



Perspectives on Biomarker and Surrogate Endpoint Evaluation: Discussion Forum Summary

Institute of Medicine, Food and Nutrition Board, Board on Health Sciences Policy, Board on Health Care Services, Committee on Qualification of Biomarkers and Surrogate Endpoints in Chronic Disease

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In 2010 the Institute of Medicine (IOM) recommended a framework for the evaluation of biomarkers in the chronic disease setting. Published in the book *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease*, the framework is intended to bring consistency and transparency to the previously disparate process of biomarker evaluation.

Following the book's release, the IOM convened a 2-day discussion forum in Washington, DC, in order to provide an opportunity for stakeholders to learn about, react to, and discuss the book. Presentations reviewed the authoring committee's work process, recommendations, and provided perspectives on the book from the point of view of participants. Thomas Fleming, professor of biostatistics and statistics at the University of Washington, gave a keynote presentation on the critical issues in the validation of surrogate endpoints, a specific use of a biomarker.

The present volume recounts the discussion forum proceedings, focusing in turn on each represented sector. A summary of Dr. Fleming's presentation then sets the committee's recommendations within the context of biomarker utilization. Lastly, this summary examines the main themes raised by stakeholders, and the challenges and opportunities presented to stakeholders by the book's recommendations.

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