

Genome Based Diagnostics Clarifying Pathways To Clinical Use Workshop Summary

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The Roundtable on Translating Genomic-Based Research for Health held a workshop in November 2010 to determine what evidence is needed and how it is viewed by different stakeholders in order to develop genomic diagnostic tests of clinical value. Genome-Based Diagnostics summarizes the presentations and discussions that took place throughout the workshop. Two presentations, in particular, sparked extensive discussion.

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The sequencing of the human genome and the identification of associations between specific genetic variants and diseases have led to an explosion of genomic-based diagnostic tests. These tests have the potential to direct therapeutic interventions, predict risk or onset of disease, or detect residual disease. As research progresses and an increasing number of associations are found, further ...

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The risk-based strategy has " strengths and weaknesses, " said Alberto Gutierrez of FDA. The standards are similar to those for drugs but they also differ in significant ways. For example, a premarket approval application (PMA) for a diagnostic is thought of by individuals to be similar to a New Drug Application in many ways, but controlled clinical trials are rarely submitted as the ...

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