



# Kidney Health Initiative

## Third Annual Stakeholders Meeting

May 20-21, 2015 Hyatt Regency Bethesda

### Agenda

**Wednesday, May 20, 2015**

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4:30 PM- **Registration Opens**  
5:30 PM

5:30 PM – **Welcome Remarks** (*please note new start time*)  
7:00 PM Patrick Archdeacon, MD and Prabir Roy-Chaudhury, MD, PhD, FASN, KHI Co-Chairs

**Keynote Presentations**

Robert Temple, MD, Deputy Director for Clinical Science, US Food and Drug Administration

Jula K. Inrig, MD, FASN, Global Medical Director and Therapeutic Strategy Lead in Nephrology for Quintiles Global Clinical Research Organization

Robert Califf, MD, Deputy Commissioner for Medical Products and Tobacco, US Food and Drug Administration, previously with Duke University

**Panel Discussion**

“Developing an Integrated Strategy for Transforming Innovation Related to Kidney Disease”

Moderators: Patrick Archdeacon, MD and Prabir Roy-Chaudhury, MD, PhD, FASN, KHI Co-Chairs

Panelists: Dr. Temple, Dr. Inrig, and Dr. Califf

7:00 PM – **Dinner Buffet Followed by Poster Reception**  
8:30 PM **Current KHI Projects: Status and Lessons Learned**

1. Pharmacokinetics in Patients Receiving CRRT
2. Outcome Measures for Lupus Nephritis
3. Innovation White Paper
4. Endpoints for Vascular Access
5. Patient Preferences
6. Data Standards in DKD
7. Pragmatic Trials in ESRD
8. Remote Monitoring
9. CDRH Regulatory Policies for Central Venous Catheters and Hemodialfiltration Systems

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**Thursday, May 21, 2015**

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7:45 AM – **New Member Orientation: KHI Project Submission Process and Portal, Hands-on Tutorial**  
8:15 AM Melissa West and Ryan Murray, KHI Staff

8:00 AM **Continental Breakfast**

8:30 AM – **Welcome Remarks**  
8:45 AM Patrick Archdeacon, MD and Prabir Roy-Chaudhury, MD, PhD, FASN, KHI Co-Chairs

8:45 AM – **Breakout #1: Kidney Health Initiative Project Pipeline**  
9:25 AM Opportunity for KHI members to present and discuss their project proposals\*

1. Achieving Consensus on Clinical Trial Biomarkers and Endpoints to Facilitate the Development of Treatments for ADPKD Early in the Course of the Disease  
David Baron, PhD, Chief Scientific Officer, PKD Foundation
2. Uremic Pruritis: Optimizing Patient Involvement to Clarify Study Design, Regulatory Pathway and Use of Patient Reported Outcomes  
Michael J. Germain, MD, Member of the ASN Geriatric Nephrology Advisory Group
3. Identifying Surrogate Endpoints for Clinical Trials in IgA Nephropathy  
Patrick H. Nachman, MD, FASN, Vasculitis Foundation

9:35 AM – **Breakout #2: Kidney Health Initiative Project Pipeline**  
10:15 AM Opportunity for KHI members to present and discuss their project proposals\*

1. Improving the Quality of Pre-clinical Studies for the Treatment of AKI  
Mark P. de Caestecker, MBBS, PhD, Member of the ASN Acute Kidney Injury Advisory Group
2. Prioritizing Symptoms of ESRD Patients for Developing Therapeutic Interventions  
Jennifer E. Flythe, MD, FASN, MPH, Member of the ASN Dialysis Advisory Group
3. Educational Needs for Invasive Radiologists on the Correct Performance of a Medical Renal Biopsy  
Patrick Walker, MD, FASN, Nephropath

*\*Note, project proposals can be found in the KHI portal. Visit the KHI website ([www.kidneyhealthinitiative.org](http://www.kidneyhealthinitiative.org)) and click on Project/ Project Proposals. Login using username and password.*

10:15 AM – **Coffee Break**  
10:30 AM

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10:30 AM-  
11: 15 AM

**Breakout #3: Future of KHI: Brainstorming Sessions**

During the keynote presentation, several ideas will be presented as potential opportunities for the Kidney Health initiative to consider. Four topic areas have been selected for further discussion. Ideas generated in this session will be applied to several therapeutic areas in the next session (11:30 AM). All recommendations from these brainstorming sessions will be catalogued and assessed for future KHI projects.

1. How could clinical trial networks and data coordinating centers increase efficiency?
2. How could an inventory of the evidence for acceptable endpoints increase efficiency for kidney disease trials and educate non-nephrologists?
3. How do we enhance patient involvement to have a positive impact on clinical trials?

11:30 AM-  
12:15 PM

**Breakout #4: Future of KHI: Brainstorming Sessions**

This session is intended to break the attendees into four therapeutic areas which will be provided onsite. Wednesday evening's keynote presentations and the ideas generated in the previous session (10:30 AM) should be used to develop a rationale as to why KHI should develop a program area dedicated to specific therapeutic areas. Recommendations will be presented to the larger group following lunch.

12:30 PM –  
1:45 PM

**Lunch**  
**Debrief and Discussion of Brainstorming Session**

Once attendees have obtained their lunch, the KHI Co-Chairs will facilitate a final session with brief summaries from the facilitators from the therapeutic area sessions followed by an interactive session on current and future directions for the KHI, including the potential to develop a cluster of programs in a defined high impact area.

1:45 PM  
2:00 PM

**Closing Remarks**

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