG Resource Committee is developing the PT programs for Next Generation Sequencing;
7. And our training programs are being adapted to include these new technologies and educational programs are in development.

ACMG also commented to the FDA that they will have to find a reasonable balance between what manufacturers can validate and what the laboratory must validate as relates to the reportable targets and that we needed to put more weight on post-market surveillance which is a common feature of orphan drug clinical trials. This recognizes that some diseases are so rare that we have to make them available to patients with less robust data but with systems in place to capture data so we know they continue to do what they appeared to be doing when first approved.

The June meeting was organized by FDA and titled *Ultra High Throughput Sequencing for Clinical Diagnostic Applications: Approaches to Assess Analytical Validity.*

## 2012 ACMG Annual Clinical Genetics Meeting
### March 27-31, 2012 - Charlotte, North Carolina

Detailed information, online registration, housing and abstract submission will be available at the ACMG Meeting Website in October 2011.

(Note the new meeting pattern: the College Annual Meeting will be held Tuesday through Saturday beginning in 2012.)

## 2013 and 2014 ACMG Annual Meeting
### Dates and Locations Announced

ACMG is pleased to announce that the 2013 ACMG Annual Clinical Genetics Meeting will be held March 19 - 23, 2013 in Phoenix, Arizona and the 2014 ACMG Annual Clinical Genetics Meeting will be held March 25-29, 2014 in Nashville, Tennessee. Both cities have expanded or new convention centers that will provide outstanding facilities for the growing College meeting.

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