



# INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

## Workshop on the Review of Omics-Based Tests for Predicting Patient Outcomes in Clinical Trials

20 F Street Conference Center  
20 F Street NW  
Washington, DC 20001

**Day 1, March 30**

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### OPEN SESSION

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7:30 am Breakfast Available

8:00 am Welcome and Opening Remarks—*Gil Omenn, Committee Chair*

8:15 am Analysis of Task — General Guidance

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### 8:30 am **SESSION 1 — Science and Technology Underlying Omics-Based Tests**

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8:30 am Lessons from EGAPP—*Ned Calonge*

8:50 am The use of archived tissue samples for development of tests—*Richard Simon*

9:10 am Analytical variation of tests and cross-platform test validation—*Charles Perou*

9:30 am Clinical trial design—*Sumithra Mandrekar*

9:50 am Session 1 Discussion

11:00 am BREAK

PLEASE COLLECT LUNCH (SANDWICHES)— return to seats

11:15 am Institutional Responsibility—*Peter Pronovost*

11:40 am Discussion of Pronovost presentation

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### 12:00 pm **SESSION 2 — Case Studies**

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12:00 pm MammaPrint—*Laura van 't Veer*

12:30 pm Oncotype Dx—*Steve Shak*

1:00 pm Discussion

1:45 pm Duke University Case Study, Principal Investigator Perspective—*Joseph Nevins*

2:15 pm Discussion—*Nevins and Committee*

3:00 pm BREAK



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## 3:15 pm **SESSION 3 — Responsible Parties**

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- 3:15 pm Panel of journal editors—  
*Cathy DeAngelis (editor-in-chief of JAMA)*  
*Véronique Kiermer (Publisher, Nature Methods; Executive Editor, Nature Cell Biology; and Executive Editor and Head of Researcher Services, Nature Publishing Group)*  
*Katrina Kelner (Editor, Translational Medicine, and Managing Editor, Research Journals, Science Magazine)*
- 4:15 pm Responsibilities of authors and principal investigators—*Scott Zeger*
- 4:45 pm Panel on institutional responsibilities—  
*Albert Reece (Dean, University of Maryland School of Medicine)*  
*Harold Paz (Dean, Penn State College of Medicine)*  
*Scott Zeger (Vice Provost for Research, Johns Hopkins University)*
- 5:45 pm Final comments
- 6:00 pm ADJOURN

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## **CLOSED SESSION**

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- 7:00 pm Committee Dinner
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## **Day 2, March 31**

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### **OPEN SESSION**

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- 8:00 am Forensic Biostatistics—*Keith Baggerly*
- 8:30 am Discussion
- 9:30 am ADJOURN OPEN SESSION

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### **CLOSED SESSION**

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- 9:30 am BEGIN CLOSED SESSION—*Committee Members*
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