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Clarifying Pathways To Clinical Use: Workshop Summary. 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.

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The Roundtable on Translating
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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

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workshop. Two presentations, in particular, sparked extensive discussion.

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important points highlighted by
the individual speakers regulation
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be a critical factor in the extent of
use of those tests and in the

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The sequencing of the human
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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

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increasing number of associations
are found, further...

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The risk-based strategy has
"strengths and weaknesses," said

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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

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Pathways, but controlled clinical trials
are rarely submitted as the ...

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