

***Refining Processes for the Co-Development of Genome-Based Therapeutics and Companion Diagnostic Tests: A Workshop*****February 27, 2013****The Keck Center of the National Academies  
500 Fifth Street, NW  
Washington, DC 20001**

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**Workshop Objectives:**

- To examine and discuss challenges and potential solutions for the co-development of targeted therapeutics and companion molecular tests for prediction of drug response.
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**8:30–8:35 A.M.****WELCOMING REMARKS**Wylie Burke, *Roundtable Co-Chair*

Professor and Chair

Department of Bioethics and Humanities

University of Washington

Sharon F. Terry, *Roundtable Co-Chair*

President and CEO

Genetic Alliance

**8:35–8:40 A.M.****Charge to workshop speakers and participants**Robert McCormack, *Workshop Co-Chair*

Head Technology Innovation and Strategy

Veridex LLC

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**SESSION I: CO-DEVELOPMENT**

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**Moderator:** Victoria Pratt, Quest Diagnostics

8:40–9:00 A.M.

**Effectiveness of Co-Development**

Felix Frueh (*confirmed*)  
Entrepreneur-in-Residence  
Third Rock Ventures

9:00–9:20 A.M.

**FDA Review of Co-Development to Date**

Elizabeth Mansfield (*confirmed*)  
Director, Personalized Medicine Staff  
Office of In Vitro Diagnostics and Radiological Health  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

9:20–10:05 A.M.

**Discussion with Speakers and Attendees**

10:05–10:20 A.M.

**BREAK**

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**SESSION II: CHALLENGES AND OPPORTUNITIES**

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10:20–10:40 A.M.

**Stakeholder Input on the Current Co-Development Paradigm**

Robert McCormack (*confirmed*)  
Head Technology Innovation and Strategy  
Veridex LLC

10:40–11:20 A.M.

**Stakeholder Presentations (10 minutes each)**

**Discussion Moderator:** Geoffrey Ginsburg, Duke University

*In Vitro Diagnostic Developers*

Walter Koch (*confirmed*)  
Vice President, Global Research  
Roche Molecular Systems, Inc.

Pamela L. Swatkowski (*confirmed*)  
Director, Regulatory Affairs  
Abbott Molecular Inc.

*Pharmaceuticals Developers*

Scott Patterson (*confirmed*)  
Executive Director, Medical Sciences  
Amgen Inc.

Richard Buller (*confirmed*)  
Vice President, Translational Oncology  
Oncology Business Unit  
Pfizer Inc.

11:20 A.M.–12:05 P.M.      **Discussion with Speakers and Attendees**

12:05–12:55 P.M.      **WORKING LUNCH**

12:55–1:45 P.M.      **Stakeholder Presentations (10 minutes each)**

**Discussion Moderator:** Patrick Terry, PXE International

*Regulatory and Legal Oversight*

Steven Gutman (*confirmed*)  
Strategic Advisor  
Myraqa, Inc.

Bradley Thompson (*confirmed*)  
Member of the Firm  
Epstein Becker & Green, P.C.

*Payers*

Bruce Quinn (*confirmed*)  
Senior Health Policy Advisor  
Foley Hoag, LLP

Joanne Armstrong (*confirmed*)  
Senior Medical Director  
Head, Women's Health  
Aetna

1:45–2:40 P.M.      **Discussion with Speakers and Attendees**

2:40–3:10 P.M.      **Stakeholder Presentations (10 minutes each)**

**Discussion Moderator:** Muin Khoury, Centers for Disease Control and Prevention

*Laboratory End Users*

John Pfeifer (*confirmed*)

Vice Chair for Clinical Affairs, Pathology and Immunology  
Professor, Pathology and Immunology  
Professor, Obstetrics and Gynecology  
Washington University School of Medicine

*Clinical End Users*

Sharon F. Terry (*confirmed*)

President and CEO  
Genetic Alliance

Mark Robson (*confirmed*)

Clinic Director, Clinical Genetics Service  
Department of Human Genetics  
Memorial Sloan-Kettering Cancer Center

3:10–3:25 P.M.

**BREAK**

3:25–4:10 P.M.

**Discussion with Speakers and Attendees**

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**SESSION III: POTENTIAL PATHS FORWARD**

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4:10–4:25 P.M.

**Pathways Toward Progress: Overview of Themes from the Day**

Debra Leonard, *Workshop Co-Chair (confirmed)*

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

4:25–5:40 P.M.

**Advancing Co-Development**

**Moderator:** Wylie Burke, University of Washington

**Respondents:**

Pamela L. Swatkowski (*confirmed*)  
Director, Regulatory Affairs  
Abbott Molecular Inc.

Richard Buller (*confirmed*)  
Vice President, Translational Oncology  
Oncology Business Unit  
Pfizer Inc.

Steven Gutman (*confirmed*)  
Strategic Advisor  
Myraqa

Joanne Armstrong (*confirmed*)  
Senior Medical Director  
Head, Women's Health  
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John Pfeifer (*confirmed*)  
Vice Chair for Clinical Affairs, Pathology and Immunology  
Professor, Pathology and Immunology  
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Washington University School of Medicine

Mark Robson (*confirmed*)  
Clinic Director, Clinical Genetics Service  
Department of Human Genetics  
Memorial Sloan-Kettering Cancer Center

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**SESSION IV: CONCLUSION**

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5:40–5:50 P.M.

**CONCLUDING REMARKS**

Robert McCormack, *Workshop Co-Chair*  
Head Technology Innovation and Strategy  
Veridex LLC

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

5:50 P.M.

**ADJOURN**

6:15 P.M.

Working Dinner Discussion on Companion Diagnostics and Precision  
Therapeutics.

**701 Penn Restaurant**  
701 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
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