



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

Board on Health Sciences Policy

Roundtable on Translating Genomic-Based Research for Health

Evidence Generation for Genomic Diagnostic Test Development: A Workshop

November 17, 2010

**The Keck Center of the National Academies
500 Fifth St., N.W.
Washington, DC 20001**

MEETING OBJECTIVE

To explore the strengths and limitations of the evidence that is being generated for clinical validity and utility.

- What evidence is required from stakeholders?
- How is evidence currently being generated?
- Are there innovative ways to generate higher quality evidence more efficiently?
- What are the barriers to generating this evidence and how can they be overcome?

7:45 – 8:30 A.M. WORKING BREAKFAST

7:45 – 8:30 A.M. **Working Breakfast**

8:30 – 8:45 A.M. PUBLIC WORKSHOP BEGINS — Keck 100

8:30 – 8:45 A.M. **Welcome and Introductory Remarks**

*Debra Leonard, Professor and Vice Chair for Laboratory
Medicine, Director of the Clinical Laboratories, Weill
Cornell Medical Center of Cornell University*

8:45 – 10:50 A.M. EVIDENCE

Session Focus: Assessing stakeholder perspectives on evidence,
illustrated through case examples

Moderator: *Roger Klein, Medical Director, Molecular Oncology at
BloodCenter of Wisconsin and Clinical Assistant
Professor of Pathology at Medical College of Wisconsin*



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8:45 – 9:05 A.M.

FDA Perspective

Robert L. Becker, Jr., Chief Medical Officer for the Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, FDA

9:05 – 9:25 A.M.

Payer Perspective

Margaret Piper, Director of Genomics Resources for the BlueCross BlueShield Technology Evaluation Center

9:25 – 9:45 A.M.

Evidence-Based Review Group Perspective

Ned Calonge, President and CEO of The Colorado Trust

9:45 – 10:05 A.M.

Healthcare Provider Perspective

Dan Hayes, Clinical Director of the Breast Oncology Program and Stuart B. Padnos Professor in Breast Cancer Research, University of Michigan Comprehensive Cancer Center

10:05 – 10:35 A.M.

Panel Discussion

10:35 – 10:50 A.M. BREAK

10:50 – 12:55 P.M. NEW MODELS FOR EVIDENCE GENERATION: APPLIED SCIENCE

Session Focus: Innovative approaches for generating evidence to enable diagnostic test development

Moderator: *Elizabeth Mansfield, Director of the Personalized Medicine Staff, Office of In Vitro Diagnostic Devices, Center for Devices and Radiological Health, FDA*

10:50 – 11:10 A.M.

Randomized Clinical Trials and Practical Clinical Trials in Pharmacogenomics

Caryn Lerman, Mary W. Calkins Professor and Director of the Tobacco Use Research Center; Deputy Director Abramson Cancer Center, University of Pennsylvania

11:10 – 11:30 A.M.

Utilizing Archived Samples to Generate New Evidence

Richard Simon, Chief of the Biometric Research Branch, National Cancer Institute



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11:30 – 11:50 A.M. **Coverage with Evidence Development**

Leslie Levin, Head of the Medical Advisory Secretariat and Senior Medical, Scientific and Health Technology Advisor for the Ministry of Health and Long-Term Care, Ontario, CA

11:50 – 12:10 P.M. **Constructing Chains of Evidence**

David F. Ransohoff, Professor, Departments of Medicine and Epidemiology, University of North Carolina at Chapel Hill

12:10 – 12:55 P.M. **Discussion**

12:55 – 1:55 P.M. WORKING LUNCH

12:55 – 1:55 P.M. **Working Lunch**

1:55 – 4:20 P.M. OVERCOMING BARRIERS FOR EVIDENCE GENERATION

Session Focus: Examination of areas/issues which are currently preventing the development of high quality evidence and potential solutions

Moderator: *Sean Tunis, Director of the Center for Medical Technology Policy*

1:55 – 2:35 P.M. **Panelist Remarks**

Aled Edwards, Director and CEO Structural Genomics Consortium; Professor, Department of Medical Biophysics, University of Toronto
Robert S. Epstein, Chief Medical Officer and President, Medco Research Institute
Gregory G. Germino, Deputy Director, NIDDK
Eric Larson, Executive Director of Group Health Research Institute

2:35 – 3:25 P.M. **Panel Discussion**

3:25 – 4:05 P.M. **Roundtable and Audience Discussion**

4:05 – 4:20 P.M. **BREAK**



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4:20 – 5:20 P.M. STRATEGIES FOR MOVING FORWARD

Session Focus: A discussion of potential next steps

Moderator: *Sharon Terry, President and CEO, Genetic Alliance*

4:20 – 5:20 P.M. Stakeholder Reaction Panelists

Robert L. Becker, Jr., Chief Medical Officer for the Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, FDA
Ned Calonge, President and CEO of The Colorado Trust
Dan Hayes, Clinical Director of the Breast Oncology Program and Stuart B. Padnos Professor in Breast Cancer Research, University of Michigan Comprehensive Cancer Center
Margaret Piper, Director of Genomics Resources for the BlueCross BlueShield Technology Evaluation Center

5:20 – 5:50 P.M. SUMMARY AND CONCLUSIONS

5:20 – 5:50 P.M. Review and conclusions

Debra Leonard, Professor and Vice Chair for Laboratory Medicine, Director of the Clinical Laboratories, Weill Cornell Medical Center of Cornell University

6:30 – 8:30 P.M. Working Dinner

6:30 – 8:30 P.M. Discussion on identified solutions for evidence generation