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In 2010, Array Makers Saw CGH Become the Standard in Cytogenetics, Prepared for Next Wave of GWAS

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In a year when the word "sequencing" was on everyone's lips, microarray-based applications advanced steadily into routine clinical use.

During 2010, arrays became the standard of care for detecting constitutional abnormalities and researchers prepared to set guidelines for using arrays in clinical cancer cytogenetics.

At the same time, array manufacturers concentrated their efforts over the past 12 months on developing new products for genome-wide association studies with the hope that renewed growth in the market will blossom in 2011. As the first GWAS projects performed on a new generation of higher-density, custom-built genotyping chips are now wrapping up, firms anticipate that the success of these studies will translate into adoption of their new products.

Indeed, if there were two words that defined the array market in 2010, they were "cytogenetics" and "GWAS." Half of the top 10 most widely read *BioArray News* stories last year concerned the cyto-testing market, while three focused on the use of chips in association studies.

Rounding out the top 10 stories of 2010, listed below, was a piece on the use of arrays in direct-to-consumer genetics, as well as a story on potential M&A activity by one the space's biggest players, Affymetrix.

Cyto-a-Go-Go

The most widely read story last year was Illumina's announcement in January that it aimed to submit a cytogenetics-themed package to the US Food and Drug Administration ([BAN 1/26/2010](#)). Greg Heath, Illumina's senior vice president and general manager of diagnostics, said the company will submit the package as part of its preliminary investigational device exception, or pre-IDE, process.

As part of that process, test makers can send analytical or clinical protocols to the FDA for review and comment before proceeding with studies and can discuss possible regulatory pathways.

Illumina was not alone in engaging the FDA with regards to obtaining clearance for array products that can be used in cytogenetics. During the year Agilent Technologies, Affymetrix, and Roche NimbleGen all discussed their plans to eventually submit packages to the agency ([BAN 7/20/2010](#)).

At the same time, the FDA has not yet settled on what criteria its review process will entail. The FDA's Office of *In Vitro* Diagnostic Device Evaluation and Safety hosted a meeting in June with test providers, array manufacturers, and other experts to address that issue ([BAN 7/6/2010](#)).

The FDA's attempt to regulate the use of arrays in cytogenetics comes at a time when the technology is becoming more accepted as the platform of choice for diagnosing genetic abnormalities.

The second most-read story of the year was the American College of Medical Genetics' recommendation in September that chromosomal microarrays become geneticists' first-line postnatal test ([BAN 9/28/2010](#)).

For David Ledbetter, chief scientific officer and executive vice president of Geisinger Health System, the new ACMG guidelines are the "first official statement that we have replaced the karyotype with a new test, the cytogenetic array."

As head of the International Standards for Cytogenomic Arrays consortium, Ledbetter has helped steer an effort aimed at setting standards for arrays to help diagnose genetic abnormalities.

In May, ISCA published a statement in the *American Journal of Human Genetics* that recommended using arrays as "first-tier" tests to assess individuals with unexplained developmental delay and intellectual disability, autism spectrum disorder, or multiple congenital anomalies ([BAN 5/18/2010](#)). BAN's coverage of the recommendation was the eighth most-read story of the year.

The success of ISCA in helping to set guidelines for the use of arrays in constitutional cytogenetics has motivated others to set standards for the use of arrays in cancer cytogenetics. The Cancer Cytogenomics Microarray Consortium this year intends to carry out a multicenter, multi-platform validation study to demonstrate that the new technology is reliable and reproducible enough for clinical use in cancer diagnostics ([BAN 11/30/2010](#)). Coverage of CCMC's study was *BioArray News*' seventh most-read story of the year.

Overall, the cytogenetics market was arguably the most dynamic segment for arrays last year, leading firms beyond the traditional array makers, like PerkinElmer, to jump in. PerkinElmer spent \$90 million to acquire Signature Genomics in April ([BAN 4/20/2010](#)).

The Top 10 Most Read BioArray News Stories of 2010

1. [Illumina to Submit Cytogenetics Package to FDA, Commits to Using Arrays in Dx](#) (Jan. 26, 2010)
2. [ACMG Recommends Replacing Karyotyping with Chromosomal Microarrays as 'First-Line' Postnatal Test](#) (Sept. 28, 2010)
3. [Critiques of BU's Longevity Study Raise Questions about GWAS Methods](#) (July 13, 2010)

4. [Affy, Illumina Arrays Remain Platforms of Choice for Consumer Genomics Firms](#) (Feb. 23, 2010)
 5. [Illumina CEO Says Next Round of GWAS Will Be Done on Arrays, Not Sequencers](#) (Jan. 19, 2010)
 6. [Duke University Medical Center Researchers Warn 'GWAS Will Hit a Wall'](#) (Feb. 2, 2010)
 7. [Cancer Cytogenomics Microarray Consortium Aims to Set Standards for Arrays in Cancer Dx](#) (Nov. 30, 2010)
 8. [ISCA Recommends Chromosomal Microarray as 'First Tier' Test for Pediatric Developmental Disorders](#) (May 18, 2010)
 9. [PerkinElmer to Acquire Cyto Array Firm Signature Genomic Labs for \\$90M to Bolster Testing Services](#) (April 20, 2010)
 10. Affymetrix Eyeing Tuck-In Acquisitions to Bolster Downstream Market Presence ([May 11, 2010](#))
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