

Sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK),
National Institutes of Health (NIH)

**Workshop on Assessment of Kidney Function
and Damage**

**DoubleTree Hotel and
Executive Conference Center**

June 9 – 10, 2008

Draft Agenda

Monday, June 9, 2008

- 7:00 – 8:00 a.m. **Registration and Continental Breakfast**
- 8:00 – 8:15 a.m. **Welcome and NIDDK Perspective on the Need for Improved Methods
To Assess Kidney Function and Damage**
Robert Star, NIDDK, NIH
- 8:15 – 8:30 a.m. **Welcome and Purpose of the Workshop and Deliverables**
Robert Toto, University of Texas Southwestern Medical Center

Theme 1: Perspectives on Biomarkers

- 8:30 – 9:00 a.m. **Biomarkers of Cardiovascular Disease with an Example of a Useful
Biomarker and of Multiple Biomarkers**
Vasan Ramachandran, Boston University School of Medicine
- 9:00 – 9:30 a.m. **What Biomarkers Are Needed To Advance Our Understanding of
Chronic Kidney Disease?**
Catherine Stehman-Breen, Amgen
- 9:30 – 10:00 a.m. **What Are the Characteristics of Biomarkers Needed To Advance
Diagnosis and Prognosis of Acute Kidney Injury?**
Chi-yuan Hsu, University of California, San Francisco
- 10:00 – 10:30 a.m. **Break**

Theme 2: State-of-the-Art: Biomarkers of Kidney Function

- 10:30 – 11:00 a.m. **Cystatin C**
Michael Shlipak, University of California, San Francisco
- 11:00 – 11:30 a.m. **Serum Creatinine-Based Estimating Equations: Application in Adults**
Lesley Stevens, Tufts University

June 9, 2008 (continued)

- 11:30 a.m. – 12:00 p.m. **Measurement of Kidney Function in Children**
George Schwartz, University of Rochester
- 12:00 – 1:00 p.m. **Lunch (on your own)**
- 1:00 – 1:30 p.m. **Imaging the Kidney: Conventional Methods**
Andrew Taylor, Emory University
- 1:30 – 2:00 p.m. **Imaging of the Kidney: Non-Conventional Methods Applicable to Humans**
Pottumarthi Prasad, Evanston Northwestern Healthcare

Theme 3: Biomarkers and Surrogate Markers of Injury and Kidney Disease Progression

- 2:00 – 2:30 p.m. **Urine Protein Excretion**
David Warnock, University of Alabama at Birmingham
- 2:30 – 3:00 p.m. **Diagnosis and Monitoring of Acute Kidney Injury**
Joseph Bonventre, Harvard Medical School
- 3:00 – 3:30 p.m. **Break**
- 3:30 – 4:00 p.m. **Assessing Risk for Progression of CKD**
Harold Feldman, University of Pennsylvania
- 4:00 – 4:30 p.m. **Diagnosis and Monitoring CKD Progression**
Tom Hostetter, Yeshiva University, Albert Einstein College of Medicine
- 4:30 – 5:00 p.m. **Frailty as a Surrogate Marker for CKD Outcomes**
Kirsten Johansen, University of California, San Francisco
- 5:00 – 5:15 p.m. **Brief Summary and Instructions for Breakout Sessions and Plans for Day 2**
Robert Toto, University of Texas Southwestern Medical Center
- 5:15 – 7:15 p.m. **Concurrent Breakout Sessions***

- Breakout Session 1: **Acute Kidney Injury** (Wisdom Room)
Prasad Devarajan, Cincinnati Children's Hospital Medical Center
- Breakout Session 2: **Identifying and Predicting CKD Progression** (Balance Room)
Andrew Levey, Tufts Medical Center
- Breakout Session 3: **Imaging for Injury and Disease Progression** (Insight Room)
Bruce Molitoris, Indiana University School of Medicine
- Breakout Session 4: **Designing Clinical Trials with Surrogate Markers** (Juniper Room)
Glenn Chertow, Stanford University School of Medicine

Monday, June 9, 2008 (continued)

5:15 – 7:15 p.m. **Poster Session** (posters available, but authors are not required to be present)

Posters to include descriptions of available datasets, ongoing clinical trials, and resources available through the NIDDK Data and Bio-Sample Repositories.

Tuesday, June 10, 2008

Theme 4: Outcome Measures and Drug Development

- 7:00 – 8:00 a.m. **Continental Breakfast and Poster Session Continued**
- 8:00 – 8:30 a.m. **Biomarkers and New Drug Indications: The FDA Viewpoint**
Federico Goodsaid, U.S. Food and Drug Administration
- 8:30 – 9:00 a.m. **Surrogate Markers in Trials of CKD: The FDA Viewpoint**
Melanie Blank, U.S. Food and Drug Administration
- 9:00 – 9:30 a.m. **Deploying Translational Biomarkers to Resolve Kidney Safety Concerns During Drug Development: An Industry Perspective**
Frank Sistare, Merck and Company, Inc.
- 9:30 – 10:00 a.m. **What You Need to Start a Drug Development Program in CKD**
Tom Daniel, Celgene Corporation
- 10:00 – 10:15 a.m. **Charge to Breakout Sessions**
Robert Toto, University of Texas Southwestern Medical Center
- 10:15 – 10:30 a.m. **Break**
- 10:30 – 11:30 a.m. **Concurrent Breakout Sessions***
- Breakout Session 1: **Acute Kidney Injury** (Wisdom Room)
Prasad Devarajan, Cincinnati Children's Hospital Medical Center
- Breakout Session 2: **Identifying and Predicting CKD Progression** (Balance Room)
Andrew Levey, Tufts Medical Center
- Breakout Session 3: **Imaging for Injury and Disease Progression** (Insight Room)
Bruce Molitoris, Indiana University School of Medicine
- Breakout Session 4: **Designing Clinical Trials with Surrogate Markers** (Juniper Room)
Glenn Chertow, Stanford University School of Medicine

June 10, 2008 (continued)

11:30 a.m. – 12:30 p.m.	Reports and Discussion from Breakout Sessions
12:30 – 1:30 p.m.	Working Lunch: Continue Reports/Discussion from Breakout Sessions
1:30 – 2:30 p.m.	Continue Reports from Breakout Sessions <i>Session Leaders</i>
2:30 – 2:45 p.m.	Closing Comments <i>Robert Toto and Robert Star</i>
2:45 p.m.	Meeting Adjourns

***Goals of Breakout Sessions:**

- Identify gaps in our knowledge and describe future areas of research.
- Discuss information on what resources are available with which biomarkers could be validated, including cataloging of ongoing studies.
- Discuss the best way to validate biomarkers in terms of sensitivity, specificity, and predictability.